LEGAL CONTEXT OF UNIVERSITY INTELLECTUAL PROPERTY AND TECHNOLOGY TRANSFER

Prepared for:

The Committee on Management of University Intellectual Property: Lessons from a Generation of Experience, Research, and Dialogue

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EXECUTIVE SUMMARY

Universities today operate amidst a rapidly growing web of patents, other intellectual property (IP) rights, and non-IP rights in tangible materials and intangible data. They are both producers and consumers of the intellectual assets protected by such rights. This report focuses on the substance and relationships of the myriad legal rules affecting universities as they navigate this web of offensive and defensive rights. The sources of laws in this regard are manifold: constitutional law; federal statutes and regulations, and cases interpreting them; state statutes and regulations, and cases interpreting them; and state common law. The laws affecting a particular situation vary depending upon both the nature of the university's corporate status (state agency, non-profit entity receiving significant state funding," or private non-profit academic institution) and whether it has received federal or state funding for the activity or facilities. Accordingly, the report covers more than just the federal rules for ownership and use of federal funded inventions established under the Bayh-Dole Act of 1980 (Bayh-Dole, or the Bayh-Dole Act).

While the passage and implementation of Bayh-Dole was a seminal event for university IP and technology transfer, it did not originate out of nowhere but rather was the culmination of ongoing debates and executive branch policy developments beginning in the early twentieth century. Following the Introduction in Part I, Part II of the report summarizes the highlights of this history, while also outlining the major developments in the implementation and amendment of Bayh-Dole since its passage. Part III details the current state and interpretations of Bayh-Dole, other relevant patent law provisions, and a range of other relevant federal laws and policy. Part IV analyzes relevant state law issues. Part V considers the legal issues in "private ordering" arrangements—such as inventor assignment agreements and technology transfer licenses—that often have the most direct impact on the transfer and use of university IP, materials, and/or data. The appendices include copies of relevant U.S. statutes and policies as well as a brief overview of developments in select foreign jurisdictions.

The majority of the report is structured along a "sources of law" approach that categorizes the analyses of current law and policy into the three Parts that correspond to federal law (Part III), state law (Part IV), and the private law arranged between universities and their employees, funders, licensee/assignees, and research partners (Part V). While this provides the cleanest way of arranging legal material, it can obscure the crucial way in which real world issues cut across multiple layers of law. At the same time, the extensive array of legal sources covered in the report and the necessity of legalistic cataloguing may obfuscate the practical import of any particular analysis.

Accordingly, this Executive Summary contains a list of "Research Findings" that arranges important particular areas of law in the report by a practical common language description. Because this report serves as background for the Committee's report and recommendations, it does not offer its own policy recommendations. Instead it analyzes the broad development of legal issues over time to offer context and an assessment of the law and regulations as they currently stand. The Research Findings therefore contain a combination of observations of less well-known aspects of the law, clarifications of frequently misunderstood points of law, and notes on problematic areas where there appears to be tension or a lack of clarity in the law itself. The Executive Summary also includes a "Guide to Using this Report" that arranges specific legal topics from across the different layers of law according to their role in the four major areas of contemporary policy interest for university IP and technology transfer: (i) IP ownership; (ii) use

of IP, data, and materials in the academic research enterprise; (iii) restrictions on acceptance and use of revenue streams; and (iv) special issues for state agency universities.

A. Research Findings

The following constitute our research findings as to the legal environment for university IP and technology transfer, following the sources of law structure of the report. As noted above, this report is intended solely as background material and analysis for the Committee's report and recommendations. Accordingly, these Research Findings are not intended to offer law or policy recommendations. Rather they constitute observations of less well-known aspects of the law, clarifications of frequently misunderstood points of law, and notes on problematic areas where there appears to be tension or a lack of clarity in the law itself

1. Overarching issues

Finding 1. ***The legal environment of university IP and technology transfer should not be reduced only to patents and/or the Bayh-Dole Act as implemented.*** "IP" is not co-extensive with "patents," and instead encompasses copyrights, trademarks, plant variety protections, and trade secrets, in addition to three types of patents (utility, plant, and design).

Finding 2. ***Through changes in the economy and public policy, universities have come to operate both defensively and offensively within a highly complex IP environment.*** University research transforms multiple inputs—funding, ideas, information, and materials—into new ideas, information, and materials. Universities must ensure that their research is at minimal risk of infringing IP, personal property, contractual, tort, regulatory, or other statutory rights of external individuals or institutions. This is the *defensive* side of university legal planning. Universities must also decide how to transfer any ideas, information, or materials they develop—or that they have secured either assignments or licenses for from external parties—to external individuals or institutions. This is the *offensive* side of university legal planning.

Finding 3. ***Like most individuals and institutions, universities operate in a mixed legal environment constituted of federal, state, and local laws and policies.*** For example, virtually all of the universities that engage in substantial research are also tax-exempt educational or scientific organizations and, as such, are subject to federal and state regulation and reporting requirements to maintain that status. State universities are particularly subject to additional layers of state statutory and regulatory law, especially when they have been formed as state agencies.

Finding 4. ***Few universities give a clear policy mandate to their technology licensing offices (TLOs), which complicates many legal decisions with regard to university IP and technology transfer.*** Within the broad framework of most TLOs' missions to transfer technologies out of the university for dissemination and commercialization to benefit the public, specific goals that universities or their TLOs often consider are: revenue maximization to fund the university's research and teaching missions; regional economic development; service to faculty; and knowledge dissemination. More recently, a fifth in the form of advancing particular social or humanitarian goals has been advocated by many within and without universities. Because prioritization of one of these might reduce the ability of the TLO to deliver on some of

the others, these specific goals can conflict with each other. Selection or prioritization by top-level university officials, and perhaps federal or state law and policy, could enable more effective legal planning and execution within universities and their TLOs.

2. Inventions and Bayh-Dole (Parts II and III.B)

Finding 5. ***Bayh-Dole covers only patentable inventions and only those conceived or first actually reduced to practice under a federal funding agreement.*** However, to the extent that any data or materials are part of a "subject invention," then the provisions of Bayh-Dole cover those data and materials, but *only* to that extent. "Funding agreement" covers "contracts," "grants," and "cooperative agreements," all of which have specific meanings under federal law.

Finding 6. ***"Actual reduction to practice" is not co-extensive with "reduction to practice" or "constructive reduction to practice" and has presented issues for some federal government contractors.*** The latter two can occur by the act of filing a fully enabled patent application with the U.S. Patent and Trademark Office (USPTO), without having actually made a physical embodiment of the invention. Actual reduction to practice occurs when a physical embodiment is made. Therefore, federal government rights to inventions can arise even from work under a funding agreement that actually reduced to practice a subject invention made under non-government funding and for which a patent had issued (or was applied for). Contractors have received federal funding *after* a particular patent has been filed for, or issued, and assumed that they owned the invention and patent free and clear of the federal government. However, if the invention had not yet been actually reduced to practice, and was then *first actually reduced* to practice under the new funding agreement, then government rights under Bayh-Dole subsequently attach to the initially "free and clear" invention/patent.

Finding 7. ***Other than the contractor right to elect title, nearly all of Bayh-Dole's key provisions, terms, and policies date back at least to the Kennedy Patent Policy in the 1960s (as influenced by the 1947 Attorney General's Report on Government Patent Practice and Policies).*** A chain of continuity exists from the first full federal government patent regulations and clauses—promulgated under the Nixon Patent Policy—to the current Department of Commerce Bayh-Dole regulations and patent clauses. The current patent clause is quite similar to both the "contractor title" patent clause and model Institutional Patent Agreement (IPA) that existed in federal government regulations by the 1970s. Congress indicated that it was *not* making substantive changes to these developed terms and policies—except as to the change to a contractor title election right as the default policy.

Finding 8. ***Bayh-Dole does not mandate contractor ownership.*** Initial title allocation can go either to the federal government or to the contractor. Retention of title by the contractor is optional: the contractor must *elect* to take title. Contractors may affirmatively choose not to take title or may fail to elect title in a timely and appropriate fashion. Federal agencies can also invoke the "exceptional circumstance" provisions of Bayh-Dole to restrict or eliminate the contractor's right to elect title in certain situations. However, the nature of this latter process makes it administratively more challenging for federal agencies to invoke these provisions than to follow the standard model of contractor election of rights.

Finding 9. ***Bayh-Dole might not guarantee or secure contractor (university) subject invention ownership by act of law.*** Contractors who fail to execute and secure adequate contractual rights and title in subject inventions from their employees might not be able to rely on the provisions of Bayh-Dole to do so by act of law. Under a recent federal appeals court ruling, universities must have inventors assign their inventions by present or immediate conveyance language (*e.g.,* "hereby assigns"), rather than future or contingent conveyance language (*e.g.*, "hereby *agrees* to assign"), to effect both their and the federal government's rights to federally funded subject inventions.

Finding 10. ***Regulations require universities to take steps effectuating the federal government's rights in subject inventions by requiring all employees except clerical and non-technical workers to execute patent agreements that protect the federal government's interests.*** While the language of the regulations does not expressly state that universities must require employees to assign their inventions, it would be very difficult to craft a patent agreement that leaves title with the employee-inventor while protecting the title allocation, licenses, and other rights of the federal government and university as required by the Act and the implementing regulations. The provisions of Bayh-Dole envision a binary initial title allocation as *only* between the contractor and the federal government. Accordingly, Bayh-Dole establishes a *de facto* requirement for universities to secure subject invention assignments from research personnel. Given a recent federal appeals court ruling (*see* Finding 9), as a practical matter such assignment needs to be in present conveyance language for any future inventions at the outset of the federally funded research. Contingent future assignment language fails to secure the federal government's (and the university's) rights in subject inventions.

Finding 11. ***By its own terms Bayh-Dole does not expressly address the rights or obligations of inventors, other than the inventor's right to share in licensing revenues. The sole procedure for university employee-inventors to retain title is for the university to not elect to retain title and then the employee-inventor can petition the funding agency to grant a request to retain title, which it may do after consultation with the university.*** The language used in Bayh-Dole and its regulations can obscure the fact that the actual assignments of title must occur through a separate legal act. Similar to Finding 10, which outlines the need for universities to secure legal assignments of subject inventions in the first place, any further transfer of a subject invention assignment held by the university, whether to the federal government or to the employee-inventor, must be effected by a legal act of assignment. The employee-inventor only truly "retains" title to a subject invention under Bayh-Dole in the case where: no assignment had yet been effected to the university (or a third party); the university does not elect to retain title; the employee-inventor petitions the funding agency; and the funding agency grants the request. In other cases, the employee-inventor must have the title assigned back to them.

Finding 12. ***Federal funding agencies can effectively authorize and consent that universities practice subject inventions held by third parties on behalf of the federal government under the Government License in Bayh-Dole.*** According to a federal district court ruling, any such use could only be invoked as a defense against patent infringement if the funding agency incorporates the "authorization and consent" language required by the separate Government Use Statute (28 U.S.C. § 1498, see Part III.J) in the funding agreement. This would allow the contractor to move any infringement suit into the Court of Federal Claims, bring in the

federal government as the defendant, and remove the contractor from the suit. Funding agencies could identify specific subject inventions to which the federal government has a Government License (see Part III.B.3.c.ii) and authorize and consent to the contractor's use of those inventions. In any § 1498 proceeding that followed, the federal government could then avoid paying compensation because of the Government License. However, a university researcher's ability to know whether there are relevant third party subject inventions for which such authorization and consent should be requested from the funding agency is often limited to cases where the patent or application has the required statement of government support or a confirmatory license has been listed in the USPTO Government Register.

Finding 13. ***The federal government has three distinct confidentiality obligations under Bayh-Dole: (i) temporary confidentiality of a subject invention disclosure for a "reasonable time" while the university prepares to file a patent application (up to one year); (ii) temporary confidentiality for the patent application and parts thereof during the 18 month pre-publication period established by the USPTO; and (iii) permanent exemption from release under Freedom of Information Act (FOIA) requests for confidential information submitted as part of a utilization report.***

Finding 14. ***The Department of Commerce (DoC) has limited rulemaking authority to implement §§ 202-204 of Bayh-Dole; DoC also has regulatory responsibility for licensing government-owned subject inventions under § 208 of Bayh-Dole, however, this aspect of DoC's authority is outside the scope of this report.*** Sections 202-204 govern: the Government License; march-in rights; utilization reports; invention disclosures; procedures for title election and/or allowing employee inventors to retain title to subject inventions; standard clauses for federal funding agreements; requirements for preference for U.S. industry in exclusive licensing arrangements; and specific requirements on nonprofit contractors (which includes universities) such as the degree of preference for small businesses in licensing and conditions for approval of assignments of subject inventions to entities or persons other than patent management firms. DoC does not have authority to engage in rulemaking for provisions of Bayh-Dole beyond these enumerated ones or that would conflict with the stated policies contained within the Act's provisions, including the title allocation and control rules.

3. Other patent law issues (Part III.C)

Finding 15. ***Patent Act rules of inventorship apply only to natural persons, not corporations or other legal persons; thus, while a university can own a patent it can never be considered to be the inventor (the natural person inventors must all be listed on the patent application); this is in contrast to the Copyright Act's work-made-for-hire doctrine in which, in certain cases, a corporation or other legal person such as a university, can both own a copyright and be the author with no rights or attribution required to be given to the natural persons who actually created the underlying work***.

Finding 16. ***All and only actual inventors must be listed on issued patents; the presence of non-inventors or absence of inventors can invalidate the patent***. Decisions as to who are the inventors must be made strictly in accordance with the inventorship rules of the Patent Act, and not with regard to academic unit or lab structure or hierarchies. So long as there was no

deceptive intent, erroneous inventor listings can be corrected by the USPTO or a court. An individual who believes that he or she was improperly not listed as an inventor on a patent application or issued patent generally may sue for correction of inventorship. However, if the individual had already assigned rights to the invention to another party, such as an employer, then he or she will not have standing to sue unless he or she can show some ongoing interest, such as a financial interest due to rights to licensing revenues.

Finding 17. ***In the case of joint inventorship, the failure of an assignee or exclusive licensee to obtain assignments or licenses, respectively, from all joint inventors (directly or through intermediary assignees or licensees with rights to convey such rights) can jeopardize the assignee or exclusive licensee's exclusivity under, and ability to enforce, the patent*** .

Finding 18. ***The CREATE Act allows universities involved in collaborative research with other institutions to avoid the risk of having research at one of the institutions count as prior art to make a current invention unpatentable, but the institutions must follow strict rules for establishment and disclosure of a joint research agreement covering the research.***

Finding 19. ***Recent U.S. Supreme Court decisions in patent licensing cases have affected both the way in which universities can license their patents and the chances of universities realizing their expected returns on those licenses***.

Finding 20. ***The common law research use exception is generally unavailable to universities for their research activities; however, the regulatory review research exception under the Hatch-Waxman Act can encompass some university life sciences research activities*** .

4. Data rights and sharing (Part III.D)

Finding 21. ***Raw data in and of itself—meaning the underlying facts that have been discovered through research—is neither patentable nor copyrightable, but may be proprietary under trade secret law or contractual arrangements; however, the compilation of data into reports, graphic representations, or other formats may result in copyrightable works where the format is original and not merely functional; in such cases, the copyright attaches only to the original format and not to the underlying data (facts) itself.***

Finding 22. ***Disposition of data arising under federal contracts is generally governed by the Federal Acquisition Regulations (FAR) system, although some agencies have their own procurement regulations; disposition of data arising under federal grants or cooperative agreements is dependent on each agency's policies.*** Federal agencies have some flexibility to fashion data rights and sharing policies for work performed under contracts, grants, and cooperative agreements. Bayh-Dole does not directly cover data, but data that is a necessary part of the disclosure needed for a subject invention will then fall under the various provisions of the Act.

5. Copyrightable works (Part III.E)

Finding 23. ***Copyrightable works by university personnel, including scholarly works by***

faculty, are likely work made for hire under the Copyright Act of 1976, absent an express written agreement signed by the parties to the contrary. The judicial or common law "teacher exception" to the work made for hire doctrine, which existed under the Copyright Act of 1909, likely did not survive enactment of the Copyright Act of 1976, (which fully replaced the Copyright Act of 1909). Full-time faculty members are generally employees of their university and produce scholarly works as part of their academic appointment (especially for purposes of tenure, retention, and/or promotion decisions) and thus those works are likely to be considered as made within the scope of employment. However, the 1976 Act expressly allows employers to disclaim their work made for hire authorship and ownership rights in a written agreement with the employee. Accordingly, many universities have put into place policies which mimic the pre-1976 Act "teacher exception" to maintain the status quo from before the Act's passage. However, such policies must be incorporated into a signed written agreement between the academic and the institution—usually the academic's employment or appointment agreement—to have the highest chance of being upheld as the written agreement necessary to alter the default work made for hire rule.

Finding 24. ***Under the Omnibus Appropriations Act, 2009, universities and researchers that receive funding from the National Institutes of Health (NIH) must submit to the National Library of Medicine's PubMed Central database an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication resulting from research supported, in whole or in part, with direct costs from NIH, to be made publicly available no later than 12 months after the official date of publication, in a manner consistent with copyright law.*** Congress has contemplated extending this law to cover research arising under funding from all federal agencies, but has not yet passed such legislation.

6. Economic espionage (Part III.F)

Finding 25. ***While trade secrets are primarily governed by state law, the Federal Economic Espionage Act of 1996 provides federal criminal penalties for: (i) misappropriation of U.S. citizen/entity trade secrets for the benefit of foreign governments, instrumentalities, or agencies; and (ii) misappropriation of a trade secret that is related to or included in a product intended for interstate of foreign commerce.*** Universities and their personnel can find themselves on either side of this issue, particularly given the free exchange of information and individuals across state and national borders in which they are involved.

7. National security and "deemed exports" (Part III.G)

Finding 26. ***University research will generally be exempt from the International Traffic in Arms Regulations (ITAR) export controls and licensing requirements so long as it qualifies as "fundamental research" which means that: (i) the university and researchers may not accept restrictions on publication of scientific and technical information resulting from the research; and (ii) the research may not be funded by the federal government in a manner that imposes specific access and dissemination controls on information resulting from the research.***

Finding 27. ***The Export Administration Regulations (EAR) contain a similar concept of exemption for "fundamental research," but the definition under the EAR is somewhat more***

accommodating of publication restrictions.

Finding 28. ***Foreign nationals involved in research at U.S. universities are considered to be representatives of their country of origin and so disclosure to them of scientific or technical information regarding items on the U.S. Munitions List (which can include software and other items not generally thought of as weaponry or ordnance) will be considered a "deemed export" of the information even though it occurs on U.S. soil.*** If the information is not exempted as resulting from "fundamental research" under the ITAR and EAR, then the university will need to secure licensing from the Department of State Directorate of Defense Trade Controls or the DoC Bureau of Industry and Security, as applicable.

Finding 29. ***The ITAR and EAR restrictions impact universities' freedom to: in-license IP, data, materials, and source code; allow foreign nationals to work on, or access information from, certain research projects; and out-license IP, data, materials, and source code to foreign firms, which may include U.S. entities controlled or owned by foreign firms.***

8. Materials (Part III.H)

Finding 30. ***There is no direct federal law governing the transfer of biological materials, although there are prohibitions on the commercial sale of human tissues and organs; states may have their own laws regarding the collection, transfer, and disposition of human biological materials***.

Finding 31. ***Materials are generally transferred under Material Transfer Agreements (MTAs) that often do not convey title to the recipients but rather only convey a use right under the personal property and IP rights of the materials provider; NIH coordinated the development and adoption of a model Uniform Biological Materials Transfer Agreement (UBMTA) in the 1990s, but it is not mandatory even for signatory institutions.***

9. Use and accounting of federal funds by universities (Part III.I)

Finding 32. ***University use of federal funds is governed by OMB Circular A-21, "Cost Principles for Educational Institutions," which establishes rules and restrictions for charging costs to federal funds for procurement of IP, including licensing and other fees for obtaining rights from third parties; there are extra restrictions on the nature and extent of IP royalty payments to persons (including corporations) (i) affiliated with the university, (ii) unaffiliated but under an agreement that contemplates a sponsored research funding agreement to be entered into with the university, or (iii) under agreements entered into after the federal funding was awarded to the university.***

10. Government Use Statute (Part III.J)

Finding 33. ***Universities may be able to avail themselves of the defensive protection of the Government Use Statute (28 U.S.C. § 1498) under contracts, grants, and cooperative agreements from federal agencies, provided that the agency includes the appropriate authorization and consent language in the funding agreement*** . In such cases, the university can

raise the defense that the allegedly IP infringing activities were done on behalf of the federal government and that any infringement-based lawsuit should be dismissed. If the court dismisses the case against the university on these grounds, then the plaintiff IP owner's only recourse is to bring a case against the federal government in the Court of Federal Claims for fair compensation for unauthorized use of the IP, but not for injunctive relief.

11. Tax exempt status and bonds (Part III.K)

Finding 34. ***Revenues from university licensing activity, sponsored research, and equity stakes in spin off companies are unlikely to jeopardize the tax-exempt status of universities.*** However, under certain circumstances some of these activities may to result in tax liabilities under the Unrelated Business Income Tax (UBIT) rules. Some of these activities may also undermine the tax-exempt status of bond issues.

Finding 35. ***Universities may jeopardize their tax exempt status, or that of their issued bonds, by assigning or granting exclusive rights to inventions or materials in advance of the creation of the assets to interested parties, such as sponsored research funders, in anything less than arms length transactions***.

12. Sovereign immunity and IP infringement by state agency universities (Part III.L)

Finding 36. ***State universities that are ruled to be state agencies may not be sued for IP infringement under the constitutional doctrine of state sovereign immunity, unless they waive such immunity; while injunctive relief against university personnel for IP infringement is possible, the named defendants must be those actually engaged in the infringement and not supervisors or administrators.*** However, federal court rulings in this regard are generally predicated on the theory that some remedy for the financial impacts of such IP infringement is available under state law and in state courts.

13. State laws (Part IV)

Finding 37. ***While the Patent Act and Copyright Act provide rules for inventorship and authorship, respectively, state law generally governs title transfers and determination of ownership of any IP.***

Finding 38. ***Some states have "freedom to create" statutes that limit the scope of IP assignment agreements that employers can demand; these apply equally to universities as to private employers.***

Finding 39. ***The tripartite "shop rights" system of common law default rules for invention title allocation generally govern in the absence of express written IP allocation agreements***

Finding 40. ***States that provide public funding for university research are increasingly imposing regulations governing the allocation, use, and transfer of IP arising under such funding.***

Finding 41. ***Universities are legal entities and legal persons organized under state law, not an aggregate or association of their faculty, and do not exist primarily for their faculty's benefit.*** Faculty may play a role in governance but they do not legally own or exert exclusive control (even in the aggregate) over the university entity.

Finding 42. ***A core principle of state nonprofit corporations law is that neither employees, directors, board members, trustees, nor any other individual directly involved in the governance or operations of a nonprofit organization may cause the organization to benefit the individual beyond the payment of fair market compensation for services rendered.*** Any direction of further benefits or assets to the ownership or exclusive use of the individual is deemed "private inurement" and prohibited.

Finding 43. ***State universities that are state agencies are often subject to specific rules for how state assets—including IP, data, and materials—may be disposed; personnel at such universities are state employees who are personally subject to restrictions on personal gain or private inurement from their university positions, or control of university/state resources, other than through their regular compensation and permitted outside consulting activities.***

14. Private ordering and contractual arrangements (Part V)

Finding 44. ***As extensive as are the federal and state statutes, regulations, and case law governing university IP and technology transfer, a substantial "free play" zone remains for universities to arrange private contractual relationships with personnel, funders, and other external parties ("private ordering" or "private law").*** Universities are generally free to engage in private ordering in this space, bounded primarily by statutory, regulatory, and case law.

Finding 45. ***Standard issues and best practices for private ordering in all aspects of university IP and technology transfer can be identified and analyzed.***

B. Guide to Using this Report

Because of the nature of legal material, this report is presented in a source-of-law format. This means that topics are arranged according to where they fit in a hierarchy of federal, state, and private law, coupled with doctrinal legal categories such as "patent law." However, many real world issues of interest to policymakers and the public cut across these legal categories. Thus, this section provides a road map to the legal issues and parts of the report that are necessary to understand the legal environment of four areas of particular contemporary import and interest.

1. IP ownership

Determinations of the legal ownership of IP arising in the university research enterprise implicate a wide range of federal, state, and private law.

- Inventorship: Part III.C.1
- Authorship: Part III.E
- Assignments of title: Part III.C.3; Part IV.B; Part V.B.1
- Restrictions on, or requirements for, specific title allocation or pre-assignment: Parts III.B.1-3, 6, 8; Part III.C; Part III.I; Part IV.B; Part IV.C; Parts IV.D-E.

2. Use of IP, data, and materials in the academic research enterprise

The freedom of university researchers to use IP, data, and materials of private parties also implicates a wide range of federal, state, and private law. State agency universities may have some extra freedom under the doctrine of sovereign immunity, although this should be considered with caution.

- Government Use License under Bayh-Dole: Part III.B.3
- Research use exceptions/exemptions: Part III.C.6
- Government Use Statute: Part III.J
- Federal data sharing policies: Part D
- Federal rules for dissemination of research publications: Part III.E
- Federal policy on the transfer of biological materials: Part III.H
- Assignments and licenses of IP: Part III.C.3; Part V
- Sovereign immunity for state agency universities: Part III.L

3. Restrictions on acceptance and use of revenue streams

The receipt of funding, licensing, and other revenue streams by universities impacts, and is impacted by, a wide range of federal, state, and private law.

- Bayh-Dole for inventions arising under federal funding: Part III.B
- Federal rules for data arising under federal funding: Part D
- Federal rules for research publications arising under federal funding: Part III.E

- OMB rules regarding use and accounting of federal funds by universities: Part III.I
- Tax exempt organization and bonds restrictions: Part III.K
- Nonprofit corporation law and state agencies: Part IV.D
- State and local research funding: Part IV.C
- Private ordering requirements from funders: Part V.B.2

4. Special issues for state agency universities

State universities that are deemed to be state agencies have an extra layer of federal and state law that impacts their IP and technology transfer activities, but that does not apply to private and quasi-public or state-related universities.

- Sovereign immunity: Part III.L
- State agencies: Part IV.D
- Law governing state employees, IP, and use of state assets: Part IV.E

I. INTRODUCTION

Universities today operate amidst a rapidly growing web of patents, other intellectual property (IP) rights, and non-IP rights in tangible materials and intangible data. They are both producers and consumers of the intellectual assets protected by such rights. Thus, despite their non-profit, academic status, they have to navigate through both "offensive" or "foreground" rights positions and "defensive" or "background" rights positions just as many private sector firms must do. Offensive or foreground rights are those that the university generally seeks to license out to others. Defensive or background rights are those that the university has either licensed in from others, or developed on it own, to defend its freedom to operate in its research, teaching, or service missions. Based on the strong rule of law foundation of the United States, even the federal government must operate as any other legal person in terms of establishing its offensive and defensive rights. For example, federal agencies do not automatically receive patent protection for an invention that their employees or contractors develop, but must apply for a patent from the U.S. Patent and Trademark Office (USPTO) just like any other legal person. Likewise, the federal government may not simply use a private citizen's patented invention or copyrighted work without compensation, just as it may not use or take citizens' physical property without fair compensation. In sum, the private, academic, and public sectors all face broadly similar issues of securing offensive proprietary positions and establishing defensive positions with regard to inventions, authored works, materials, and data.

This report focuses on the substance and relationships of the myriad legal rules affecting universities as they navigate this web of offensive and defensive rights. It will adopt the convention of referring to rights under patents, copyrights, trademarks, and trade secrets collectively as "IP," while referring to tangible property rights in physical materials as "Materials Rights," and non-IP intangible rights in data as "Data Rights." The sources of laws affecting universities in this regard are manifold: constitutional law; federal statutes and regulations, and cases interpreting them; state statutes and regulations, and cases interpreting them; and state common law. The laws affecting a particular situation vary depending upon both the nature of the university's corporate status (state agency, non-profit entity receiving significant state funding, or private non-profit academic institution) and whether it has received federal or state funding for the activity or facilities. Accordingly, the report covers more than just the federal rules for ownership and use of federal funded inventions established under the Bayh-Dole Act of 1980 (Bayh-Dole, or the Bayh-Dole Act). [1] It is especially important to note that Bayh-Dole covers *only* patentable inventions arising from federally funded research. Thus, non-patentable inventions such as those that might only be protected as a trade secret, authored works falling within the ambit of copyright, marks and other devices falling within the ambit of trademarks, physical materials eligible for neither patent nor trade secret protection, and intangible property such as data, all can have significant value to both universities and other parties but are not covered by the rules promulgated under Bayh-Dole.

Notwithstanding the foregoing, the Bayh-Dole rules have certainly occupied a central place in the discussion and practice of university technology transfer. Further, there is general agreement that Bayh-Dole sparked much greater interest in university IP and technology transfer

[1] P.L. 96-517, 94 Stat 3015 (1980) (*codified at* 35 U.S.C. §§ 200-212).

than had previously existed. Accordingly, a substantial part of this report will cover the development and implementation of Bayh-Dole. Part II outlines the extensive judicial, executive, and legislative activities that led to the current Bayh-Dole system of rules. Because Bayh-Dole evolved out of a backdrop concerned first and foremost with the ownership and use of patent rights emerging from federally funded research (both intramural and extramural), Part II treats the history of this development from the federal government's perspective. But because the federal government was equally concerned with its defensive patent and copyright position—that is its ability to use patents and copyrights held by private persons—Part II also briefly recounts the development of what is sometimes referred to as the "IP Takings Clause" or the "Government Use Statute."[2]

Federal grants and contracts still fund the majority of academic R&D at both public and private universities.[3] Accordingly, Bayh-Dole will almost always be a consideration for research results that include patentable inventions. At the same time, there are a number of other federal law areas that impact either the offensive or defensive IP position of universities. Thus, Part III focuses on the full range of current federal laws and policies affecting university IP and technology transfer including: (i) Bayh-Dole and other relevant Patent Act provisions/doctrines; (ii) data ownership and use rules; (iii) relevant Copyright Act provisions; (iv) the Economic Espionage Act; (v) export controls; (vi) policy pertaining to the transfer of biological materials; (vii) Office of Management & Budget (OMB) rules for use and accounting of federal funds by universities; (viii) the Government Use Statute; (ix) limitations on ownership and use of university IP and other assets imposed by the Internal Revenue Code (IRC) and Internal Revenue Service (IRS) rules governing tax-exempt entities; and (x) the constitutional doctrine of state sovereign immunity which may effectively limit the liability of some state universities for unauthorized use of privately held patents and copyrights.

Part IV then analyzes the various state law issues affecting university IP and technology transfer including: (i) trade secret law; (ii) common law and contract-based rights surrounding ownership, assignment, licenses, and "shop rights" in the employed inventor/creator context; (iii) state and local laws or regulations governing IP rights arising from research funded by that political entity; (iv) nonprofit organizations law and laws governing state agencies; and (v) laws covering state employees, state agency universities, and the use and transfer of state assets, including IP, materials, and data, by these individuals and agencies. Part V considers legal issues in "private ordering" arrangements such as inventor assignment agreements and technology transfer licenses that often have the most direct impact on the transfer and use of university IP, materials, and/or data. The Appendices include copies of relevant U.S. statutes, regulations, and policies as well as a brief overview of relevant developments in select foreign jurisdictions. The report also contains an Executive Summary and Guide to Using the Report for the aid of the reader.

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[2] The clause is currently codified outside of the patent and copyright laws—which are currently codified in Titles 35 and 17 of the U.S. Code, respectively—and is instead codified in the judiciary title of the U.S. Code at 28 U.S.C. § 1498. This may have led to the relative obscurity of this important statutory law. This report will refer to this statutory law as the "Government Use Statute."

[3] Federal funds accounted for 60 percent of science and engineering (S&E) research expenditures at U.S. academic institutions in fiscal year 2008 according to the *Survey of Research and Development Expenditures at Universities and Colleges, FY 2008*, National Science Foundation (NSF), Division of Science Resources Statistics.

II. History of Federal Government Patent Policies Pertaining to University IP and Technology Transfer

A. Early Developments

During the first century of the United States, all three branches of government had to grapple with whether the federal government stood as a sovereign with special rights as to ownership and use of intellectual property, or whether it instead was primarily just another legal person in this regard. At the same time, the federal government had to work through new systems of both federal and state IP approaches, including patents (utility, plant, and design), copyright, trademarks, trade secrets, and, later, plant variety protection rights. [4] Whereas, the British Crown and some of the sovereigns of Europe had doctrines such as "crown rights" that provided special rights to the government for use of IP held by private parties, as well as for ownership of IP created by government employees or contractors, the United States had to determine whether any of these were sanctioned by the U.S. Constitution or appropriate for the values of the new republic.

As early as 1812, Congress appears to have rejected the crown right approach and instead negotiated arms length purchases of patent rights from private citizens. [5] Seminal federal court decisions throughout the nineteenth century established a number of relevant legal principles. First, mid-level government officials did not necessarily have the authority to initiate a taking on behalf of the federal government. [6] Second, the unauthorized practice of a patent by the federal government may not be a "taking" or exercise of eminent domain for constitutional purposes. [7] Third, federal officials might have personal liability for patent infringement by a federal agency that they had authorized. [8] Fourth, despite the judicial rejection of crown rights, the federal government and its contractors enjoyed the protections of sovereign immunity, at least insofar as there was no proper judicial venue for entertaining IP suits by private citizens against the federal government and its authorized contractors. [9] Also during the nineteenth century, the federal government began funding "intramural" [10] research within the Department of Agriculture and the Department of War. Yet, it had no ownership policies for IP arising from such work and federal employees were generally allowed to patent and retain all rights to inventions arising from their research—the federal government did not even obtain a non-exclusive license. [11] By the end of

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[4] This report use the term "intellectual property" and "IP" to refer collectively to all of these systems of exclusive rights.

[5] *See, e.g.*, Act of Mar. 2, 1812, ch. 34, 12 Stat. 691 (authorizing purchase from one Winslow Lewis his patent right to a "new and improved method of lighting Lighthouses, and for other purposes.").

[6] Pitcher v. U.S., 1 Ct. Cl. 7 (1863).

[7] *Id.*

[8] James v. Campbell,104 U.S. 357 (1881).

[9] Schillinger v. United States, 155 U.S. 163 (1894).

[10] "Intramural" research is that done within government facilities by government employees.

[11] *See, e.g.*, Act of July 4, 1836, ch. 360, 24 Stat. 126 (authorizing purchase of two patents from one Captain

the nineteenth century, federal courts began applying the same state common law "shop right" rules to inventions by federal employees as they did to private industry employees. [12]

At the beginning of the twentieth century, the federal government began reconsidering how it should access IP held by private parties that it needed for government purposes. The increasing technological basis of modern warfare was leading to an increase in patents on military devices that the federal government needed to practice. In response, Congress enacted the Act of June 25, 1910[13] that allowed the federal government to practice privately held IP without authorization, but in turn authorized the Court of Claims to hear petitions by the IP owners for fair compensation. The statute, in its amended form, has become known as the "Government Use Statute" or "IP Takings Statute." It was challenged shortly thereafter when the German corporation Krupp sued to enjoin Crozier, Chief of Ordnance of the U.S. Army, from manufacturing Krupp's patented field guns and carriages in U.S. arsenals. The case went to the U.S. Supreme Court where Krupp's claim to a right of injunction for the infringement was rejected by the Court based on the existence of the new Government Use Statute. [14] The Court held that because the statute authorized the federal government to practice the patent without authorization of the patent owner, then the sole remedy available was compensation awarded through the Court of Claims as provided by the statute.

After *Crozier*, it was generally assumed that federal government contractors enjoyed the same protection under the Government Use Statute as federal employees did. [15] However, at the height of World War I, the U.S. Supreme Court held that this was not the case. [16] Wartime concerns resulted in quick action and Congress voted to amend the Government Use Statute through the Naval Appropriations Act of 1918 to allow federal agencies to authorize contractors to practice privately held patents on behalf of the federal government without authorization from the patent owners. [17] The U.S. Supreme Court upheld the statute nine years later and reaffirmed that the sole remedy for patent owners in matters of infringement by the federal government or

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William H. Bell: the first for "a machine for elevating heavy cannon," and the second for "a traverse board for pointing cannon."); Act of Aug. 8, 1846, ch. 169, 29 Stat. 82. (authorizing purchase of patents for a "manger stopper" from the widow of a Navy master commandant). It is unclear whether these military officers invented these devices while actively on the job, used military resources to do so, or even possibly were specifically hired or commissioned to do so. Further it is unclear whether the Government wanted only the rights to practice the inventions—which it could possibly have had under a common law employer shop rights license recognized at the time. *See* McClurg v. Kingsland, 42 U.S. 202 (1843).

[12] U.S. v. Talbert, 15 S.Ct. 4 (1894); U.S. v. Burns, 79 U.S. 246 (1870); Solomons v. U.S ., 11 S.Ct. 88 (1890). The shop rights doctrine has three parts. First, inventions created by employees on employer time, or using employer resources, must convey a nonexclusive, nontransferable license to the invention to the employer. Second, if the employer can show that the employee was actually specifically "hired to invent" that kind of invention, then the employee must assign the invention to the employer. Third, if the employee was not on employer time and did not use employer resources to invent, then the invention is his free and clear. However, a written agreement between employer and employee allocating IP rights supersedes these common law default rules.

[13] Act of June 25th, 1910, c. 423, 36 Stat. 851.

[14] Crozier v. Fried. Krupp Aktiengesellschaft, 224 U.S. 290 (1912).

[15] *See, e.g.*, Karl Fenning, *Patent Infringement By the Government*, 37 Yale L.J. 773, 776 (1928).

[16] Cramp & Sons Ship & Engine Bldg. Co. v. Int'l Curtis Marine Turbine Co., 246 U.S. 28 (1918).

[17] Act of July 1. 1918, c. 114, 40 Stat. 705, codified at 35 U.S.C. § 68, later recodified at 28 U.S.C. § 1498.

its contractors was to seek compensation under the statute in the Court of Claims. [18] Further cases interpreting the amended Government Use Statute complicated the picture for federal government contractors. In *Wood v. Atlantic Gulf & Pacific Company*,[19] the U.S. District Court for the Southern District of Alabama held that in order for the statute to apply, the federal government must authorize or consent to its contractor's infringement of a patent. In *Newport News Shipbuilding and Dry Dock Co. v Isherwood*,[20] the U.S. Supreme Court held that the statute did not apply because the contractor had built ships for the federal government while it still had a separate licensing agreement with the patent owner to use the patent. Accordingly, this meant that the federal government and its contractors would be bound to any licenses the contractor was a party to before or during the federal contract work. This might have been fine in peacetime, but the dramatic upswing in military manufactures needed during wartime meant that the federal government needed to be able to procure such manufactures through its contractors at much lower prices.[21]

Congress amended the Government Use Statute again to clarify these issues in the Royalty Adjustment Act in 1942.[22] The amendment added language codifying the judicial requirement for clear "authorization and consent" by a federal agency for the contractor to use the specified patents or copyrights without authorization of the owner and still be covered by the statute. It also sought to clarify that contractors were not bound to existing licenses with patent owners while doing work for the federal government if the hiring agency incorporated clear authorization and consent language to use the patents in question independent of any license. [23] Finally, the amendment also served to settle any confusion in the courts as to whether the Government Use Statute applied to federal *subcontractors*, as well as prime contractors, by explicitly adding them. The statute then remained unchanged until after World War II, when it was reworded and transferred out of Title 35, to Title 28, which covers the judiciary and judicial procedure.[24] A full discussion of the current state of the Government Use Statute in included in Part III.J.

Meanwhile, "extramural"[25] research had begun in the nineteenth century at Land Grant Universities, Agricultural Colleges, and Agricultural Experiment Stations organized under the

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[18] Richmond Screw Anchor Co. v. United States, 275 U.S. 331 (1928).

[19] 296 Fed. 718 (S.D. Ala. 1924).

[20] 5 F.2d 924 (4th Cir. 1925).

[21] *See, e.g.*, *Hearings Before Committee on Patents, House of Representatives, on H.R. 7620*, 77th Cong., 2d Sess. 17 (1942), Letter of Henry Stimson, Secretary of War, addressed to the Speaker of the House.

[22] 56 Stat. 1013 (1942). The text of the amendment reads:

> For purpose of this Act and the Act of June 25th, 1910, as amended (40 Stat. 705; 35 U.S.C. 68), the manufacture, use, sale, or other disposition of an invention described in and covered by a United States patent or in an application for patent therefore, by a contractor, a subcontractor, or any person, firm, or corporation for the Government and with the authorization and consent of the Government, shall be construed as manufacture, use, sale, or disposition for the United States.

[23] *Hearings Before Committee on Patents, House of Representatives, on H.R. 7620*, 77th Cong., 2d Sess. 17 (1942), Letter of Henry Stimson, Secretary of War addressed to the Speaker of the House.

[24] Act of June 25, 1948, ch. 646, 62 Stat. 941, 35 U.S.C. § 68 repealed by 62 Stat. 998 (1948).

[25] "Extramural" research is research funded by the Government but not performed by government employees. It can take place at government-owned, contractor-operated facilities ("GOCOs") or contractor-owned facilities.

Morrill Act,[26] the Second Morrill Act,[27] and the Hatch Act of 1887.[28] In the absence of federal policy guidance, universities held patents as independent legal entities, while professors occasionally patented inventions resulting from their research and simply took title as individuals.[29] The practice of assigning inventions made by faculty researchers to the employing university appears to have emerged around the time of the World War I.[30] By the 1930s, a number of universities had by the 1930s adopted institutional patenting policies.[31] The federal government was also developing a substantial practice of funding extramural research at private sector firms. Accordingly, many of the federal patent policies that emerged over time were primarily directed to private sector contractors.

As early as the 1920s, the Executive branch began studying the nature of patents arising under federal funding.[32] In 1933, the U.S. Supreme Court ruled that federal employees had no obligation to assign their patents to the federal government, absent clear evidence that they had been hired to invent just that sort of thing, and confirmed that the general principles of the common law shop rights doctrine applied equally to the federal government as to private employers.[33] As World War II ushered in a heightened era of federal funding of intramural and extramural science and technology, the federal government found itself to be funding many new patented inventions. Thus, in 1944, President Roosevelt issued an Executive Order that called for a separate register be created in the U.S. Patent Office for the recording of all federal government rights and interest in patents and patent applications.[34] Roosevelt also desired to establish a uniform government-wide patent policy for both federal employee and contractor employee inventions. A year earlier he had requested the U.S. Attorney General (AG) to undertake a comprehensive investigation of the nature and extent of federal patent policies. The report anticipated the significant boom in post-war research funded by the federal government and sought to answer a single question: "What disposition of patent rights as between the Government, its employee or contractor, and what use of patent rights owned by the Government,

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[26] Act of July 2, 1862, ch. 130, sec. 1, 12 Stat. 503, codified as amended at 7 U.S.C. § 301 *et seq*.

[27] Act of Aug. 30, 1890, ch. 841, sec. 4, 26 Stat. 419, codified as amended at 7 U.S.C. § 321 *et seq*. (alternately referred to as the "Agricultural College Act of 1890").

[28] Act of Mar. 2, 1887, ch. 314, sec. 1, 24 Stat. 440, codified as amended at 7 U.S.C. § 361a *et seq.* (alternately referred to as the "Hatch Experiment Station Act")

[29] *See, e.g.*, U.S. Patent No. 1,647 to Samuel Morse (of New York University) in 1840; U.S. Patent No. 136,708 to William Dale (of Pennsylvania State College) in 1873; U.S. Patent No. 174,465 to Alexander G. Bell (of Boston University) in 1878; U.S. Patent No. 389,021 to Adolf Sommer (of University of California) in 1888; and U.S. Patent Nos.638,837 thru 638,840 to Reginald Fessenden (of University of Pittsburgh) in 1899.

[30] *See, e.g.*, U.S. Patent No. 1,212,945 to Thomas P. Haslam in 1917 (assigned to Kansas Agricultural College); U.S. Patent No. 1,218,472 to T. Brailsford Robertsonin in 1917 (assigned to University of California, by agreement); U.S. Patent No. 1,392,767 to Edward C. Kendall in 1921 (assigned to University of Minnesota); and U.S. Patent No. 1,491,900 to Daniel G. Chilson in 1924 (assigned to University of Arizona).

[31] *See* Richard Spencer, "University Patent Policies," Northwestern University Law School manuscript, September 1, 1939.

[32] *See* U.S. v. Dubilier Condenser Corp*.,* 289 U.S. 178, 206 (1933).

[33] *Id.*

[34] Exec. Order No. 9424, 3 C.F.R. 303 (1943-1948).

will best serve the public welfare and stimulate the progress of science and the useful arts?" [35]

Thus, by the end of World War II, all three main areas of federal patent policy were in development. For intramural research and inventions created by federal employees on the job, the federal government was moving towards a version of the shop rights system used by private employers. For extramural research and inventions created by federal contractors, the federal government was generally allowing the contractor or the contractor's employees to retain title. And finally, for patents held by private parties that the federal government needed to practice, the federal government could invoke the Government Use Statute even if it could not, or did not want to, obtain a license directly from the patent owner.

B. Roots of the Bayh-Dole Act

In 1947, the Department of Justice issued the AG's three volume report entitled "Investigation of Government Patent Practices and Policies, Report and Recommendations of the Attorney General to the President" (the "1947 Attorney General's Report"). This report set the stage for nearly all of the current debates and policies with regard to both intramural and extramural research patent policies. The AG found that with regard to inventions made by federal employees, "[i]nventions financed with public funds should inure to the benefit of the public, and should not become a purely private monopoly under which the public may be charged for, or even denied, the use of technology which it has financed." [36] The AG recommended that the federal government should obtain all rights to inventions made by federal employees: (i) during working hours; (ii) with a substantial contribution by the federal government in the form of facilities, equipment, materials, funds, information, time paid for by the federal government, or services of other federal personnel; or (iii) which bear a direct relation to the employee's official duties. [37] In cases where there was a less significant contribution by the federal government, or a minor relationship between the invention and the federal employee's official functions, the AG recommended that ownership should be left to the employee, subject to some important caveats. First, the federal government would retain a perpetual, nonexclusive, irrevocable, royalty-free license to make, have made, use and dispose of the invention. Second, the federal employee would have an obligation to exploit the invention diligently him or herself or grant nonexclusive licenses at a reasonable royalty to all applicants. [38] In all other cases, the AG recommended that all rights should be left to the employee. In essence, the AG was recommending the adoption of an aggressive form of the shop rights doctrine. President Truman later implemented these recommendations in Executive Order 10096 in 1950, which is still in force, as amended. [39]

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[35] Department of Justice, I Investigation of Government Patent Practices and Policies, Report and Recommendations of the Attorney General to the President 2 (1947).

[36] *Id.*

[37] *Id.*

[38] *Id.* at 3.

[39] "Providing for a Uniform Patent Policy for the Government With Respect to Inventions Made by Government Employees and for the Administration of Such Policy", Exec. Order No. 10096, 3 C.F.R. § 292 (1949-1953) *currently codified at* 37 C.F.R. § 501. The policy was challenged as unconstitutional in the 1970s and 1980s but survived. Heinemann v. U.S., 796 F.2d 451 (Fed. Cir. 1986) (finding the Truman Order constitutional based on

The AG also found that the "public interest" required that patents arising from federally funded research and development work (R&D) be assigned to the federal government: "Public control will assure free and equal availability of the inventions to American industry and science; will eliminate any competitive advantage to the contractor chosen to perform the research work; will avoid undue concentration of economic power in the hands of a few large corporations; will tend to increase and diversify available research facilities within the United States to the advantage of the Government and of the national economy; and will thus strengthen our American system of free, competitive enterprise." [40] Further, leaving patent rights with the contractor might permit suppression of an invention paid for by the public, or the imposition of charges for use by the public to private advantage. This could "unbalance" federal research by making those programs likely to lead to patents more desirable. "Expert opinion and experience within and without the Government" was cited to support the contention that enough competent private and institutional labs would accept contracts specifying federal ownership of patentable invention arising from them. Nonetheless, the AG concluded that in "emergency situations" exceptions could be made to this basic policy for situations in which the contractor already had made a substantial independent contribution to the field of research.

The AG then recommended a uniform patent policy in which all federal contracts for extramural R&D should stipulate that the federal government would own any resultant patents. [41] The head of each federal agency, however, could certify that an emergency existed and, with the approval of a central "Government Patents Administrator," award a contract allowing the contractor to retain title to any patent inventions arising under it, on terms and conditions that the Administrator would prescribe or approve, and only so long as the contractor had already made a substantial independent contribution to the field. However, any such exceptional contract would be subject to the following conditions: (i) the head of the agency and the Administrator would certify that reasonable efforts were made to find a contractor that would accept federal ownership of patents, but these efforts were unsuccessful; (ii) the contract would stipulate that the contractor would retain patent rights only to those inventions in which its independent contribution antedated the work called for in the contract; (iii) the contractor would grant the United States a nonexclusive, irrevocable, royalty-free license to make, have made, use and dispose of any inventions awarded to it under the contract; and (iv) the contractor (or its assignee) would agree to place the invention in adequate commercial use within a designated period, and if at the end of such time the federal government determined that such use was not being made, then the contractor (or its assignee) would be required to offer nonexclusive licenses at a reasonable royalty to all applicants. [42] The recommended requirements presaged the "Government License" and "March-in Rights" developed in the Kennedy Patent Policy (discussed below) and codified in Bayh-Dole, as discussed in Part III.B below. The AG also clearly distinguished among the three types of federal funding agreements still used today—procurement contracts, grants, and cooperative research agreements—and recommended that all

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Executive powers and Congressional acquiescence for many years); Kaplan v. Corcoran, 545 F.2d 1073 (7th Cir. 1976) (same).

[40] Department of Justice, I Investigation of Government Patent Practices and Policies, Report and Recommendations of the Attorney General to the President 4 (1947).

[41] *Id.* at 5.

[42] *Id.*

three could be treated under the same basic policy and exceptions framework.

A further central finding of the 1947 Attorney General's Report was that a uniform government-wide patent policy was indeed warranted and that it would "extend to all Federal agencies the benefits of sound patent principles, will avoid competition among the agencies, and will strengthen the Government's bargaining position." [43] Exceptions to the basic policy, if any, should also be governed by uniform principles and governed by the proposed Government Patents Administrator, to avoid conflict and breakdown of the basic policy. The AG also concluded that because the policy governed only employment and contracting within the Executive Branch, that it could be effected through an executive order and then implemented by departmental regulations. It would not alter or conflict with the existing patent laws or system. The AG recommended that the proposed Government Patents Administration should include both the Government Patents Administrator and an oversight body named the "Advisory Patents Board."[44]

The 1947 Attorney General's Report contained other findings and recommendations that are less relevant to the legal focus of this report, but still notable for current university IP and technology transfer policy debates. First, it found that systems of special financial rewards, promotions, or salary increases based on development of patentable inventions could be undesirable because they might induce secrecy and lack of cooperativeness. [45] They could also pose administrative challenges in selecting the persons to be rewarded, especially where the invention was the result of a group effort, and create dissatisfaction among those not rewarded (even though they had done equally worthwhile, but unpatentable, work), possibly resulting in the slighting of work not leading to patentable inventions. The AG recommended that any rewards systems treated patentable and unpatentable research results equally.

Second, it found that federally-owned inventions would best serve the public interest by being made available to all on a royalty-free, nonexclusive basis. [46] If further risky development were needed so that private firms could market the invention, then the federal government should finance such development. Notwithstanding this, it still found that patenting of such inventions was superior to simply dedicating the inventions to the public, because patenting would afford greater protection and control of the invention for the public interest. The AG recommended that: all federally-owned inventions be made fully, freely, and unconditionally available to the public without charge, by public dedication or by royalty-free, nonexclusive licensing; as soon as any such inventions were completed they should be patented or published (with full disclosure to the Patent Office to count as prior art to prevent others from patenting the invention); all federally-owned inventions should be listed and promoted in the register created under the Roosevelt Executive Order, with copies distributed widely; to the extent funds were available, projects should be initiated to demonstrate and publicize promising federally-owned inventions, especially to small businesses; the Government Patents Administrator or other federal agency could recommend preliminary experimental, developmental, or pilot-plant operations to establish the practicality or effectiveness of a particular federally-owned invention; and the Government

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[43] *Id.* at 8.

[44] *Id.*

[45] *Id.* at 3.

[46] *Id.* at 6-7.

Patents Administrator should prepare and submit to the President for approval a program to encourage and sponsor the use and practice of federally-owned inventions by small and new business concerns, and report periodically on the use of federally-owned inventions.

Third, it recommended that the Government should obtain foreign rights similar to whatever rights it had in the United States to any federally-funded invention. [47] If the federal government later determined that it did not need such foreign rights, then it could release them back to the employee or contractor. President Truman issued an Executive Order implementing this recommendation that same year. [48] It appears to be the first uniform directive to apply to all departments and agencies regarding patent rights arising from both intramural and extramural research funding.

Fourth and finally, the AG recommended that federal employees and contractors be required to agree, with regard to inventions made by them that the federal government determined should be kept secret, that they would not disclose the inventions to any unauthorized person, or assign any rights to them, or file any domestic or foreign patents, until and unless authorized to do so by the federal government. [49]

Despite the quick implementation of some of the AG's recommendations by the Truman Administration, none of the others were acted on throughout the 1950s. During that time, a number of federal statutes were passed that specifically allocated patents arising from federally-funded extramural research to either the federal government or the contractors. [50] In the absence of a uniform government-wide patent policy, the various agencies went their separate ways with different contractor title or license policies for patents arising from federally funded research. It was not until the Kennedy Administration that a uniform, government-wide policy governing inventions arising from extramural research was established (the "Kennedy Patent Policy"). [51] The Kennedy Patent Policy established nearly all the key concepts and terminology of the modern technology transfer system, albeit with many of them adopted from the recommendations of the 1947 Attorney General's Report. In particular, the core elements of the Government License and March-In Rights were in place. The Kennedy Patent Policy also included detailed requirements for contractors who acquired exclusive patent rights. For example, the contractor would have to submit periodic written reports to the funding agency regarding progress on commercialization of the invention. In cases where the federal agency retained the patent rights, the Kennedy Patent Policy imposed some conditions on the agency itself. First, if

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[47] *Id.* at 7.

[48] Exec. Order No. 9865, 3 C.F.R. 651 (1943-1948).

[49] Department of Justice, I Investigation of Government Patent Practices and Policies, Report and Recommendations of the Attorney General to the President 7 (1947).

[50] Act of June 29, 1935, § 10(a), as added by title I of the Act of August 14, 1946, 60 Stat. 1085 (codified at 7 U.S.C. § 427(i)(a)); Act of April 5, 1944, § 3, 58 Stat. 191 (codified at 30 U.S.C. 323); Act of August 14, 1946, § 205, 60 Stat. 1090 (codified at 7 U.S.C. 1624(a)); National Science Foundation Act of 1950, § 12, 82 Stat. 360 (codified at 42 U.S.C. § 1871(a)); Atomic Energy Act of 1954, § 152, 68 Stat. 943 (codified at 42 U.S.C. § 2182); National Aeronautics and Space Act of 1958, § 305, (codified at 42 U.S.C. § 2457); Coal Research Development Act of 1960, §6, 74 Stat. 337 (codified at 30 U.S.C. § 666); Helium Act Amendments of 1960, § 4, 74 Stat. 920 (codified at 50 U.S.C. § 167b); Arms Control and Disarmament Act of 1961, § 32, 75 Stat. 634 (codified at 22 U.S.C. § 2572); Foreign Assistance Act of 1961, § 219, 83 Stat. 806 (codified at 22 U.S.C. § 2179).

[51] Memorandum for the Heads of Executive Departments and Agencies, 28 Fed. Reg. 10,943, October 12, 1963, 3 C.F.R. 861 (1959-1963). The Memorandum is reproduced in Appendix A.

the funding agency chose not to file for foreign patents, then the contractor would be able to file for that patent subject only to a non-exclusive license to the federal government for governmental purposes and on behalf of any foreign government that would get such rights under a treaty or agreement with the United States. [52]

The key divergence of the Kennedy Patent Policy from the 1947 Attorney General's Report was that the Kennedy Patent Policy sought to establish a balance between federal government and contractor ownership of patents arising from federally funded research: ". . . the public interest might also be served by according exclusive commercial rights to the contractor in situations where the contractor has an established nongovernmental commercial position . . . ." Under the Kennedy Patent Policy, funding agencies should consider whether inventions arising during the course of or under federal funding agreements could productively be practiced directly by the public, or whether intervening R&D and "risk capital" was needed to turn the invention into a product that could be made available to the public. In part because of this, the Kennedy Patent Policy seemed primarily focused on private sector contractors, rather than university and nonprofit research organization contractors. This also seems to be borne out by a requirement of the Kennedy Patent Policy that contractors who retained either title or exclusive rights must bring those inventions to "the point of practical application," defined as "to manufacture in the case of a composition or product, to practice in the case of a process, or to operate in the case of a machine and under such conditions as to establish that the invention is being worked and that its benefits are reasonably accessible to the public."

Of importance for later statutory and regulatory provisions, the Kennedy Patent Policy used different phrases when referring to licensing and practical application. For example, to avoid March-In Rights, the contractor would either need to have "taken effective steps within three years after a patent issues on the invention to bring the invention to the point of practical application or [have] made the invention available for licensing royalty free or on terms that are reasonable in the circumstances . . . ." Thus, the contractor would have to either make products or services embodying the inventions "reasonably accessible to the public" or make the inventions available for licensing royalty free or "on terms that are reasonable in the circumstances." Likewise, the Kennedy Patent Policy gave federal agencies the right "to require the granting of a license to an applicant royalty free or on terms that are reasonable in the circumstances to the extent that the invention is required for public use by government regulations or as may be necessary to fulfill health needs, or for other public purposes stipulated in the contract" when contractors retained title to the invention. In both cases, the licensing language also tracked the licensing language used in the 1947 Attorney General's Report. Thus, "reasonably accessible to the public" was the phrase for direct delivery of products or services embodying the inventions to the market; licensing inventions "royalty free or on terms that are reasonable in the circumstances" was the phrase for licensing activities of contractors.

The Kennedy Patent Policy was never implemented in government-wide regulations. However, a number of agencies promulgated regulations that comported with the Kennedy Patent Policy. It also opened the door for the Institutional Patent Agreement (IPA) programs of the National Institutes of Health (NIH) in the Department of Health, Education, and Welfare (HEW) and the National Science Foundation (NSF). It did so by allowing for more contractor ownership of federally funded inventions than the 1947 Attorney General's Report

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[52] *Id.* at § 1(h).

recommended. It also commissioned a number of helpful ongoing studies, including the *Government Patent Policy Study* conducted by Harbridge House and finished in 1968 (the "Harbridge House Report"). [53] While the overall findings were inconclusive, the Harbridge House Report offered some interesting specific findings that helped shape the federal patent policy debates of the 1970s. First, it suggested that the NIH Medicinal Chemistry Program, initiated in 1962 prior to the Kennedy Patent Policy and which largely allocated title of resultant patents to the federal government, was hindering the commercialization of pharmaceutical compounds apparently by discouraging R&D firms from working with the program because of the allocation of title to NIH. The program rules were changed after the release of the Harbridge House Report, although there was no necessary linkage between the two events. Second, the Harbridge House Report recommended that different rules for ownership of federally-funded inventions should apply to universities and non-profits, on the one hand, and large private sector companies on the other. The Harbridge House Report pointed out the roots of the general confusion about where universities and nonprofits fit under the Kennedy Patent Policy as originating in the language that required an "established commercial position" for title to lie in the contractor. [54] The Harbridge House Report found that while large companies were likely to take on federal contract research work even if patents arising under the work were owned by the federal government, universities and non-profits were not. [55] This was seen as a result of the inability of universities and non-profits to commercialize such research results directly.

Also in 1968, NIH in many ways fully reversed course from the patent policy of the Medicinal Chemistry Program when it developed and began using a standard form IPA for extramural funding agreements with universities that had an approved patent policy. [56] The IPA gave contractors the contractual right to elect to retain title to inventions arising under NIH funding agreements. It also contained some additional provisions beyond those required under the Kennedy Patent Policy that would be adopted by Bayh-Dole as enacted (but some of which were then modified in the 1984 Bayh Dole Amendments). [57] These included: a restriction against assignment of inventions to third parties except to a patent management or licensing organization, such as private firms like Research Corporation and university-affiliated foundations like Wisconsin Alumni Research Foundation (WARF) or Washington Research Foundation (WRF); a limitation on the term of an exclusive license; a requirement for royalty income to be shared with inventors and any remaining amounts after expenses used for university educational and research purposes; and a requirement that any patent application arising from the funding agreement contain a reference to the federal funding support. [58] The NIH model IPA, and the later NSF

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[53] Harbridge House, Government Patent Policy Study, Final Report for the FCST Committee on Government Patent Policy (1968) [hereinafter "Harbridge House Study"].

[54] 4 Harbridge House Study p. IV-93.

[55] 1 Harbridge House Study p vi.

[56] *See* John H. Raubitschek and Norman J. Latker, *Reasonable Pricing—A New Twist for March-In Rights Under the Bayh-Dole Act*, 22 SANTA CLARA COMP. & HIGH TECH. L.J. 149, 153 (2005). The origins of the IPA concept dates back to 1953. *See* Government Patent Policies: Institutional Patent Agreements, Hearings before the Senate Subcommittee on Monopoly and Anticompetitive Activities of the Select Comm. on Small Business (95 th Cong., 2d Sess., May 22, 1978) (Statement of Norman J. Latker, Patent Counsel, Department of Health, Education, and Welfare). A standard form of an IPA included in Government regulations in the 1970s is attached as Appendix C.

[57] *See infra* Part II.C.

[58] *See* Raubitschek, *supra* note 56 at FN 16.

model IPA, would be explicitly acknowledged as the models for Bayh-Dole, both as to specific language provisions and to the impressive track record of commercialization developed under the IPA programs, especially when contrasted with the dismal commercialization record of federally funded inventions for which the Government retained title. [59]

In 1971, the Nixon Administration issued a modified and restated version of the Kennedy Patent Policy, which appeared primarily designed to further increase the allocation of title to contractors and, where the federal government retained title, the granting of exclusive licenses to contractors (the "Nixon Patent Policy"). [60] Due to the continued existence of the specific patent allocation statutes that hindered the Kennedy Administration, the Nixon Administration was likewise constrained from establishing a truly uniform federal patent policy. Notwithstanding this, President Nixon ordered the Administrator of the General Services Administration (GSA) to promulgate implementing regulations for the Nixon Patent Policy. [61] Because the Nixon Patent Policy, like the earlier Kennedy Patent Policy, provided guidelines for both title allocation and licensing of federally-owned patents, [62] GSA undertook two separate rulemakings. As this report focuses on universities, it will track only the rulemaking directed to title allocation decisions under federally-funded research.

The GSA first issued a draft of the new title allocation regulations in 1972, [63] and then issued an interim set of regulations in 1973 (the "Interim GSA Patent Policy Regulations"). [64] The heart of the regulations was a long form [65] and short form [66] set of prescribed patent clauses to be included in funding agreements. The long form was to be used with industry contractors and nonprofit contractors (when developmental work was to be performed). The short form could be used for basic and applied research by nonprofit organizations. The long form had three variations for use when the decision to allocate title was for the federal government, [67] for the contractor, [68] or to be deferred until actual inventions arose, as applicable. [69] The short form had two variations for use when the decision to allocate title was for the federal government, [70] or to be deferred until actual inventions arose, again as applicable. [71] However, even where the federal

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[59] *See* 126 CONG. REC. 8731, 8737-8749 (Apr. 23, 1980).

[60] Memorandum for Heads of Executive Agencies and Departments on Government Patent Policy, 36 Fed. Reg. 16,887 (August 23, 1971). The Nixon Patent Policy is reproduced in Appendix B.

[61] *Id.* at § 2.

[62] This dual role would be replicated in Bayh-Dole itself, which has provisions covering title allocation and licensing of government-owned inventions.

[63] Federal Procurement Regulations, Allocation of Rights in Inventions, 38 Fed. Reg. 23,782, 23,791, Sept. 4, 1973.

[64] *Id.*

[65] *Id.* at § 1-9.107-5.

[66] *Id.* at § 1-9.107-6.

[67] *Id.* at § 1-9.107-5(a)

[68] *Id.* at § 1-9.107-5(b)

[69] *Id.* at § 1-9.107-5(c).

[70] *Id.* at § 1-9.107-6(a).

[71] *Id.* at § 1-9.107-6(b).

government was to take title, the contractor could petition to retain greater rights than the nonexclusive license set out in the standard clause ("Greater Rights Determinations"). [72]

The Interim GSA Patent Policy Regulations appear to be the first time that contractor employee-inventors were specifically addressed. A process was established for a contractor's employee-inventor to request retention of greater rights in the event that the contractor did not seek them, so long as the contractor authorized this. [73] This indicated that GSA, and likely the funding agencies, assumed that contractors would have in place patent assignment agreements such that the contractor would own any inventions arising from the funding agreement. This would have been a reasonable assumption as to private sector contractors, although perhaps less so for public sector contractors.

In *Public Citizen v. Sampson*, Public Citizen and a collection of 17 members of Congress challenged the regulations in court on the basis that the regulations' authorization for federal agencies to grant title to federally-funded inventions to contractors harmed the plaintiffs as taxpayers (improper use of federal funds and property), consumers (the contractors would have a monopoly position on federally funded inventions and charge higher than competitive prices to the public), and members of Congress (the regulations usurped their Constitutional authority to determine the disposition of federal property). [74] The court dismissed the case on motion of the defendant, the Administrator of GSA, that none of the plaintiffs had standing to sue GSA because they were not directly harmed by the regulations. While the court did not rule on the propriety of either the Nixon Patent Policy or the promulgated regulations, or as to the merits of the plaintiffs' arguments, in dicta it noted that Congress could act when it wanted to regulate the authority of federal agencies in the disposition of patents that were federal property. [75] The court declined in this dicta to suggest that federally-funded inventions were *necessarily* federal property. It did, however, state that if any such inventions were found to be federal property, then the agencies *would not* have the authority to assign title in such patent property absent clear congressional authorization. [76]

Notwithstanding the efforts of GSA to implement the title allocation regulations and standard patent clauses, NSF developed and began using its own IPA, substantially similar to that of NIH, in 1973. [77] Following the resolution of *Public Citizen*, the GSA reissued a revised final version of the rules in 1975 (the "GSA Patent Policy Regulations"). [78] While there were many specific textual changes, the overall contours, terminology, and clauses of the GSA Patent Policy Regulations were quite similar to those of the Interim GSA Patent Policy Regulations. These regulations remained in place even after passage of Bayh-Dole, until final rulemaking was completed in 1987 incorporating the Reagan Patent Policy, Reagan Executive Order, and

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[72] *Id.*

[73] *Id.* at § 1-9.109-6.

[74] 379 F.Supp. 662 (D.D.C., 1974).

[75] *Id.* at 667 (citing 42 U.S.C. §§ 2182, 2457).

[76] *Id.* (citing Houghton v. U.S., 23 F.2d 386 (4 th Cir., 1928)).

[77] *See* Raubitschek, *supra* note 56 at 153.

[78] 40 FED. REG. 19814 (1975), *codified at* 41 C.F.R. Part 1-9 [hereinafter "GSA Patent Policy Regulations"]. The full text of the GSA Patent Policy Regulations is contained in Appendix D.

amendments to Bayh Dole under the Trademark Clarification Act of 1984. [79] They provide critical "infrastructure" clauses and terms as well as the framework for understanding both the statutory provisions of Bayh-Dole and the regulations promulgated thereunder.

Thus, by the mid-1970s, intramural and extramural federal patent policies with regard to title allocation were fairly well developed. Federal employees generally had to assign inventions arising from their work. Federal contractor employees were also generally assigning their inventions to the contractor, although this was as much due to the increase in private and public sector organizations taking control of their patentable inventions for commercialization. Relying on this general invention assignment practice of contractors, the federal government did not dictate the terms of patent assignment agreements between contractors and their employees, but simply required that an assignment sufficient to guarantee the federal government's rights must be in place.[80] At the same time, unless an IPA was in place, the invention title allocation as between the federal government and the contractor was subject to the determination procedures of the Nixon Patent Policy, as implemented in the GSA Patent Policy Regulations and standard patent clauses incorporated into the particular funding agreement.

C. Bayh-Dole Act: Enactment, Implementation, and Amendments

The Commission on Government Procurement appears to have been the first federal government body to suggest a one-size-fits-all patent ownership policy when it reported the results of its work in 1976.[81] That same year, the Federal Council for Science and Technology (FCST) took the idea a step further and created a draft bill. [82] Although the FCST bill was not

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[79] *See infra* Parts III.B.4-7.

[80] GSA Patent Policy Regulations, § 1-9.107-5(a) (§ e(3) of long form patent clause) ("The Contractor shall obtain patent agreements to effectuate the provisions of this clause from all persons in his employ who perform any part of the work under this contract except nontechnical personnel, such as clerical workers and manual laborers.") and § 1-9.107-6(a) (§ e(1) of short form patent clause) (". . . the Contractor shall . . . obtain patent agreements to effectuate the provisions of this clause from all persons who perform any part of the work under this contract except nontechnical personnel, such as clerical employees and manual laborers.").

[81] 2 Subcommittee on Domestic and Int'l Scientific Planning and Analysis of the House Comm. On Science and Tech., 94th Cong., Background Materials on Government Patent Policies: Reports of Committees, Commissions, and Major Studies 195 (Comm. Print 1976). The Commission sought to implement three areas of reform. First, patent title should go to the contractor *except*: (i) when the Government intends to fund the invention all the way to commercialization; and (ii) when universities and non-profits were the Government contractor. Oddly, this was then exactly the opposite of Bayh-Dole as enacted. Second, march-in rights should be strengthened, in part by creating a Government Patent Review Board that would have the authority to grant compulsory licenses where: (a) the contractor had been given a reasonable opportunity to commercially develop the invention and had failed; or (b) the contractor had developed the invention but refused either to make it commercially available through its own facilities or to license it on reasonable terms to another party to do so. The Board would also have the authority to revoke all patent rights granted to the contractor (and essentially "take back" the patent) if the contractor: (x) failed to promptly disclose an invention; (y) supplied materially false information concerning the invention; or (z) used the patent to violate antitrust laws. Third, unconscionable or "windfall" profits of the contractor based on its ownership of federally funded inventions should be limited.

[82] Federal Council for Science and Technology, Committee on Government Patent Policy, Draft Bill Entitled "Federal Intellectual Property Policy Act of 1976." Reprinted in Federal Council for Science and Technology, Combined Report on Government Patent Policy 82-119 app. D (Dec. 31, 1973; Dec. 31 1974; Dec. 31, 1975; and Sept. 30, 1976). Highlights of the bill included: contractors would have the right to retain title with some limited exceptions; the Government would have rights to patent anything that the contractor elected not to retain; and the

introduced into Congress, Representative Raymond Thornton, who chaired the House Subcommittee on Science, Research and Technology and served on the Recombinant DNA Advisory Committee, introduced a similar bill in 1977. [83] However, no hearings were held on it and it languished without action. [84]

The following year, GSA announced that it would incorporate a newly worded IPA in the Federal Procurement Regulations (FPR) for government-wide use by any agency not prohibited from doing so by statute. [85] However, this was stayed at the request of Gaylord Nelson, Chairman of the Senate Select Committee on Small Business. [86] The Senate Subcommittee on Monopoly and Anticompetitive Activities of the Select Committee on Small Business then took up five days of hearings on the nature and use of IPAs, including whether they were properly authorized under Federal statutory law and the Nixon Patent Policy.

President Carter backed a new uniform government patent policy, [87] and his Administration was able to get a bill introduced to Congress in 1980. [88] He envisioned a system of exclusive licenses limited to specific fields of use that would be granted to federal contractors for inventions they developed under federal funding. If the contractor failed to commercialize the invention within that field of use, then the federal government could terminate the relevant license. At the same time, he supported the grant of patent title to contractors who were universities or small businesses in recognition of their "special place in our society."

This is where the confusion starts as to the "real" Bayh-Dole Act and its legislative history. The statutory provisions we know as Bayh-Dole today were ultimately signed into law as part of H.R. 6933, but this was *only after* the text of S. 414 (the Senate bill separately introduced in 1979 by Senators Birch Bayh and Robert Dole) was used to replace all of the relevant original text of H.R. 6933 in an amendment-by-substitution legislative procedure. Sections 1 through 5 of the original H.R. 6933 were various amendments to the patent and trademark laws relating to things such as reexamination proceedings and fees and funding for the USPTO. They had nothing to do with disposition of federally owned or funded inventions. Section 6 contained the bill's provisions for a new Chapter 38 in Title 35 (Patents) of the U.S. Code that would codify "The Government Patent Policy Act of 1980."

Government would have the right to take away some or all patent rights from the contractor if commercialization was insufficient or if public policy demanded it.

[83] H.R. 6249, 95th Cong. 1 (1977).

[84] *See* University and Small Business Patent Procedures Act: Hearings on S. 414 Before the Senate Committee on the Judiciary, 96th Cong. 51 (1979).

[85] GSA, Final Rule: Federal Procurement Regulations, Part 1-9, Patents, Data, and Copyrights, 43 Fed. Reg. 4424 (Feb. 2, 1978).

[86] Government Patent Policies: Institutional Patent Agreements, Hearings before the Senate Subcommittee on Monopoly and Anticompetitive Activities of the Select Comm. on Small Business 1-12 (95 th Cong., 2d Sess.) (May 22, 1978).

[87] Industrial Innovation Initiatives: Message to Congress on Administration Actions and Proposals, Pub. Papers 2070, 2071 (Oct. 31, 1979).

[88] H.R. 6933, 96th Cong. (1980). The sections of the bill relevant to Government patent policy provided that: (i) small businesses and nonprofit research institutions would be given the presumption of ownership in patent rights; and (ii) large businesses would get exclusive licenses only for specific fields of use, but the contractor could retain temporary title for up to 4.5 years before specifying the field of use.

The actual statutory provisions that became the Bayh-Dole Act were introduced by Senators Birch Bayh and Robert Dole in the Senate as the University and Small Business Patent Procedures Act (S. 414), on February 9, 1979 and referred to the Senate Committee on the Judiciary Committee. S. 414 focused only on the disposition of federally owned or funded inventions and had no sections or provisions for the USPTO fees/funding allocations and reexamination proceedings. Most critically, it avoided many of the controversies plaguing other federal patent policy bills by covering only nonprofit, university, and small business contractors. The retention of federally funded patent rights by large business federal contractors was a lightning rod for commentators concerned with unjust windfalls and monopolies for such businesses. This first version of the bill contained all of the provisions of Bayh-Dole as later enacted, but contained two additional provisions: section 204, "Return of Government Investment," directed at allowing the federal government to recoup its funding where subject inventions proved to be financially successful; and section 210, "Coordination of Federal licensing practice," authorizing the Department of Commerce (DoC) to coordinate the licensing of federally owned inventions by federal agencies. [89] The provisions of S. 414 clearly derived from the Nixon Patent Policy, GSA Patent Policy Regulations, and IPAs, but with some slightly different language in parts, and were to be codified as a new Chapter 18 in Title 35 (Patents) of the U.S. Code, entitled "Patentability of Inventions Made With Federal Assistance."

The Senate Committee on the Judiciary held hearings on S. 414 in late 1979 and issued a report—Senate Report No. 96-480—which is the *only* Congressional report that counts as formal legislative history for Bayh-Dole. [90] The Committee amended the bill into essentially its final form by dropping the recoupment provision and DoC's federal patent licensing coordination role, and reported it back out to the Senate on December 12, 1979. [91] Section 200 set out the purpose of the Act. Section 201 set out definitions that in all cases mapped directly from definitions found in the Kennedy Patent Policy, Nixon Patent Policy, or GSA Patent Policy Regulations. Section 202 set out the basic right of contractors to elect to take title, and the conditions attendant thereto. This section included the Government License, disclosure, and utilization reporting requirements that all also tracked the existing Executive Branch policies and regulations. Section 203 established the March-In Rights provisions, again taken directly from existing Executive Branch policies. Section 204 set out the preference for U.S. industry that contractors should exercise when licensing subject inventions for commercialization. This provision underscored the understanding that contractors affected by Bayh-Dole would generally be licensing out their subject inventions, not directly practicing them. Section 205 provided for confidential treatment of information and data obtained from contractors pursuant to invention disclosures (confidential treatment for utilization reports was established in Section 202). Section 206 authorized the Office of Federal Procurement Policy (OFPP) to promulgate regulations implementing sections 202-204. The next few sections applied to *federally owned* rather than *federally funded* inventions: section 207 authorized federal agencies to patent and license their federally owned

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[89] 96th Cong., 1st Sess., S. 414, § 2, Feb. 9, 1979.

[90] Hearings and reports for H.R. 6933 and any other bills in Congress during the years 1978-1980 are directed to substantially different bills that did not have the provisions of Bayh-Dole.

[91] The final amended version also excepted the Tennessee Valley Authority from the list of agency/technology specific title allocation statutory rules superseded by Bayh-Dole as discussed below, as well as made some other relatively minor amendments to the remaining provisions.

inventions; section 208 authorized the GSA to promulgate rules governing the licensing of federally owned inventions; and section 209 established restrictions on the licensing of federally owned inventions. Section 210 provided one of the key breakthroughs of Bayh-Dole—it superseded the myriad statutory provisions scattered throughout the U.S. Code that required different title allocation rules for extramural federally funded invention/patent rights developed by nonprofit, university, and small business contractors according to the nature of the research, technology, and/or funding agency. Had even this one statutory provision been in place for the Kennedy or Nixon Administrations, federal government patent policy and technology transfer might have developed far more effectively in the pre-Bayh-Dole decades. Section 210 also made it clear that the bill did *not* supersede these myriad title allocation rules for all other contractors. It also expressly authorized the title allocation rules—both extant and in the future—under the Nixon Patent Policy or any successor policy for such contractors. Finally, § 211 expressly disclaimed any immunity from the antitrust laws for contractors by virtue of the bill's provisions.

After some debate—which also constitutes legitimate legislative history for Bayh-Dole—the Senate passed S. 414 on April 23, 1980. [92] However, it was defeated after being introduced as H.R. 2414 in the House of Representatives. Instead, the House passed the Carter Administration's favored H.R. 6933 bill on November 17, 1980, which then advanced to the Senate. The Senate amended H.R. 6933 by substituting in the entirety the provisions of its own S. 414 for all of Section 6 in H.R. 6933 (leaving Sections 1-5 intact), [93] passed it on November 20, 1980, and then returned the amended H.R. 6933 to the House. [94] Thus, only debate occurring in the Senate on H.R. 6933 *after* the provisions of S. 414 were added to it in the amendment-by-substitution process count as formal legislative history for Bayh-Dole. Due to the pressing nature of the provisions of Sections 1-5 of H.R. 6933, the House essentially capitulated on the battle over the content of Section 6 and passed the Senate's amended version with little discussion, and with no further amendments, the next day. [95] The House viewed the Senate's Section 6 (Bayh-Dole) as incomplete because members of the House had wanted to pass a truly uniform government patent policy that would cover all contractors, not just small businesses and universities. However, the House contented itself with resolving to revisit the issue in the next Congress.

The bill was signed into law as simply "An Act to amend the patent and trademark laws" on December 12, 1980 as Public Law Number 96-517. [96] Section 6 later came to be known as "The

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[92] 126 CONG. REC. 8731, 8737-8749 (Apr. 23, 1980).

[93] H.R. 6933, Amendment SU 1779, proposed by Senator Dole and agreed to by Voice Vote of Senate, November 20, 1980. Section 6 retained the codification at Chapter 38, but now had the title "Patent Rights in Inventions Made With Federal Assistance."

[94] 126 CONG. REC. 30360-30366 (Nov. 20, 1980).

[95] 126 CONG. REC. 30556-30560 (Nov. 21, 1980). Representative Kastenmeier's comments on introducing and urging passage of the Senate amendments to H.R. 6933 are illuminating for context: ". . . the bill we passed on Monday . . . is intact except for section 6 . . . . In essence, the Senate deleted it. I regret that action, but nonetheless it is a fact, and the outlook is virtually nonexistent for anything we can do in that regard. . . . Under the circumstances, I would say . . . that we will have to wait until next year to pursue again the uniform patent policy section, and I would join . . . in doing that. But in the meantime, rather than hold hostage these noncontroversial areas, I think we have no real option but to move forward with this and send it to the White House." *Id.* at 30560.

[96] Codified as amended at 35 U.S.C. § 200 *et seq*. The full text of Bayh-Dole as passed and enacted is contained in Appendix E.

Bayh-Dole Act," perhaps in part because the more descriptive title of S. 414, the "University and Small Business Patent Procedures Act," did not carry through even to Section 6 of H.R. 6933. Related to this, because H.R. 6933 directed the provisions of Section 6 to be codified as a new Chapter 38, but the actual text of S 414 which was substituted in for Section 6 had the individual statutory sections designated as §§ 200 *et seq*., the original codification of Bayh-Dole created an odd sequencing in which Chapter 38 followed Chapter 17 of Title 35's patent section (because Chapter 17 was composed of §§ 181-188 with no other 100s sections following it). This was later remedied under minor Bayh-Dole amendments in 1982. [97] Bayh-Dole's provisions became effective on July 1, 1981, with OFPP authorized to promulgate implementing regulations at any time after receipt of recommendations from the Office of Science and Technology Policy (OSTP).

As a sub-agency of the Office of Management and Budget (OMB), OFPP issued interim final regulations as OMB Bulletin 81-22 on June 30, 1981. [98] The regulations became effective July 1, 1981—to match up with Bayh-Dole's effective date—and were to expire on December 31, 1981, when replaced by a final OMB Circular. Substantively, Bulletin 81-22 followed the same terminology and essential concepts of the Nixon Patent Policy and GSA Patent Policy Regulations, except of course as limited to the "retention by the contractor" long form version of the patent clause in the GSA Patent Policy Regulations. However, the patent clause in Bulletin 81-22 used a substantively different "practical application" definition that focused on having the benefits of the subject invention "available to the public on reasonable terms." This was in contrast to the definition in the GSA Patent Policy Regulations, which focused on having the benefits of the subject invention "reasonably accessible to the public." However, as discussed above, this was likely because the core provisions of Bayh-Dole were limited to nonprofit organizations and small businesses which would generally be expected to license out their inventions for widespread commercialization rather than commercialize the inventions themselves. Accordingly, Bayh-Dole and its regulatory implementation appear to have simply adopted a modified version of the licensing oriented phrase "available for licensing royalty free or on terms that are reasonable in the circumstances" that originated in the Kennedy Patent Policy and had remained in continuous use since then to signify the licensing restriction.

The continuity of other requirements from the GSA Patent Policy Regulations to Bulletin 81-22 that were not actually required under Bayh-Dole belies the conservative nature of the federal patent policy process at the regulatory level. For example, Bayh-Dole as enacted only required that contractors disclose a subject invention "within a reasonable time after it is made," while Bulletin 81-22 required contractors to disclose a subject invention within six months after the contractor's personnel in charge of patent matters were notified by the inventors about the subject invention. This time restriction followed directly from the same time restriction in the GSA Patent Policy Regulations, albeit with a modified trigger. [99] Other time requirements in Bulletin 81-22 were changed from those contained in the GSA Patent Policy Regulations. However, few if any of these changes appear to have been specifically because of the language

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[97] P.L. 97-256, Title I, § 101(5), 96 Stat. 816, Sept. 8, 1982.

[98] 46 Fed. Reg. 34,776, July 2, 1981.

[99] In the GSA Patent Policy Regulations, the trigger was the conception or actual reduction to practice of the subject invention, whereas in Bulletin 81-22, it was the date of notification of the conception or actual reduction to practice from the inventors to the contractor's patent administrators.

or intent of Bayh-Dole. Rather, they seem to be simply further steps in the continuing evolution of the federal government's patent policy, and thus represented a kind of tightening up of certain requirements based on new experiences. For example, in the GSA Patent Policy Regulations, contractors had to elect to retain title to subject inventions (in cases where the federal agency had used the "retention by contractor" patent clause in the funding agreement) at the time of disclosing the subject invention to the funding agency. But in Bulletin 81-22, contractors could take up until 12 months to elect to retain title from the date that their patent administrators learned of the invention, whereas they had to disclose the subject invention to the funding agency within six months of that date.

Bulletin 81-22's sunset date was extended twice: first to January 31, 1982, [100] and then to February 28, 1982. [101] The final OMB rulemaking implementing Bayh-Dole as enacted, OMB Circular A-124, was published on February 19, 1982 and became effective March 1 that year. [102] While many comments had been received by OFPP during the rulemaking process, Circular A-124 was substantially the same as Bulletin 81-22.

Despite Congress' sidestepping of the large business contractor issue in Bayh-Dole, there was still a desire in some parts of the federal government to extend the contractor title-election default rule to large businesses. At the same time, the clarity of Bayh-Dole's one-size-fits-all rule was muddied by the uncertainty as to which companies would be deemed too large to fall within the Act's ambit. Accordingly, in 1983 President Reagan replaced the Nixon Patent Policy with his own Memorandum to the Heads of Departments and Agencies that adopted the rules and policies of Bayh-Dole to become the new federal patent policy covering all contractors who fell outside of the scope of Bayh-Dole (the "Reagan Patent Policy"). [103] This essentially unified federal patent policy across *all* federal contractors, subject to distinctions discussed in Part III below.

The following year, Congress amended Bayh-Dole as part of the Trademark Clarification Act of 1984. [104] One amendment, in particular, has been debated among commentators. Section 210(c) was modified to acknowledge the new Reagan Patent Policy and require that whatever Executive Branch policy was promulgated for federal contractors not covered by Bayh-Dole itself would have to impose at a minimum the Government License and March-In Rights through funding agreements with those contractors. [105] By contrast, the Reagan Patent Policy directed agencies to use the provisions of Bayh-Dole in funding agreements with contractors not covered by Bayh-Dole, but it allowed the agencies to waive any of those provisions at the agency's discretion if necessary to secure contractor participation and commercialization of any resultant subject inventions. While the amendment of § 210(c) may appear to have been an "endorsement" or

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[100] 47 FED. REG. 117 (Jan. 4, 1982).

[101] 47 FED. REG. 4628 (Feb. 1, 1982).

[102] 47 FED. REG. 7556 (Feb. 19, 1982). The Bulletin's

[103] Memorandum to the Heads of Executive Departments and Agencies: Government Patent Policy, 19 Weekly Comp. Pres. Doc. 252 (Feb. 18, 1983). The Reagan Patent Policy is reproduced in Appendix F.

[104] Trademark Clarification Act of 1984, Title V, Government Research and Development Patent Policy, P.L. 98-620, 98 Stat. 3335, Nov. 8, 1984. There were minor amendments to Bayh-Dole in 1982, but they simply re-designated the codified Act from its original location as Chapter 38 in Part IV to Chapter 18 in Part II, both within Title 35 of the U.S. Code. P.L. 97-256, Title I, §§ 101(5)-(6), 102, 96 Stat. 816, Sept. 8, 1982.

[105] *See* Senate Report No. 98-662 at 5808 (1984).

"authorization" of the Reagan Patent Policy by Congress that effectively extended Bayh-Dole to cover large businesses, such an interpretation is not directly supported by the legislative history.

Other amendments to Bayh-Dole in the Trademark Clarification Act of 1984 included: (i) an extension of the definitions of "invention" and "subject invention" to cover plants protectable under the Plant Variety Protection Act; [106] (ii) the addition of another exception to the contractor title election rule in § 202(a) for funding agreements involving GOCO facilities of the Department of Energy primarily dedicated to that Department's naval nuclear propulsion or weapons related programs; (iii) changes to the procedures under § 202(b) for agencies to apply the exceptions to the title rule of § 202(a); (iv) further changes to the procedures under § 202(b) for the dispute resolution procedures for contractors who disagreed with an agency's invocation of one of those exceptions in a funding agreement; (v) amendments to various parts of § 202(c)'s disposition of rights provisions; [107] (vi) modifications to the original restrictions on nonprofit contractor's potential assignments and granting of exclusive licenses to third parties and use of licensing revenues; [108] (vii) the addition of a dispute resolution process, to be established by regulations promulgated under the Act as amended, as a new subsection to the March-In Rights provisions of § 203; (viii) a shift of rulemaking authority under Bayh-Dole from OFPP to DoC—perhaps just formalizing OFPP's delegation of leading and coordinating the implementation of Bayh-Dole to DoC under Circular A-124—and requiring such rulemaking to be subject to public comment before issuance; (ix) the addition of a new subsection (b) to § 207 that authorized DoC to assist in the licensing and utilization of federally owned inventions and foreign patent procurement; (x) an amendment of § 208 to replace GSA with DoC for purposes of promulgating

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[106] 7 U.S.C. § 2321 *et seq.*

[107] Subsection (1) was changed to indicate that the time requirement to report a subject invention begins after the contractor personnel responsible for patent matters become aware of the subject invention, replacing the original trigger of when the subject invention was "made" (conceived or first actually reduced to practice); subsection (2) was changed to put an express time limit of two years on the contractor's right to elect to retain title to a subject invention, and further requiring that if a publication, on sale, or public use event triggered the one year statutory period for filing a patent application, then the agency could shorten the two year limit to 60 days before the end of the one year statutory period; subsection (3) was changed to require contractors who elected title to subject inventions to file applications before any statutory novelty or loss or right time limits expired similar to the changes to subsection (2); subsection (4), the Government License clause, was changed to expressly allow an agency to require additional rights such as a right to assign or have assigned foreign patent rights in the subject invention that the agency determines are necessary to meet the obligations of the United States under any treaty, international agreement, arrangement of cooperation, memorandum of understanding, or similar agreement, including military agreements relating to weapons development and production; and subsection (5) was amended to change the permissive charge to a mandatory charge to agencies to keep confidential information obtained from contractors as part of utilization reports, and expanding this confidentiality to information obtained during March-In Rights proceedings under section 203.

[108] Nonprofit contractors could: assign subject inventions to patent management entities even if those entities also engaged in, or had a substantial interest in firms that engaged in, the actual manufacture, sale, or utilization of products or processes embodying the subject invention; and grant exclusive licenses with no restrictions, subject to only to a general restriction that all licenses should be granted to small business firms except where that proves "infeasible after a reasonable inquiry." Also, a modification of terms of the requirement that the balance of royalties or income earned on a subject invention, after payment of expenses (including payments to inventors) incidental to the administration of the subject invention, could be used for scientific research or education in the case of Government-owned, contractor-operated facilities, including a requirement that the licensing of subject inventions owned by these facilities be done by contractor employees on location at the facility, to the extent that this proves the most effective for technology transfer.

regulations governing the terms and conditions of licensing federally owned inventions (other than those owned by the Tennessee Valley Authority); and (xi) the addition of the new § 212, "Disposition of rights in educational awards."

DoC began a rulemaking process in 1985 to implement all of these amendments through a new Chapter IV in Title 37 of the Code of Federal Regulations (CFR) consisting of a new Part 401.[109] The proposed rules closely followed Circular A-124 with changes primarily to effect the statutory amendments. The next year, DoC issued an Interim Final Rule that included further minor modifications based on public and agency comments on the proposed rule. [110] Then on March 18, 1987, DoC published the final rule implementing Bayh-Dole as amended (the "Bayh-Dole Regulations"), to become effective on April 17, 1987. [111] This contained only minor revisions as well. In some ways, then, Bayh-Dole only became fully implemented in 1987, after all of the issues raised by the Reagan Patent Policy and 1984 amendments were finalized and implemented through final rule making.

Following a matter of days after the effective date of the Final Bayh-Dole Regulations, President Reagan issued Executive Order 12591, "Facilitating Access to Science and Technology" ("1987 Reagan Executive Order"). [112] This Executive Order conformed Executive Branch technology and patent policy to both the recently enacted Federal Technology Transfer Act [113] and Bayh-Dole amendments in the Trademark Clarification Act of 1984. It also incorporated the Final Bayh-Dole Regulations as references for the Federal Acquisition Regulations (FAR) patent allocation rules for large businesses not directly covered by Bayh-Dole. [114]

Between 1984 and 2000, only minor conforming and typographical correction amendments were made to Bayh-Dole.[115] In 2000, substantive changes were made to Bayh-Dole primarily in sections dealing with federally owned inventions. However § 200, "Policy and objective," was

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[109] Department of Commerce, Notice of proposed rule making, 50 FED. REG. 13524 (Apr. 4, 1985).

[110] Department of Commerce, Interim final rule, 51 FED. REG. 25508 (Jul. 14, 1986).

[111] Department of Commerce, Final rule, 52 FED. REG. 8552 (Mar. 18, 1987).

[112] Executive Order 12591, "Facilitating Access to Science and Technology," 52 FED. REG. 13414, Apr. 22, 1987.

[113] P.L. 99-502 § 9(c), 100 Stat. 1785, Oct. 20, 1986 (adding a new § 210(e) to Bayh-Dole as codified that confirmed the precedence of the Stevenson-Wydler Technology Innovation Act of 1980 over Bayh-Dole to the extent that the former permitted or required certain dispositions of rights in subject inventions inconsistent with Bayh-Dole).

[114] The implementing rules for the Reagan Patent Policy continue to be codified in FAR Subpart 27.3. The switch from the Federal Procurement Regulation system (FPR) to the Federal Acquisition Regulation system (FAR) was effected in 1983. *See* Department of Defense *et al.*, Final Rule, Establishing the Federal Acquisition Regulation, 48 FED. REG. 42102 (Sep. 19, 1983).

[115] In 1986, conforming amendments were passed to accommodate the new Internal Revenue Code of 1986 by updating reference thereto. P.L. 99-514 (1986). In 1991, a change was made to § 202(b)(3) to change the period for Comptroller General reports on the implementation of Bayh-Dole by federal agencies from every year to every five years. P.L. 102-204 (1991). In 1992, a minor conforming amendment was made to § 203 to reflect the name change of the United States Court of Claims to the United States Court of Federal Claims. P.L. 102-572 (1992). In 1994, a conforming amendment was made to accommodate a citation change for one of the patent allocation statutes superseded by § 210 for purposes of Bayh-Dole. P.L. 103-272 (1994). In 1996, another minor conforming amendment was made to delete a reference in § 210 to the FTTA as amending the Stevenson-Wydler Technology Innovation Act of 1980. P.L. 104-113 (1996). In 1998, another conforming amendment for a statutory citation in § 210 was made. P.L. 105-393. (1998). And in 1999, typographical formatting errors were fixed in § 202. P.L. 106-113 (1999).

amended to change a key clause from "to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise;" to "to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery."[116] Section 202 was also amended to change the nature of how federal agencies are to assign inventions made by federal employees to nonprofit, small business, or individual contractors who co-invented the subject invention with the federal employee. [117] Sections 207 and 209 were also changed substantively, but are limited to federally owned subject inventions. [118] No other substantive changes have been made to date. [119]

III. Federal Laws and Regulations Affecting University IP and Technology Transfer

A. Overview of the Valuable Research-Related Assets of Universities

Science and technology research have three key variable inputs beyond the baseline inputs of fixed capital assets and human resources: funding, information, and materials. In private sector R&D, these three inputs are usually identified, tracked, and then linked to outputs generally consisting of products or services (and in some cases information in the form of assigned or licensed IP). Traditionally, universities have not done this as carefully. In large part this is because the outputs of university research are different from those of the private sector and are often dedicated to the public domain. Universities do not themselves commercialize any of the research results they generate and do not produce products or services from their R&D outputs to any substantial commercial degree. Instead, universities generate outputs in the form of educated students, scientific and technological advances as reported in academic journals, copyrighted works, and to varying degrees, inventions (patented or otherwise), data, know-how, and materials.[120]

B. Bayh-Dole Act

As discussed above in Part II.C., the Bayh-Dole Act was passed and signed into law in

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[116] P.L. 106-404 (2000).

[117] *Id.*

[118] *Id.*

[119] In 2002, typographic formatting errors in §§ 202 and 203 were fixed and statutory citation conforming amendments for §§ 201, 209, and 210 were made. P.L. 107-273 (2002). And finally, in 2005 the last Bayh-Dole amendment to date was another statutory citation conforming amendments for § 210. P.L. 109-58 (2005).

[120] Patented inventions are but a small proportion of the university's output and only a subset of these end up being successfully developed into commercial products or services. For example, in a preliminary in-house assessment of outputs from Colorado State University (CSU) research between 1989 and 2008, close to 30,000 science and engineering (S&E) publications by CSU authors were listed in Web of Science, while about 1,000 patents and patent applications by CSU inventors were listed in the public patent listings or the CSU technology transfer database for the same period. Thus, patents corresponded to about 3 percent of the published output.

1980.[121] Its provisions became effective on July 1, 1981, with first OFPP and then later DoC authorized to promulgate implementing regulations. In many ways, Bayh-Dole was the culmination of the steady evolution of federal extramural research patent policy begun in the Kennedy Patent Policy and continued through to both the GSA Patent Policy Regulations promulgated under the Nixon Patent Policy (which built on the Kennedy Patent Policy) and the IPAs developed by NIH and NSF.[122] Thus, rather than the *ex nihilo* event that it is often portrayed to have been, the passage of Bayh-Dole was instead largely the legislative enactment principles and requirements that had already been established. The major change that Bayh-Dole effected was legislation of the contractor title election rights established in the IPAs and the long form of the Standard Patent Rights Clauses for small businesses and nonprofit contractors (with some exceptions as noted below). It achieved this through both the detailed subsections on small business and nonprofit contractor rights and obligations in § 202 and the suspension of the myriad contractor title allocation rules interspersed throughout the U.S. Code for these same contractors in § 210.

The Bayh-Dole Act has been amended numerous times since 1980, with the most notable amendments occurring in 1984.[123] A few sections of Bayh-Dole cover only federally owned inventions.[124] Those sections are not treated in depth in this report. The full current text of Bayh-Dole as amended is attached as Appendix G. The current DoC regulations promulgated under the Act (the "Bayh-Dole Regulations") are discussed together with the analyses of the statutory sections that authorized them below. In reviewing the sections below, the reader is strongly encouraged to read the corresponding provision of Bayh-Dole in tandem with the analysis.

1. Policy and Objective – § 200

Bayh-Dole is an unusual law in that it contains a codified "Policy and Objective" section. Thus, whereas those seeking congressional intent for most other statutes only have legislative history documents, those seeking congressional intent for Bayh-Dole can look to § 200.[125] The question is whether § 200 constrains or requires certain interpretations of the substantive sections of the Act. There has been no direct ruling that it does so. Congress amended § 200 in 2000 to replace the phrase "to promote free competition and enterprise" with "to promote free competition and enterprise without unduly encumbering future research and discovery."[126] There is little legislative history to judge what Congress intended by this amendment.

There has been little judicial interpretation of § 200. In *University of Rochester v. G.D. Searle & Co., Inc.*, Rochester argued that the Bayh-Dole Act relaxed the written description requirements of 35 U.S.C. § 112 to encourage commercialization of inventions generated from

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[121] P.L. 96-517 § 8 (Dec. 12, 1980).

[122] *See supra* Part II.B.

[123] *See supra* Part II.B.

[124] 35 U.S.C. §§ 207-209

[125] *See, e.g.*, Fenn v. Yale Univ., 393 F.Supp.2d 133 (D.Conn. 2004); Platzer v. Sloan-Kettering Institute for Cancer Research, 787 F.Supp. 360, 364, 368 (S.D.N.Y. 1992).

[126] P.L. 106-404 § 5 (2000).

public funding,.[127] The U.S. Court of Appeals for the Federal Circuit (Federal Circuit) rejected Rochester's argument stating that, "none of the eight policy objectives of [§ 200] encourages or condones less stringent application of the patent laws to universities than to other entities."[128] In *Wisconsin Alumni Research Foundation v. Zenon Pharmaceuticals* , the Federal Circuit determined that it did not have jurisdiction under 28 U.S.C. § 1295(a) over a case concerning the Bayh-Dole Act, because that Act only governed federal research funding agreements—a matter of contract law and thus not of patent law.[129] However, Judge Rader noted during his dissent in the subsequent *en banc* rehearing of the case that Bayh-Dole should be considered a patent law because of: its inclusion in Title 35; the overlapping language in § 201 with terms of art used to describe patents; and the stated intention in § 200 "to use the patent system to promote the utilization of inventions arising from federally supported research or development."[130]

2. Definitions – § 201

The definitions section of the Act carries nuances with critical legal import. Indeed, much of how the Act operates in practice turns on its defined terms such as "practical application," "contractor," "funding agreement," and "subject invention."

a. "Funding agreement" – § 201(b)

This term includes "contract[s], grant[s], and cooperative agreement[s]" which have specific meanings under federal law.[131] This has led some commentators and federal officials to argue

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[127] 358 F.3d 916, 929 (Fed. Cir. 2004).

[128] Id.

[129] 252 Fed.Appx. 319 (Fed. Cir. 2007).

[130] 263 Fed.Appx. 865 (Fed. Cir. 2008).

[131] Contrast the statutory requirements governing "procurement contracts," "grant agreements," and "cooperative agreements" governing Government agencies use of each kind of agreement:

> Section 6303. Using procurement contracts
>
> An executive agency shall use a procurement contract as the legal instrument reflecting a relationship between the United States Government and a State, a local government, or other recipient when -
>
> (1) the principal purpose of the instrument is to acquire (by purchase, lease, or barter) property or services for the direct benefit or use of the United States Government; or
>
> (2) the agency decides in a specific instance that the use of a procurement contract is appropriate.
>
> Section 6304. Using grant agreements
>
> An executive agency shall use a grant agreement as the legal instrument reflecting a relationship between the United States Government and a State, a local government, or other recipient when –
>
> (1) the principal purpose of the relationship is to transfer a thing of value to the State or local government or other recipient to carry out a public purpose of support or stimulation authorized by a law of the United States instead of acquiring (by purchase, lease, or barter) property or services for the direct benefit or use of the United States Government; and
>
> (2) substantial involvement is not expected between the executive agency and the State, local government, or other recipient when carrying out the activity contemplated in the agreement.

that universities that receive funding from the federal government under grant agreements—the most common funding mechanism for university research—are not therefore acting "on behalf of the U.S. Government" in a way that could bring them under the Government License established under 35 U.S.C. § 202(c)(4) and discussed in Part III.B.3.c(ii) *infra*.[132] A further controversy has arisen under the "Other Transactions" authority that Congress granted to the Department of Defense (DoD). An initial temporary grant of authority to the Defense Advanced Research Projects Agency (DARPA) arose in 1989 under the National Defense Authorization Act for Fiscal Years 1990 and 1991. [133] This was made permanent in 1991 and extended to all of DoD and all military departments under the National Defense Authorization Act for Fiscal Years 1992 an 1993. [134] Under the codification of this authority, at 10 U.S.C. § 2371, DoD can enter into research and other funding arrangements that do not have to be classified as either contracts, grants, or cooperative agreements, and hence are covered by neither Bayh-Dole nor the FAR. This allows DoD to negotiate a wider range of IP allocation and rights provisions than would be allowable under Bayh-Dole or the FAR. [135]

b. "Contractor" – § 201(c)

While most of Bayh-Dole's provisions focus on small business and nonprofit legal entities, the definition of "contractor" explicitly includes any "person" who is a party to a federal funding agreement. Because the term "person" in legal contexts is normally interpreted to include any

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> Section 6305. Using cooperative agreements.
>
> An executive agency shall use a cooperative agreement as the legal instrument reflecting a relationship between the United States Government and a State, a local government, or other recipient when –
>
> (1) the principal purpose of the relationship is to transfer a thing of value to the State, local government, or other recipient to carry out a public purpose of support or stimulation authorized by a law of the United States instead of acquiring (by purchase, lease, or barter) property or services for the direct benefit or use of the United States Government; and
>
> (2) substantial involvement is expected between the executive agency and the State, local government, or other recipient when carrying out the activity contemplated in the agreement.

31 U.S.C. §§ 6301-6305 (2006).

[132] *See, e.g.*, Pulsinelli, Gary, *Share and Share Alike: Increasing Access to Government-Funded Inventions Under the Bayh-Dole Act*, 7 MINN. J.L. SCI. & TECH. 393, 404-407, 462-468 (2006) (citing "Transcript of Committee on Intellectual Property in Genomic and Protein Research Innovation," National Academies 146 (Feb. 27, 2004) *available at* http://www7.nationalacademies.org/step/Genomics_Committee_Meeting_1_transcript.pdf (transcribing, among others, presentation by Dr. Mark Rorhbaugh, Director, Office of Technology Transfer, National Institutes of Health, discussing NIH policies on technology transfer in the biotechnology area, including interpretations of Bayh-Dole); note that this transcript is currently not available on line).

[133] P.L. 101-189, Div. A, Title II, Part F, § 251, 103 Stat. 1352 (Nov. 29, 1989) (adding § 2371 to Title 10 (Armed Forces) of the U.S. Code). DoD has promulgated regulations under 10 U.S.C. § 2371 that are codified at 32 C.F.R. Part 3.

[134] P.L. 102-190, Div. A, Title VIII, § 826, 105 Stat. 1290 (Dec. 5, 1991).

[135] *See* GAO, Intellectual Property: Information on the Federal Framework and DoD's Other Transaction Authority (GAO-01-980T, Jul. 17, 2001) (Statement of Jack L. Brock, Managing Director, Acquisition and Sourcing Management and John B. Stephenson, Director, Natural Resources and Environment, before the Subcommittee on Technology and Procurement Policy, Committee on Government Reform, House of Representatives).

legal person—including entities with legal personhood status such as corporations—and because Congress is well acquainted with the more restrictive term "natural person" that restricts "person" to living individuals, the term "person" as used in the definition of "contractor" likely means all legal persons.[136] This in turn impacts the definition of "funding agreement" because it then means that a "funding agreement" can involve any natural/legal person, small business firm, or nonprofit organization, *provided* that person/firm/organization has a contract, grant, or cooperative agreement with a federal agency (other than the Tennessee Valley Authority) for performance of experimental developmental, or research work. Reciprocally, the requirement that a "contractor" be a party to a "funding agreement" provides the only real limitation to what the term "contractor" encompasses.

c. "Invention" – § 201(d)

This term effectively restricts the provisions of Bayh-Dole to innovations protectable under either U.S. Code Title 35, Patents, or the Plant Variety Protection Act, as codified in U.S. Code Title 7. This includes utility patents, design patents, plant patents, and statutory invention registrations ("SIRs"). It excludes innovations protectable only by copyright, trademark, trade secret, or any other proprietary rights not included in Title 35 or the Plant Variety Protection Act in Title 7.

d. "Subject invention" – § 201(e)

This term and its definition can be a trap for the unwary. [137] The scope of what comes under the sweep of "subject invention" is quite broad because of the disjunctive "conceived or first actually reduced to practice." "Subject invention" covers not only inventions that were first conceived under federal funding, but also inventions that were already conceived outside of any federal funding, but were actually reduced to practice under federal funding. This can be confusing because an adequately enabled patent application can constitute a "constructive reduction to practice" that satisfies the patentability requirement for reduction to practice—even if the invention has not actually been reduced to practice by means of production of a physical embodiment of the machine, manufacture, or composition of matter, or successful use of the process, as applicable.[138] Thus, an invention that has a patent applied for, or even issued, outside of federal funding, could still become a subject invention if federal funding is later used to

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[136] This is further supported by the use of the term "persons" in 35 U.S.C. § 210(b)-(c) to denote, among other things, the large businesses who were excluded from the core provisions of Bayh-Dole, but who were then brought under an analogous set of rules by the Reagan Patent Policy. Thus if "person" as used in this definition were limited to natural persons, then there would be an inconsistent use of the term "person" across Chapter 35 (the U.S. Code title codifying Bayh-Dole and related statutes). Because the Chapter has been subjected to numerous substantive and housekeeping amendments since its first enactment, it seems unlikely than an inconsistency of this magnitude would have been ignored. *See supra* Part II.C.

[137] *See, e.g.*, Pilley v. United States, 74 Fed. Cl. 489 (2006) (holding that Government had rights in invention conceived and constructively reduced to practice by a patent application filing before inventor contracted with the Federal agency to perform other R&D with invention because the invention was first actually reduced to practice under the Government contract).

[138] *See* USPTO, Manual of Patent Examination & Practice § 2138.05 [hereinafter "MPEP"].

actually reduce it to practice.[139]

The scope of the term "subject invention" is also broad because it covers all *inventions* arising under a funding agreement, not just all *patents*. This distinction is critical because it means that "subject inventions" include even the inchoate property rights in a process, machine, manufacture, composition of matter, or plant variety even before any patent issues on such invention. This distinction is not mere semantics either, as these kinds of pre-patent issuance property rights are routinely assigned or licensed by their owners. Likewise, patent applications can also be assigned or licensed by their owners.

e. "Practical application" – § 201(f)

This term and definition have spawned substantial controversy, and provide the basis for arguments that Bayh-Dole empowers federal agencies to exercise downstream price control on products and services that embody subject inventions. While the operative language for the trigger of this purported right occurs in the March-In Rights of 35 U.S.C. § 203 (discussed below in Part III.B.4), that language relies in critical part on the definition of "practical application." The contested phrase is "and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms." Thus, there are two required parts to the definition: i) the invention is being produced or practiced in an actual embodiment; and ii) the invention's "benefits" are available to "the public" on "reasonable terms" (to the extent permitted by law or federal regulations).

On its face, this would seem to give a kind of downstream price control authority to Federal agencies who funded the invention, with an enforcement mechanism of March-In Rights (discussed further in Part III.B.4 below).[140] However, this interpretation has been discredited or disregarded by a key federal agency,[141] the Senate sponsors of the original Act (Birch Bayh and Robert Dole),[142] and one of the core drafters of the original Act.[143] Independent research conducted for this report reveals that the use of the phrase "reasonable terms" derives from requirements for *licensing* on reasonable terms that originated in the Kennedy Patent Policy.[144] Contractors (such as universities) who were not in a position to deliver products or services to

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[139] Note that if the patent were already issued, then the patentee or assignee, if any, might have to file for a reissue or certificate of correction so that the USPTO could insert the required notice of government rights in the patent under 35 U.S.C. § 202(c)(6) discussed *infra* in Part III.B.3.

[140] *See, e.g.*, Peter S. Arno and Michael H. Davis, *Why Don't We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed Upon Patents Deriving in Whole or In Part From Federally Funded Research,* 75 TUL. L. REV. 631 (2000-2001); Peter S. Arno and Michael Davis, *Paying Twice for the Same Drugs*, WASH POST (March 27, 2002 at A21).

[141] National Institutes of Health, Office of the Director, In the Case of NORVIR, Manufactured by ABBOTT LABORATORIES, INC. (July 29, 2004).

[142] National Institutes of Health, Hearings on Ritonavir (May 25, 2004) (Statement of Senator Birch Bayh to the National Institutes of Health); Birch Bayh and Robert Dole, *Our Law Helps Patients Get New Drugs Sooner*, WASHINGTON POST (April 11, 2002 at A28).

[143] Raubitschek, *supra* note 56 at 153 (2005); National Institutes of Health, Hearings on Ritonavir (May 25, 2004) (Norman J. Latker, Statement Before NIH On Essential Inventions Petition Regarding Norvir).

[144] *See supra* Part III.B.

the marketplace embodying those subject inventions for which they retained title were obligated to license out the invention for another party to commercialize. They were not permitted to satisfy this obligation by offering unreasonable licensing terms such that the offer was essentially a sham and no licensee would accept them.

3. Disposition of Rights; Mandatory Funding Agreement Provisions – § 202

Section 202 is arguably the core of Bayh-Dole as it sets out the terms and conditions for covered federal funding arrangements with regard to disposition of rights to subject inventions.

a. Basic disposition of rights – § 202(a)

This clause establishes the default rule that nonprofit and small business contractors "may elect to retain title to any subject invention." It is important to unpack this critical phrase. "May elect" means that the contractor has the discretionary power to retain title. If it does not exercise this power according to the timing and other requirements set out below, then the federal funding agency can void the power and take title to the subject invention. Or, if the contractor notifies the funding agency that it will not elect title, then the funding agency may take title to the subject invention. "To retain title" means that because the contractor presumably has rights to title for the subject invention under assignment obligations of its employee inventors (as discussed below) it will be allowed to keep such title (if it elects to do so), rather than have to assign it over to the federal government. "To any subject invention" broadens the scope of what title is at issue because, as defined above, "subject invention" means any patentable invention arising under a funding agreement, *not* just any *patented* invention or even just the patent itself (if any). The section also restricts the class of contractors empowered to elect title to nonprofits (including universities) and small businesses, even though other sections of Bayh-Dole can apply to other types of contractors.

The requirement to elect title (or elect *not* to take title) under this section can create some odd outcomes for technologies that can be protected under different types of IP or other proprietary rights, such as software, data, and materials. In such cases, so long as any part of the technology is potentially patentable—and hence a subject invention under Bayh-Dole—then the university must elect to take title or else risk that the funding agency will exercise its rights to require the university to assign the subject invention to the agency. But once the university elects to take title, it must diligently pursue patent protection under its obligations in the funding agreement. Funding agencies can work with university contractors to resolve these types of issues in funding agreements. But absent any such contractual arrangements or official agency policy rules, university contractors cannot unilaterally decide to elect to take title and then fail to diligently prosecute patents on the subject invention.

Software developed under federal funding agreements has presented particular issues in this regard, especially when it contains "data" (as defined under the FAR as discussed below in Part III.D) and is developed under a procurement contract. First, while software currently may be patentable, case law has changed the boundaries of whether and how it may be patentable over the past few decades. Accordingly, both the software industry and universities involved in software development often rely more on copyright, trade secrets, and/or contractual measures (such as end user license agreements or EULAs) rather than patents to protect software. But if the software developed under federal funding contains anything that could be considered a

patentable invention, then a subject invention has arisen and the university must disclose it and elect whether or not to take title. If it elects to take title—even if only to preserve its rights to the software without potentially losing the subject invention portion to the funding agency—then it must diligently pursue patent protection. At the same time, if the software is developed under a procurement contract and includes a subject invention, then it is subject to the provisions of both Bayh-Dole and the FAR. If the software is deemed to contain "data" (as defined in the FAR) and the standard FAR clause used in the funding agreement for the data portion grants the federal government unlimited rights (see Part III.D below), then this may create a conflict for the university as between its obligations under Bayh-Dole (if it indeed elects to retain title to the subject invention in the software) and the FAR clauses.

Because funding agreements can contract around the statutory provisions, the actual scope of the right to retain title is ultimately contractual as a practical matter. However, contractors could use the statute to argue for title in cases where the funding agreement is unclear or where the contractor can argue that the funding agency did not properly invoke one of the exceptions to the default contractor title rule. At the same time, contractors must use the appeals process of § 203(b). The last sentence of that subsection seems to establish that the contractor limitations and obligations of both § 203(c) and other provisions of Bayh-Dole operate by act of law, even though most of those in § 203(c), must be set out as contractual obligations in funding agreements.[145] However, as discussed below, in cases such as disputed rights between contractors and their employee inventors, actions of the latter can divest the former of title to subject inventions. Thus, the last sentence of § 203(c) must be read narrowly to literally mean only that any affirmative rights that nonprofit and small business contractors might otherwise have—outside of becoming contractors under funding agreements—that are inconsistent with the provisions of Bayh-Dole are superseded by the Act.

b. Limitations of Federal agency use of § 202(a) title exceptions – § 202(b)

This subsection establishes the burden on federal agencies for reporting why they would invoke an exception to the contractor title rule in a given situation. The Bayh-Dole Regulations further implement the detail on how these reports must be written and submitted. [146] The nature of these reports arguably burdens agencies such that they are disinclined to invoke the exceptions to title even in situations that might warrant it. The subsection also charged the Comptroller General to regularly report on the implementation of Bayh-Dole to Congress. Originally this report was to be submitted annually, but later the requirement was changed to every five years. In 2009, the requirement for this reporting was eliminated altogether under the Omnibus Appropriations Act,[147] although the statutory text in Bayh-Dole as codified was not removed. Lastly, the subsection establishes that contractors who want to challenge title exception determinations must use an appeals process set out in § 203(b), although the Bayh-Dole Regulations set forth a separate regulatory section for such appeals process. [148]

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[145] This interpretation has explicitly been adopted by at least one court. Madey v. Duke, 413 F.Supp.2d 601, 611 (M.D.N.C. 2006).

[146] 37 C.F.R. 401.3(e).

[147] P.L. 111-8, Div. G, Title I, § 1301(h), 123 Stat. 829 (2009).

[148] 37 C.F.R. 401.4.

c. Mandatory provisions to be included in funding agreements – § 202(c)

This subsection mandates that each funding agreement contain provisions to effectuate the requirements of the subsection. This is noteworthy as § 202(a) provides that these requirements operate by act of law as well. [149] It is unclear whether this is redundant or whether the contractual requirement serves some purpose (other than simply notice to the parties). There is no clear judicial interpretation of this issue. As speculation, it could be that because some of the provisions can be modified—at least by the implementing regulations—that Congress wanted to ensure that it would not have to amend the statute to accommodate ministerial policy changes to, say, invention reporting procedures. However, this could have been achieved by simply stating that the parties are bound by the implementing regulations. At the same time, the fact that the policies could change over time would mean that the parties might need to determine which policies govern a particular extramural project. The requirement of a funding agreement with the then current policies memorialized in it could ameliorate that problem. Further, the practice of using funding agreements with specific IP title and rights of the parties included was long established and serves other documentation purposes.

A central issue is whether failure of the contractor to comply with either the requirements of § 202(c) or its funding agreement allows the funding agency to take title to the invention. Some of § 202(c)'s subsections expressly provide for this. Further, in *TM Patents v. IBM*, the U.S. District Court for the Southern District of New York held that any failure of the contractor to comply with the requirements of § 202(c) results in the federal government acquiring title to the subject invention at issue. [150]

(i) Subject invention disclosure requirement – § 202(c)(1)

Subject invention disclosure requirements are set forth in the Standard Patent Rights Clauses of the Bayh-Dole Regulations. [151] The nature of disclosing subject inventions is largely the same as from the earlier GSA Patent Policy Regulations. The primary changes to this procedure have been in the deadlines for disclosure. Currently, it is two months from the date that the inventor(s) have disclosed it to a contractor's personnel in charge of managing IP. Under the GSA Patent Policy Regulations it was six months from the date of conception. It is unclear how much this two month deadline is monitored or enforced by funding agencies. Many agencies now encourage the use of the iEdison reporting system for invention disclosures. [152] Failure to disclose inventions can result in loss of title election rights by the contractor. [153] However, the right for the federal government to take title is discretionary to the funding agency and does not operate automatically upon any infraction of Bayh-Dole. [154] At the same time, contractors must ensure

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[149] *See* Madey v. *Duke*, 413 F.Supp.2d 601, 611 (M.D.N.C. 2006).

[150] 121 F. Supp. 2d. 349 (S.D.N.Y. 2000).

[151] 37 C.F.R. 401.14 (Standard patent rights clauses).

[152] *See infra* Part III.B.3.c(iii).

[153] Campbell Plastics Engineering & Mfg, Inc. v. Brownlee, 389 F.3d 1243 (Fed. Cir. 2004).

[154] Central Admixture Pharmacy Services, Inc. v. Advanced Cardiac Solutions, P.C., 482 F.3d 1347 (Fed. Cir. 2007)

that they execute express contracts with employee inventors obligating the latter to disclose subject inventions, and then assign such rights and execute such documents as are necessary to secure the contractor's and federal government's rights in the subject inventions. Failure to do so can result in the employee inventor assigning the rights elsewhere, which act is not superseded by Bayh-Dole as an operation of law. Nor does Bayh-Dole give the contractor a private cause of action to secure the disclosure, assignment, or documentation from the employee inventor. [155]

(ii) Government License – § 202(c)(4)

This subsection codifies the nonexclusive license to the federal government on subject inventions (Government License) that has been a staple of federal patent policy since the Kennedy Patent Policy. The Government License requires no triggering event to become effective, and indeed may become operative as a matter of law as well as by contract through the funding agreement. [156] However, contractors are expected to send confirming documentation to the funding agency upon request. In the event that they do not send such confirmatory license documentation, their title to the subject invention becomes voidable at the discretion of the funding agency. [157]

The Government License was invoked by Duke University as one of its defenses to a patent infringement suit in *Madey v. Duke*.[158] Duke asserted that because much of its alleged infringing activity was work done under contract to the federal government, which had a Government License to Madey's patents from an earlier funding agreement, Duke now stood in as the agent of the federal government with rights to practice the patents as licensee. While the trial court initially seemed to favor this as an alternate ground to the common law research use exception, [159] the Federal Circuit made it clear on appeal that any invocation of a Government License must be supported by specific evidence that: i) the patents in suit arose from federal funding and issued either after Bayh-Dole was implemented or that any pre-Bayh-Dole funding agreement contained a clause reserving rights to the government; and ii) the current research was performed on behalf of the federal government and with specific authorization to practice the Government License on the Government's behalf. [160]

On remand, the trial court determined that because the Bayh-Dole Act creates no private

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(holding that where a contractor's employee inventor who had retained title under § 202(d) failed to comply with the Government License requirement under § 202(c)(4), the employee inventor's title was only *voidable* by the funding agency—upon its affirmative action to do so—and not *void ab initio*).

[155] *See* Gen-Probe Incorporated v. Center for Neurologic Study , 853 F.Supp. 1215 (S.D. Cal. 1993) (holding no private cause of action for nonprofit contractor who failed to secure contractual obligation from researcher to disclose and assign subject invention).

[156] *See* Madey v. Duke, 413 F.Supp.2d 601, 611 (M.D.N.C. 2006).

[157] Central Admixture Pharmacy Services, Inc. v. Advanced Cardiac Solutions, P.C., 482 F.3d 1347 (Fed. Cir. 2007) (holding that where a contractor's employee inventor who had retained title under § 202(d) failed to comply with the Government License requirement under § 202(c)(4), the employee inventor's title was only *voidable* by the funding agency—upon its affirmative action to do so—and not *void ab initio*).

[158] 307 F.3d 1351 (Fed. Cir. 2002).

[159] *See infra* Part III.C.6.a.

[160] 307 F.3d 1351, 1363-64.

right of action it cannot create a private defense either. [161] Further, the trial court determined that any invocation of the Government License must be either in suits where the federal government is also a party or as part of a Government Use Statute (28 U.S.C. § 1498) defense. The court's rationale for the latter is that something more than the mere existence of a Government License to certain patents and a new funding agreement to a private party for research that might infringe those patents must exist. In other words, the new funding agreement must contain essentially the same kind of authorization and consent language as would extend the cover of the Government Use Statute to the contractor. Accordingly, the trial court ultimately rejected Duke's invocation of the Government License defense, although it did allow that the existence of a Government License could play a role in any proceeding in the Court of Federal Claims if Duke were successful in its separate Government Use Statute defense. The federal government could then assert that it owes no compensation to Madey because of the Government License.

Thus, funding agencies could begin inserting authorization and consent language into funding agreements to at least authorize contractors to use existing subject inventions in which the federal government has a Government License. This could likely be written functionally, *e.g.*, "the federal government authorizes and consents to the contractor's use of all patented inventions to which the federal government has a license under 35 U.S.C. § 202(c)(4)." Such language would avoid the problem of having to identify specific subject inventions that are subject to a Government License. Of course, if such subject inventions are identified at the time of the funding agreement, then specific authorization and consent language could be used. Further issues with the exact nature of the Government License and whether federally funded researchers are, or can be authorized to be, working "on behalf of the Government" are set out in Parts III.B.2.a-b above.

This subsection also provides that funding agencies can require greater rights—including assignment rights—if necessary to comply with international treaties and agreements to which the United States is a party.

(iii) Utilization reports – § 202(c)(5)

This subsection, and its implementation in the Bayh-Dole Regulations and Standard Patent Rights Clauses,[162] sets out the manner in which funding agencies can require utilization reports from contractors who elect to retain title. The nature of the utilization reporting process is largely the same as it was under the GSA Patent Policy Regulations, except for the development of optional online filing through iEdison in 1995, as discussed below. This subsection further provides that such reporting shall be treated as "privileged and confidential"—even as against Freedom of Information Act requests [163]—by the funding agency, but does not address confidentiality as between the contractor and the contractor's licensees or assignees.

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[161] Madey v. Duke University, 413 F.Supp.2d 601, 612-13 (M.D.N.C. 2006) (citing the following cases for holding no right to a private action under Bayh-Dole, but *not* for the proposition that no private defenses might exist: Platzer v. Sloan-Kettering Inst. for Cancer Research, 787 F.Supp. 360, 364-65 (S.D.N.Y. 1992); Gen-Probe, Inc. v. Center for Neurologic Study, 853 F.Supp. 1215, 1217-18 (S.D. Cal. 1993); Fenn v. Yale Univ ., 393 F.Supp.2d 133, 141-42 (D. Conn. 2004)).

[162] 37 C.F.R. §§ 401.8, 401.14.

[163] Freedom of Information Act, P.L. 89-554, 80 Stat. 383 (Sep. 6, 1966) (*codified as amended at* 5 U.S.C. § 552).

Subsection (h) of the Standard Patent Rights Clause commits the contractor to submitting, on request by the funding agency, utilization reports "no more frequently than annually" that contain information regarding: (i) the status of development of the invention; (ii) the date of first commercial sale or use of a product containing the invention; (iii) the gross royalties received by the contractor; and (iv) "such other data and information as the agency may reasonably specify."[164] To comply with these requirements, non-practicing entity contractors such as universities will need to obtain some information from their licensees (if any), as the latter will actually engage in development and sales of products using the invention. But exactly how much detail and possibly confidential information on such development and sales must be obtained by contractors from their licensees is a matter of debate. All that the contractor likely has to report to satisfy the requirements of Bayh-Dole is evidence that *it* is taking effective steps to achieve practical application of the subject invention. While the mere existence of a licensee might not be enough to satisfy this requirement, there is no case law or statutory or regulatory interpretation that indicates that any more than some evidence of commercialization efforts on the part of the contractor's licensee is required.

In response to a 1994 report showing insufficient reporting of inventions by at least one major research institute contractor, NIH created what was then called the "Edison" system. NIH contractors can enter utilization reports, invention disclosures, title elections, and close out reports[165] that are then searchable by NIH for monitoring and review purposes. [166] DoC expressly authorized, but did not mandate, such electronic reporting in an interim rule. [167]

A few years after the introduction of both Edison and the interim rule, the General Accounting Office (GAO) issued a report finding that insufficient reporting of inventions and commercialization was still occurring—even among NIH contractors who used Edison. [168] The report suggested that Congress amend Bayh-Dole to specifically require DoC to create and adopt a standardized, improved, and streamlined reporting process that sounded quite similar to Edison, but for contractors across all funding agencies. [169] Congress declined to do so. GAO also suggested that DoC could effect some improvements in the reporting process by amending the

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[164] Note that roman numerals have been added to the listed items here for clarity—they do not exist in Subsection (h) itself.

[165] Under 37 C.F.R. § 401.5(f), funding agencies may add additional reporting clauses to the funding agreement to: "(1) Provide a report prior to the close-out of a funding agreement listing all subject inventions or stating that there were none[;] (2) Provide, upon request, the filing date, serial number and title; a copy of the patent application; and patent number and issue date for any subject invention in any country in which the contractor has applied for patents[; and] (3) Provide periodic (but no more frequently than annual) listings of all subject inventions which were disclosed to the agency during the period covered by the report."

[166] *See* General Accounting Office, Technology Transfer: Reporting Requirements for Federally Sponsored Inventions Need Revision 12 (RCED-99-242) (August 1999), *also available at* www.gao.gov.

[167] Assistant Secretary for Technology Policy, Department of Commerce, Rights to Inventions Made by Nonprofit Organizations and Small Business Firms Under Government Grants, Contracts, and Cooperative Agreements; Electronic Filing of Written Submissions; Definition of the Term "Patent Application" or "Application for Patent", 60 Fed. Reg. 41811 (August 14, 1995) (codified at 37 C.F.R. Part 401).

[168] General Accounting Office, Technology Transfer: Reporting Requirements for Federally Sponsored Inventions Need Revision 6-13 (RCED-99-242) (August 1999), *also available at* www.gao.gov.

[169] *Id.* at 19, 31-33.

existing regulations within the current scope of authority granted under Bayh-Dole. [170] To date, DoC has declined to do so. Beginning in 1997, other agencies began voluntarily joining the Edison system which then was rechristened as "Interagency Edison" or "iEdison." [171]

(iv) Special requirements for non-profits and universities – § 202(c)(7)

This subsection establishes special requirements to be included in funding agreements with nonprofit contractors, including universities. These conditions are also included in alternate clauses of the Standard Patents Rights Clauses to be used with nonprofits and universities. The first such condition is that nonprofit contractors may not assign subject inventions to third parties without authorization from the funding agency, unless the assignee is a patent management company. Originally, this clearly seems to have meant external patent management entities used by universities at the time of Bayh-Dole's enactment, such as Research Corporation, University Patents, Inc., and foundations set up by universities themselves such as WARF or WRF. [172] However, the current statutory language seems to leave open the unexpected consequence that universities may be able to assign their elected subject inventions to *any* non-practicing entity, including so-called patent trolls. [173] There appears to be no government-wide standard for how federal agencies should determine when to authorize assignments in situations where contractors request to assign to a third party *other* than a patent management firm. The second such condition is that the nonprofit contractor must share royalties with the inventor (including any federal employee inventor who assigned his or her rights in the subject invention to the contractor under § 205). No formula or minimum values are given for this and DoC expressly declined to issue any as part of its rulemaking under Bayh-Dole. In *Platzer v. Sloan-Kettering Institute*, the U.S. District Court for the Southern District of New York held that the Bayh-Dole Act neither expressly nor impliedly dictates any particular royalty/revenue sharing formula or rate.[174] The court further suggested that a sharing rate that was too much in favor of inventors could hamper one of the Act's goals: to encourage university and nonprofit contractors to use proceeds from subject invention licensing activities to support educational and research efforts at the institution. The third such condition, accordingly, is that the nonprofit contractor must use the balance of licensing income, after expenses including payments to inventors, for the support of scientific research or education. The fourth such condition is that the nonprofit contractor must give preference to small businesses when licensing subject inventions. For these last two conditions, there is no evidence that the funding agencies either monitor or police them.

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[170] *Id.* at 33.

[171] *See* "iEdison Overview" *available at* https://s-edison.info.nih.gov/iEdison/checklist.jsp . The current list of agencies and offices using iEdison is available at https://s-edison.info.nih.gov/iEdison/AgencyContactList.jsp.

[172] *See supra* Part II.B.

[173] This report does not take a position on whether or what types of non-practicing entities should be deemed "patent trolls," nor whether those so named are engaged in anything other than legitimate (if controversial) business practices.

[174] 787 F.Supp. 360, 365, 367-368 (S.D.N.Y. 1992).

d. Granting title to inventors – § 202(d)

This subsection allows the inventor(s) to retain title to subject inventions in certain circumstances. First, the contractor has to elect not to retain title to the subject invention. Then, the funding agency can consider the inventor(s)' request for title, in consultation with the contractor. However, under U.S. patent law, the original title to a patentable invention vests with the actual inventors.[175] There is no analogue in the Patent Act to the Copyright Act's "work made for hire" statutory provision which provides that employers or contracting parties, including corporate or non-natural persons, can be considered the true and sole "author" of a work.[176] In the absence of any contract allocating title to inventions, state common law does provide a right to employers to demand assignment of an invention (and any patent or application held by the inventor on it) if the inventor was "hired to invent" that particular subject matter.[177] Further, employers can contractually arrange for employees to assign inventions to them. But in all of these cases, the natural person inventor(s) must always be listed as the inventors on any issued patent. The employer will then be listed as the assignee on the patent.

Accordingly, a contentious issue under § 202(d) has been whether and how university researchers operating under federal funding agreements are obligated to assign their rights in any subject inventions for which they are inventors. The GSA Patent Policy Regulations appeared to assume that Federal contractors would generally already have employee patent assignment policies or agreements in place that would assign *all* rights to *all* inventions created as part of any technical or research employee's job duties.[178] The current Standard Patent Rights Clauses largely echo the employee patent agreement requirements of the GSA Patent Policy Regulations. However, nothing in these clauses *expressly* requires the contractor to have a patent assignment agreement in place with all inventive employees that requires the immediate assignment to the contractor of all rights in future subject inventions. Some universities assumed that Bayh-Dole obligated inventor employees to assign subject inventions by act of law so long as the university timely elected to retain title. They then sough to exercise this "right" even where no express agreement was in place with the employee. This interpretation was rejected by federal district courts in *Gen-Probe, Inc. v. Center for Neurologic Study*[179] and *University of Pittsburgh v. Townsend*.[180]

Many universities developed practices whereby they only bound their inventor employees to agree to assign inventions when they arose and upon request of the university. In some cases this was done in a specific employment agreement, offer letter, or separate patent assignment agreement. In other cases it was done through faculty handbooks or other official statements of policy.[181] However, neither of these paths secure the assignment of inventions to the university at

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[175] *See* Part III.C.1 *infra*.

[176] *Id.*; 17 U.S.C. §§ 101, 201(b).

[177] *See* Part IV.B.3 *infra*.

[178] *See* Part II.B *supra*.

[179] 853 F.Supp. 1215 (S.D. Cal. 1993).

[180] 2007 WL 2263079 (E.D. Tenn. 2007) *aff'd on other grounds* 542 F.3d 513 (6th Cir. 2008).

[181] *See, e.g.*, *id.*

the time of execution of the agreement, date of hire, or date of issuance of the policy, as applicable. At most, they secure a contractual obligation for the inventor to assign the invention at some later date.

In *Board of Trustees of Leland Stanford Junior University v. Roche Molecular Systems, Inc.* , the Federal Circuit held that a present or immediate conveyance to a private company of a Stanford researcher's interest in inventions arising from his work—"I hereby assign"—defeated an earlier future contingent conveyance to Stanford in those same inventions—"I hereby *agree* to assign"—even though the research was done under a funding agreement and the invention was a subject invention under Bayh-Dole. [182] The Federal Circuit asserted that Bayh-Dole regulates only the relationships and allocation of patent ownership as between federal funding agencies and small business or nonprofit contractors. This view is supported by the fact that there are only two provisions in Bayh-Dole that cover inventors themselves—the requirement for nonprofit and university contractors to share royalties with inventors under § 202(c)(7) and the provision for inventors to retain title under § 202(d).

Section 202(d) has also been invoked by a researcher who claimed that Bayh-Dole trumped any contractual arrangements between inventors and their employers because only the federal funding agency has the authority to decide disputed ownership of subject inventions. In *Fenn v. Yale* the U.S. District Court for the District of Connecticut found that the inventor had misled both Yale and NIH (the funding agency) about the nature of dispute and that Bayh-Dole did not preempt state law contractual rights in this matter. [183] This case is further discussed in Part IV below for its state law issues.

But if the assignment of a subject invention's title from inventors to their university employers does not operate by act of law when the university elects title, then this creates the possibility for some odd results that are clearly counter to the spirit of Bayh-Dole. For example, this seems to allow employee inventors to circumvent the carefully established allocation of rights and obligation between funding agencies and contractors. By assigning their rights in the invention to third parties before executing any final assignment to their university, they can take subject inventions out of the Bayh-Dole system altogether. This would eliminate the Government License, March-In Rights, and other important provisions because they only apply to the contractor who elects title.

Accordingly, some have suggested that Bayh-Dole and/or "agreements to assign" vest a kind of equitable title to the invention in the university-employer. This gains support from Senate Report No. 96-480—the sole congressional report counting as legitimate legislative history for Bayh-Dole—and an accompanying Congressional Budget Office report that claim that Bayh-Dole either vests title in, or automatically grants title to, subject inventions to the contractor. Further, because the contractor has a *statutory* right to elect to retain title to *any* subject invention, and the funding agency has a *statutory* right to take title in certain cases, then inventors can retain at most a conditional or residual title to the invention. This is supported by the presence of § 202(d) which appears to provide the *only* legal way for the inventor to wind up with title to a subject invention. Under § 202(d), the funding agency has full discretion whether to consider the employee inventor's request to retain title, and if so, whether to grant it. Finally, under § 202(c)(7)(A), as discussed above, university contractors are prohibited under their funding

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[182] 583 F.3d 832 (Fed. Cir. 2009).

[183] 393 F.Supp.2d 133 (D. Conn. 2004).

agreements from assigning any subject inventions to which they elect title, without the consent of the funding agency (unless the assignment is to a patent management company). This reinforces the notion that the university cannot even choose to assign its retained subject inventions to its employees. The only path for employee inventors to wind up with title is by the contractor declining to elect title, and then the funding agency agreeing both to consider a request by the employee inventor and then deciding to grant such request, in consultation with the contractor.

All of this would be frustrated if the inventor could simply assign his or her rights to a third party before assigning them to the university. Further, with the Federal Circuit's ruling in *Stanford* that even an agreement to assign the rights in the future is insufficient to vest some sort of title in the university, then all current subject inventions that have not been fully assigned to a university are in jeopardy of being diverted out of the Bayh-Dole system. At the same time, the Federal Circuit's ruling may be a correct interpretation of the statutory language of Bayh-Dole as it currently stands. The contractual arrangements between university contractors and employee inventors—including faculty members—might not be controlled by Bayh-Dole generally, or § 202(d) specifically. Instead, state law rules regarding patent ownership and express contractual arrangements might be the primary determinants in which party winds up with title. This would comport with other rulings that the Patent Act does not determine *ownership* of inventions, but only *inventorship*.[184] Thus, the issues raised in *Stanford* and other cases may reveal a flaw in Bayh-Dole that was likely predicated on an assumption that universities would have adequate assignment agreements in place with their inventor employees.

4. March-In Rights – § 203

March-In Rights have been part of federal patent policy since the Kennedy Patent Policy. [185] Prior to Bayh-Dole there may have only been one or two incidents in which federal agencies exercised March-In Rights. [186] This led some to call the rights a "paper tiger" that would never be exercised even if codified in a statute. [187] Under Bayh-Dole there have only been three formal proceedings in which federal agencies considered exercising March-In Rights. [188] In none of these cases did the agency choose to do so. March-In Rights have remained a controversial topic, in part because they have not need exercised since the passage of Bayh-Dole. Some have argued that they should be considered and used in a wider range of circumstances than they are actually authorized for under Bayh-Dole. At their core, March-In Rights are simply a mechanism to ensure that subject inventions that are retained by contractors are practiced, or at least moved down the commercialization pathway in good faith and with reasonable efforts by the contractor. They also provide a mechanism for the federal government to issue compulsory licenses for major health or public safety crises such that enough of the products or services embodying the

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[184] *See infra* Parts III.C.3 and IV.B.

[185] *See supra* Part II.B.

[186] *See* Raubitschek, *supra* note 56 at 154-55.

[187] *Id.*

[188] Government Accountability Office, Federal Research: Information on the Government's Right to Assert Ownership Control Over Federally Funded Inventions 10-11 (GAO-09-742, July 2009).

subject inventions—say vaccines or poison antidotes—can be made available through the federal government to respond to such crises. Of the three Bayh-Dole March-In Rights proceedings to date, only the first involved an allegation of non-use or insufficient commercialization. The other two alleged unreasonable pricing and rested on an erroneous argument that March-In Rights gave price control power to the federal government.

The first Bayh-Dole March-In Rights proceeding involved four patents on subject inventions arising from NIH funded research at Johns Hopkins University (Hopkins). Hopkins elected title and exclusively licensed the technology to Becton-Dickinson & Co. (BD), which marketed its first products using this technology in 1985. Four years after Hopkins filed its original patent application on the technology, a researcher at the Fred Hutchinson Research Center developed a similar technology and formed CellPro, Inc. (CellPro) to commercialize it. When Hopkins and BD learned about CellPro and its technology, they offer CellPro a license. CellPro declined and then instituted an unsuccessful declaratory judgment action in the U.S. District Court the Western District of Washington in 1992 seeking a ruling that it was not infringing the Hopkins patents. Hopkins and BD subsequently sued CellPro in 1994 in the U.S. District Court for the District of Delaware. After a complicated proceeding, Hopkins won a judgment for infringement,[189] and then treble damages based on a finding of willfulness. [190] But after the initial infringement finding, CellPro petitioned NIH to exercise March-In Rights based on an argument that Hopkins *et al* had either failed to bring the patented technology to the point of practical application or that they failed to reasonably satisfy health or safety needs. [191] NIH instituted proceeding under § 203 and found that: (i) Hopkins *et al*. was proceeding diligently with commercializing the patents; and (ii) health and safety needs were being filled by CellPro's current sales of its machines. Hopkins agreed to allow CellPro to continue selling its machines in a limited, monitored way under a revised injunction from the patent infringement proceedings until another Hopkins licensee, Baxter Healthcare Corporation, would have a suitable alternative product commercially available, which was expected soon. From this proceeding it is clear that NIH will seriously consider the speed of commercialization efforts in determining whether to exercise March-In Rights. Had Hopkins demonstrated no compelling story about their diligence in commercializing, and had Baxter not been able to show a near ready commercial market substitute for CellPro's machines, then the NIH may well have exercised it March-In Rights to require Hopkins to grant a license to CellPro, or stepped in and granted it itself if Hopkins did not comply.

The second Bayh-Dole March-In Rights proceeding involved the patents behind Abbott Laboratories' (Abbott) Norvir® ritonavir AIDS drug, which had been developed with NIH funding.[192] The circumstances were unusual in that Abbott is a large business not directly covered by Bayh-Dole, but instead fell under the adopted Bayh-Dole provisions of the Reagan Patent Policy. Essential Inventions, Inc., a public advocacy group, petitioned NIH to exercise March-In Rights on Abbott's Norvir® patents based solely on a dramatic price increase by

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[189] Johns Hopkins Univ. v. CellPro, 931 F. Supp. 303 (D. Del. 1996).

[190] Johns Hopkins Univ. v. CellPro, 978 F. Supp. 184 (D. Del. 1997).

[191] *See* NIH, Determination in the Case of Petition of CellPro, Inc . (Aug. 1, 1997), *available at* http://www.nih.gov/icd/od/foia/cellpro/pdfs/foia_cellpro39.pdf.

[192] NIH, In the Case of Norvir®, Manufactured by Abbott Laboratories, Inc ., *available at* http://ott.od.nih.gov/Reports/March-in-norvir.pdf (July 29, 2004).

Abbott on drugs covered by the patents mid-way through the patent term. [193] The petition was based, however, on a flawed claim that March-In Rights give federal agencies price control over downstream products embodying subject inventions. [194] The claim's proponents argued that it was based on the legislative history of Bayh-Dole, and published articles on it in various forums.[195] However, both Senators Bayh and Dole forcefully rebutted these claims and showed how the proponents had either misunderstood or misrepresented the actual legislative history. [196] During NIH hearings on the petition, Senator Bayh demonstrated how the claim's authors had used quotes from hearing on bills *other* than Bayh-Dole and seemed to have deceptively pieced together "quotes" comprised of fragments of sentences from totally different hearings. He also alleged that they misunderstood the legislative process that led to the final inclusion of the provisions of the original S. 414 as Section 6 in H.R. 6933 as passed. [197] Independent research done for this report corroborates Senator Bayh's statements about Bayh-Dole. Further, the "reasonable pricing" interpretation of March-In Rights has been refuted by authors of federal patent policy leading up to, and including, Bayh-Dole and its implementation. [198] In the end,

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[193] Essential Inventions, Inc., Petition to use Authority Under Bayh-Dole Act to Promote Access to Ritonavir, Supported by National Institute of Allergy and Infectious Diseases Contract No. AI27220 (Jan. 29, 2004) *available at* http://www.essentialinventions.org/legal/norvir/norvir-29Jan04petition.pdf (Jan. 29, 2004).

[194] Peter S. Arno & Michael H. Davis, *Why Don't We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed Upon Patents Deriving in Whole or in Part From Federally Funded Research*, 75 TUL. L. REV. 631, 658 (2001).

[195] *Id.*; Peter S. Arno & Michael Davis, *Paying Twice for the Same Drugs*, WASH. POST, Mar. 27, 2002, at A21.

[196] Birch Bayh & Robert Dole, *Our Law Helps Patients Get New Drugs Sooner*, WASH. POST, Apr. 11, 2002, at A28.

[197] Bayh's testimony is excerpted here:

> It was first brought to my attention that attempts were underway to rewrite history when I saw an article in the Washington Post on March 27, 2002, entitled *Paying Twice for the Same Drugs*. The crux of the article was that:
>
> > Bayh-Dole … states that practically any new drug invented wholly or in part with federal funds will be made available to the public at a reasonable price. If it is not, then the government can insist that the drug be licensed to more reasonable manufacturers, and if refused, license it to third parties that will make the drug available at a reasonable cost.
>
> This view mistakes how our law works. Bob Dole and I responded in a letter to the editor of the Washington Post on April 11, 2002 setting the record straight.
>
> You can imagine my surprise when I see the same arguments were being formally presented in a petition to NIH in an attempt to control drug prices. The quotations in the petition flagrantly misrepresent the legislative history supporting Bayh-Dole. The petition shows complete lack of understanding of how the legislative process works. The current petition says: "The clear language of the Bayh-Dole act requires reasonable pricing of government supported inventions." It later adds: "The legislative history evidences an intent to require that government supported inventions be priced reasonably."
>
> All but one of the citations in the petition used to conclude that march-in rights were intended to control prices actually refer to hearings on bills other than Bayh-Dole. While perhaps interesting, these are not pertinent legislative history.

Statement of Senator Birch Bayh to the National Institutes of Health (May 25, 2004), *available at* http://ott.od.nih.gov/meeting/senator-birch-bayh.pdf. For further detail on what Senator Bayh was trying to explain, see Part II.B *supra.*

[198] *See* Raubitschek, *supra* note 56 at 153 (2005); Statement of Norman J. Latker, Before NIH On Essential

while few people were pleased with Abbott's decision to dramatically increase the price of Norvir®, NIH was persuaded that Abbott had fulfilled its commercialization requirements under Bayh-Dole and so an exercise of March-In Rights was not warranted. It declined to adopt Essential Inventions positions as to either the "reasonable pricing" interpretation of § 203 or that the high prices of Norvir® constituted a sufficient health or safety emergency so as to warrant the exercise of March-In Rights.

The final March-In Rights proceeding to date was *In the Case of Xalatan® Manufactured by PFIZER, INC*.[199] This petition was also premised on the faulty "reasonable pricing" argument. Using nearly identical language as used in the Norvir® ruling, NIH also declined to exercise March-In Rights in this case.

5. Preference for U.S. Industry – § 204

This section captures Bayh-Dole's focus on promoting commercialization of subject inventions for the benefit of the U.S. economy. While there has been much speculation about whether it will ever be enforced[200]—as well as what "manufactured substantially" means—there has been little judicial interpretation of this section. In *Ciba-Geigy Corporation v. Alza Corporation*, the defendants argued that Ciba-Geigy, as the exclusive licensee of patent owner Regents of the University of California (Regents), did not intend to manufacture substantially in the United States under the terms of the license and § 204. [201] The defendants alleged that this made the license illegal and unenforceable because either the licensee's failure to manufacture substantially in the United States rendered the agreement void or the licensee's violation of § 204 transformed its exclusive license into a nonexclusive license that would deprive it of standing to bring the infringement suit without joining the Regents as co-plaintiffs. Based on the sovereign immunity issues involved, the Regents had given its Ciba-Geigy the rights and power to bring an infringement lawsuit so that the Regents would not have to join the suit and waive its sovereign immunity.[202] However, this power rested on the nature of the exclusive license granted. The U.S. District Court for the District of New Jersey found that the inventions and patent in question might not even be a subject invention covered by Bayh-Dole. However, the court found that even if they were, then the actions of the manufacturer did not automatically make the license illegal or void. The court pointed out that the contract allowed the licensee to manufacture substantially in the United States and thus was fully legal and compliant on its own terms. Further, breach by

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Inventions Petition Regarding Norvir, National Institutes of Health, Hearings on Ritonavir (May 25, 2004), *available at* http://www.ott.od.nih.gov/meeting/norman-J-latker.pdf; Letter from Carl E. Gulbrandsen, Managing Director, Wisconsin Alumni Research Foundation, to Dr. Mark Rohrbaugh, Director of the Office of Technology Transfer, Office of Intramural Research, National Institutes of Health (April 15, 2004), *at* http://ott.od.nih.gov/meeting/carl-e-gulbrandsen.pdf; Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research* , 82 VA. L. REV. 1663 (1996).

[199] NIH, *In the Case of Xalatan® Manufactured by PFIZER, INC.* , *available at* http://www.ott.nih.gov/policy/March-in-xalatan.pdf.

[200] A failure to comply with § 204 is also a trigger for the exercise of March-In Rights under § 203(1)(d).

[201] 804 F.Supp. 614 (D.N.J. 1992).

[202] *See* Part III.I *infra* for further discussion of sovereign immunity as it applies to state universities that are deemed to be state agencies.

the licensee of the substantial manufacture requirement did not automatically convert the exclusive license into a nonexclusive one. Neither did such breach require the funding agency to march in and grant a license to a third party. Instead, the agency merely had the discretionary power to do so, and the licensee maintained his exclusive rights until and unless the agency took affirmative steps to act on this discretionary power.

Section 204 raises the additional issue of whether it is compliant with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs). In particular, since Article 64 of TRIPs prohibits signatory states from discriminatory IP policies, the requirement of § 204 for substantial manufacture in the United States as a condition of the exclusive license could be interpreted as favoring U.S. firms and discriminating against foreign firms. In fact, Brazil raised this exact point in a "request for consultation" under Article 4 of the Understanding on Rules and Procedures Governing the Settlement of Disputes (DSU), Article XXII of the General Agreement on Tariffs and Trade 1994 (GATT 1994), Article 64 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), and Article 8 of the Agreement on Trade-Related Investment Measures (TRIMs Agreement). [203] This action by Brazil was actually a response to a United States request for consultation on the "local working" requirement that required local production of patented subject matter as a condition of exclusive patent rights under Brazil's 1996 industrial property law (Law No. 9,279 of 14 May 1996; effective May 1997). [204] However, the parties settled their dispute with no decision as to the compliance of § 204 with TRIPs. [205]

6. Uniform Clauses and Regulations – § 206

This section gives rulemaking authority to implement §§ 202-204 and establish standard funding agreement clauses to DoC. [206] The current Bayh-Dole Regulations and Standard Patent Rights Clauses were authorized under this section. DoC retains authority to amend these regulations and clauses within the parameters of Bayh-Dole's statutory provisions. Accordingly, DoC could amend or modify regulations governing the Government License, March-In Rights, utilization reports, invention disclosures, procedures for title election and/or allowing employee inventors to retain title to subject inventions, requirements for preference for U.S. industry in exclusive licensing arrangements, and specific requirements on nonprofit and university contractors (such as the degree of preference for small businesses in licensing and conditions for approval of assignments of subject inventions to entities or persons other than patent management firms).

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[203] World Trade Organization, United States—U.S. Patent Code, Request for Consultations by Brazil, WT/DS224/1, G/L/437, IP/D/24, G/TRIMS/D/18 (Feb. 7, 2001).

[204] World Trade Organization, Brazil—Measures Affecting Patent Protection, Request for Consultations by the United States, WT/DS199/1, G/L/385, IP/D/23 (Jun. 8, 2000).

[205] World Trade Organization, Brazil—Measures Affecting Patent Protection, Notification of Mutually Agreed Solution, WT/DS199/4, G/L/454, IP/D/23/Add.1 (Jul. 19, 2001).

[206] *See supra* Part II.C.

7. Precedence of chapter – § 210

This section achieves a couple of critical federal patent policy goals. First, it overcame the labyrinth statutory patent title allocation rules that had hampered efforts to create a uniform government-wide patent policy since the Kennedy Administration. [207] If no other section of Bayh-Dole than this had been passed, then the Act would have been a great success. It would have allowed the Executive Branch to create and enforce a uniform patent policy. Second, the section establishes that Bayh-Dole does not abrogate Executive Branch authority to make patent policy for contractors beyond those covered by Bayh-Dole. At the same time, it requires that any funding agreement with such contractors must include the Government License and March-In Rights.[208] It also makes clear that the section's override on other statutory title allocation rules does *not* apply to those contractors not directly covered by Bayh-Dole. Accordingly, large business contractors would still be subject to such myriad title allocation rules regardless of what the funding agreement states.

C. Other Relevant U.S. Patent Law Provisions

1. Inventorship

While it is commonly understood that under U.S. patent law the original title to a patentable invention vests with the natural person inventor—and not with any corporate entity that employs or contracts with them—nothing in the Patent Act as codified in Title 35 (Patents) of the U.S. Code expressly states this.[209] However, it is generally understood to arise from various provisions within Title 35 as a kind of penumbral rule. [210] Notwithstanding this, the Patent Act does establish express rules of inventorship that are particularly important when there may be co-inventors, such as in university research. [211] Failure to include all inventors ("non-joinder") can cloud title and enforceability by rendering the patent invalid. [212] In *Chou v. Univ. of Chicago*, the Federal Circuit held that a graduate student research assistant had standing to sue for nonjoinder even though she had assigned all her rights in the invention to her university employer. [213] Because she had an expectation of royalty sharing in the patent under the university's policy, she had sufficient economic interest in being named an inventor, even though she would have no ownership rights to it. This case is also important for the state law issues it raised, which will be treated in Part IV.B.2 below.

In cases of joint inventorship, an "inventorship entity" that acts like a general partnership is

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[207] *See supra* Part II.B.

[208] *See supra* Part II.C.

[209] Patent Act of 1952, P.L. 82-953, 66 Stat. 792 (Jul. 19, 1952) (*codified as amended as* Title 35 of the U.S. Code).

[210] Commentators generally point to 35 U.S.C. §§ 101, 102(c), and 102(f).

[211] 35 U.S.C. § 116.

[212] *See* Pannu v. Iolab Corp., 155 F.3d 1344 (Fed. Cir. 1998).

[213] 254 F.3d 1347 (Fed. Cir. 2001).

created.[214] This is not an "entity" with legal personhood status, like a corporation, but rather just a collective of the inventors in which each member of the inventorship entity has the power to assign or license their rights to the patent. At the same time, because inventorship rights are indivisible, each joint inventor's share covers the entirety of the patent, regardless of what his or her inventive contribution was.[215] As discussed below in Part III.C.3, any joint inventor's license to a third party will destroy the ability of the other joint inventors to grant an exclusive license. The corollary of this is that *all* joint inventors—to the extent that they are still all, and the only, co-owners of the patent—must be joined as plaintiffs in any suit to enforce the patent.[216] This is because if even one is not so joined, then that non-joined inventor could still license or assign his or her rights in the patent to the defendant.[217] The challenge for patent assignees—including employer assignees such as universities—is that it is hard to be sure that all inventors have been joined in the patent application. In large R&D labs there are a number of individuals who may be in a position to make a contribution to conception of at least one claim which might then qualify them as a co- or joint inventor. Further, hierarchical relationships such as professor-student, or principal investigator-technician/research assistant, can result in faulty assumptions or intentional obfuscation about who should properly be joined as a co-inventor. If the stakes are high enough and an infringement defendant is concerned that they might lose a patent suit because the patent is likely to be ruled valid, enforceable, and infringed, then there can be extensive efforts on the part of that defendant to try and locate a plausible omitted inventor who is willing to grant it a retroactive license.

There can also be "misjoinder" of inventors in which an individual is named as an inventor but in fact did not make a substantial contribution to the invention. Misjoinder may be fairly common especially in large labs where a principal investigator (PI) believes that he or she should be listed as an inventor on every patent application coming out of his or her laboratory. However, as harmless an exercise in vanity this may seem, it can also invalidate the patent. Accordingly, it is critical for universities to be diligent about ensuring that all and only those who made substantial contributions to the invention are listed as inventors on the patent application.

Misjoinder and nonjoinder can be remedied under the correction of inventorship statutory provision of 35 U.S.C. §256. However, there must have been no deceptive intent behind the misjoinder or nonjoinder. A court can order the correction of inventorship upon a finding that a true inventor was omitted, or an illegitimate inventor was listed, so long as no deceptive intent was found. In this way, the patent can be saved from invalidation during an infringement proceeding. Thus, misjoinder or nonjoinder are not necessarily fatal to a patent owner's infringement suit, but the added complexity is surely not worth the convenience of casualness by the patent applicant *ex ante*.

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[214] *See, e.g.*, DONALD D. CHISUM, 1 CHISUM ON PATENTS § 3.08[2] (1996).

[215] 35 U.S.C. §116.

[216] *See* Waterman v. Mackenzie, 138 U.S. 252, 255 (1891); Schering Corp. v. Roussel-UCLAF SA, 104 F.3d 341 (Fed. Cir. 1997).

[217] 35 U.S.C. § 262. In Ethicon, Inc. v. United States Surgical Corp ., the Federal Circuit affirmed the trial court's grant of a motion to dismiss the infringement case based on the trial court's finding that there was an omitted, or non-joindered, inventor who had retroactively licensed the infringement defendant. 135 F.3d 1456 (Fed. Cir. 1998). The trial court also ordered the correction of inventorship on the patent under 35 U.S.C. § 256. *Id.*

2. CREATE Act & inter-institutional research collaboration

Prior to passage of the Cooperative Research and Technology Enhancement (CREATE) Act,[218] confidential information or data exchanged between researchers at separate, unaffiliated institutions that led to an invention could constitute prior art, which could destroy the novelty or non-obviousness of the invention and make it ineligible for patenting. [219] For universities, this interpretation had implications for their ability to obtain patents, as academic researchers routinely engage in communications and exchanges of data with colleagues at different institutions. Either a proportion of university inventions would be rendered unpatentable due to such "prior art" disclosed by those outside colleagues, or, in the interest of maintaining the novelty and nonobviousness of their inventions, university researchers might begin refraining from inter-institutional research collaborations. The CREATE Act amended the Patent Act to overcome these undesirable implications by stipulating conditions under which information exchanged between collaborators at different institutions would not be considered prior art. Specifically, the Act extended an existing safe harbor for subject matter exchanged between researchers employed within the same institution to include subject matter exchanged between researchers at different institutions. [220] The three conditions necessary to come under the safe harbor include: 1) a "joint research agreement" must be in effect between the parties on or before the date that the claimed invention was made; [221] 2) the claimed invention must be within the scope of the joint research agreement; and 3) the names of the parties to the joint research agreement must be disclosed in the patent application. The Act does not speak directly to determination of inventorship, which would still be determined under § 116 of the Patent Act as described in Part III.C.1 above. The Act does not restrict any party's actions, should that party choose to publicly disclose or otherwise limit or destroy the novelty or non-obviousness of the later claimed invention. Rather, it simply ensures that a proper contractual relationship between or among research institutions will overcome the patent law default rule that disclosures of unaffiliated parties must be treated as part of the prior art when considering a later arising invention or patent application.

3. Separation of inventorship and ownership: assignments and licensing of patents under the Patent Act

It is critical to separate *inventorship* from *ownership*. The Patent Act gives patents the attributes of personal property, establishing that they are freely alienable. [222] Inventors (and any subsequent assignee owners) can assign their patents and patent applications, as well as grant exclusive licenses under them, so long as such assignments and exclusive licenses are in

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[218] P.L. 108-453, 118 Stat. 3596 (2004) (*codified at* 35 U.S.C. § 103(c)).

[219] OddsOn Products, Inc. v. Just Toys Inc., 122 F. 3d 1396 (Fed. Cir. 1997).

[220] 35 U.S.C. Section 103(c).

[221] Notably, the term "joint research agreement" is defined to contain the same sorts of agreements as those captured under the term "funding agreement" in Bayh-Dole, namely, contracts, grants, and cooperative agreements entered into for the performance of experimental, developmental, or research work.

[222] 35 U.S.C. § 261.

writing.[223] Presumably, nonexclusive licenses can be granted verbally, as well as in writing. The Patent Act provides that any "certificate of acknowledgment under the hand and official seal of a person authorized to administer oaths" in the United States or abroad is *prima facie* evidence of an assignment or license.[224] However, the Patent Act also provides a *bona fide* purchaser defense to any assignee whose title is contested by another who claims to be an assignee: (i) if the latter did not record the assignment in the USPTO within three months from either the date of its purported receipt of assignment or before the later assignee's receipt of assignment; and (ii) if the former had no actual, constructive, or implied knowledge of the assignment to the latter.[225] Additionally, while the Patent Act establishes the nature and requirements of ownership, assignments and exclusive licenses, it is not the exclusive source of law for these transactions, because the contracts underlying them are governed by state law.[226]

These issues were raised in the Federal Circuit's decision in *Board of Trustees of Leland Stanford Junior University v. Roche Molecular Systems, Inc.*, which also had implications for Bayh-Dole as discussed above in Part III.B.3.d.[227] Stanford University had relied on future contingent assignment language—"I hereby *agree* to assign . . ."—in its Copyright and Patent Agreement (CPA) with one of its researchers. The researcher, with Stanford's knowledge, engaged in consulting work with Cetus, a private firm that was doing collaborative research with Stanford, and signed a Visitors Confidentiality Agreement (VCA) with that firm which included a present assignment—"I hereby assign . . ."—of any IP arising from the researcher's work there. Later, when a patentable invention arose in the field of polymerase chain reaction (PCR) and was disclosed by the researcher and his colleagues to Stanford, the university duly notified NIH (the funding agency), elected to take patent, and had a patent issued on the technology. Roche Molecular Systems ("Roche") then bought Cetus' PCR business through an asset purchase agreement. Stanford attempted to negotiate a license with Roche to the PCR patents, but Roche declined, asserting that it either owned or had a license to the patents already.

Stanford then sued Roche for patent infringement. The trial court found for Stanford and rejected Roche's argument that it owned the patent because the present assignment language in the VCA was executed by the Stanford researcher *before* Stanford secured the *actual* assignment of the patent rights from the researcher. But this decision was based on a finding by the trial court—later overruled by the Federal Circuit—that Bayh-Dole rendered the VCA's assignment provision void.[228] Stanford also argued that even if the present assignment language in the VCA trumped the future assignment language in the CPA, then Stanford's later receipt of the researcher's actual assignment and Stanford's subsequent recordation of the assignment with the USPTO gave it title to the patents as a *bona fide* purchaser because neither Cetus nor Roche had recorded their assignment under the VCA with the USPTO. The trial court rejected that argument in this case only because it found that the researcher's knowledge of the VCA and

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[223] *Id.*

[224] *Id.*

[225] *Id.*

[226] Board of Trustees of Leland Stanford Junior University v. Roche Molecular Systems, Inc., 583 F.3d 832 (Fed. Cir. 2009). The state law aspects of ownership and licensing of patents will be covered in Part IV.B *infra*.

[227] 583 F.3d 832 (Fed. Cir. 2009).

[228] *See supra* Part III.B.3.d.

assignment to Cetus was actually or impliedly known by Stanford—the researcher was Stanford's employee at the time and knowledge by an employee can generally be imputed to an employer—and because Stanford had authorized the collaborative research with Cetus. The Federal Circuit affirmed the trial court's finding in this regard.

4. Declaratory judgment actions

In 2007, the U.S. Supreme Court dramatically reshaped licensing law by holding that a licensee who is enjoying all of the legal protections of a patent license can nonetheless bring a declaratory judgment action to obtain a ruling that the underlying patent is invalid, unenforceable, or not infringed.[229] While licensing law is a combination of federal and state law, declaratory judgment actions in federal courts are solely authorized by the Declaratory Judgment Act, a federal statute.[230] On its face, *MedImmune, Inc. v. Genentech, Inc* , was really a narrow technical interpretation of the U.S. Constitution's Article III limitation of federal court's jurisdiction to "cases" and "controversies," in the context of the "actual controversy" requirement of the Declaratory Judgment Act. But in practical effect the case represented an unsettling shift in expectations about patent challenges in the licensor-licensee relationship.

The common understanding before *MedImmune* was that licensees had to repudiate the license by ceasing royalty payments, for example, before having standing to bring a declaratory judgment action to find the licensed patent invalid, unenforceable, or non-infringed. This repudiation allowed the licensor/patent owner to bring its own patent infringement suit directly as plaintiff, or as a counterclaim as the defendant in a declaratory judgment brought by the licensee. Under *MedImmune*, however, so long as the licensee complies with its license obligations the licensor/patent owner can neither bring a direct patent infringement suit, nor even counterclaim patent infringement. At the same time, the patent owner cannot effectively protect itself by contractually prohibiting the licensee from challenging the patent because such provisions are generally unenforceable under the doctrine established in cases such as *Lear v. Adkins*.[231]

MedImmune is particularly problematic for non-practicing entity patent owners such as universities who incur substantial opportunity costs when they grant an exclusive license to a licensee who pays relatively little up front, in exchange for paying a potentially sizable royalty stream if or when products based on the patents are successfully commercialized and sold in the marketplace. In effect, licensees can now take a license just to buy time to develop a product with relative freedom to operate and then attempt to invalidate the patent once a product looks like it will become profitable and royalties would have to be paid. While some have suggested that the solution to this is simply for patent owners to demand full payment of the net present value of the royalty stream up front, this will simply not be possible for many small and mid-sized entities (SMEs) who license technologies from universities. Stanford's Office of Technology Licensing instituted a system whereby licensees who challenge an underlying patent through a declaratory judgment action while keeping the license in place must pay twice the original royalties, and then three times the royalties if the patent is adjudged valid, infringed, and

[229] MedImmune, Inc. v. Genentech, Inc., 549 U.S. 118 (2007).

[230] 28 U.S.C. §2201(a).

[231] 395 U.S. 653 (1969).

enforceable.[232] Some commentators have advocated that licensors use letter of credit mechanisms to effect a present assignment of rights to future payments. [233] Another proposal is that licensors take some combination of stock and stock options in the licensee that SMEs can afford to pay up front (in lieu of cash), while allowing the licensor to participate in the potential upside of successful commercialization in a manner that is fully accrued to the licensor upon the execution of the license and equity deal. [234]

5. Patent exhaustion

In 2008, the Supreme Court issued an opinion in *Quanta Computer, Inc. v. LG Electronics, Inc.*[235] that has implications for how licensing agreements must be structured to avoid limitations under the patent law doctrine of "exhaustion" or "first sale." LG Electronics (LG) held a number of patents on integrated circuit (IC) chips that could be used in computers. It also held patents on computer systems, which consist of connections of IC chips and other components to create a functioning computer. LG manufactured and sold IC chips to downstream assemblers who then built the chips into computers for end users. LG also licensed its system patents to such assemblers. Intel, another well-known IC chip manufacturer, employed a similar business model, including its own portfolio of IC chip and computer systems patents. LG and Intel competed both in the market and in IP claims. With both companies having strong offensive and defensive IP positions, any IP litigation between them would almost certainly be costly and protracted. In order to establish a "patent peace" with Intel, LG agreed to license most of its patent portfolio to Intel, with the caveat that the license did not include a sublicense right (or any license right) for Intel's assembler manufacturer customers to assemble computer systems covered by LG's patents and using non-Intel parts. Intel was further obligated to deliver a notice of this absence of a license to combine Intel and non-Intel parts to its assembler customers. The inference was that the assemblers must go to LG to obtain a system assembly license. Quanta, one of these assemblers, bought the chips from Intel, acknowledged the IP limitation notice, yet proceeded to build systems that combined the Intel chips and non-Intel components without obtaining a license from LG. LG then sued Quanta and others for patent infringement.

Among other defenses raised by Quanta was that of patent exhaustion. Quanta asserted that because it had lawfully purchased the chips from Intel—who had every right to manufacture and sell them under the license from LG—then those purchased chips were now outside of the patent monopoly and could freely be used by Quanta for their established purpose: to be assembled into a functioning computer system. The case could have turned on a theory of implied license instead—Quanta's purchase of the chips would be completely pointless and frustrated as a commercial transaction if it could not use the chips for their primary (some would say only) practical use, therefore a use license must be implied. But Intel had no right to license Quanta to

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[232] Leland Stanford Junior University, Office of Technology Licensing, Form of Exclusive License § 7.5 *available at* http://otl.stanford.edu/documents/revstdagmt_08.pdf.

[233] Rochelle Cooper Dreyfuss & Lawrence S. Pope, *Dethroning Lear? Incentives to Innovate After MedImmune* , 24 BERKELEY Tech. L. J. 971 (2009).

[234] Sean M. O'Connor, *Using Stock and Stock Options to Minimize Patent Royalty Payment Risks after MedImmune v. Genentech*, 3 NEW YORK UNIVERSITY JOURNAL OF LAW & BUSINESS 381 (2007).

[235] 128 S.Ct. 2109 (2008).

practice LG's systems patent. Additionally, any argument that Intel must have intended for an implied license to be granted to Quanta for the systems claims would have been rebutted by Intel's actions when it dutifully passed along the notice to Quanta that the latter would have no license to use the chips in computer systems covered by LG's patents. Quanta acknowledged the notice and did not dispute that it was unlicensed by LG to assemble the chips into computer systems. The Federal Circuit affirmed the part of the trial court's opinion that denied Quanta's summary judgment motion based on the assertion of law that the exhaustion doctrine does not apply to method claims in patents. The Supreme Court overturned the Federal Circuit's ruling by holding that method claims *can* be exhausted. It also held that because the LG-Intel license authorized Intel to make and sell chips that "substantially embody" the patents at issue, then the exhaustion doctrine prevented LG from asserting the systems patent claims against lawful purchasers of Intel-manufactured chips such as Quanta.

Taken to its logical conclusion, the *Quanta* Court's ruling has disturbing implications. When one party's patents might only cover the chip itself, while a completely unrelated third party holds the system patent that will cover the primary or even sole use of the chip as a component, the chips "substantially embody" both patents *and the third party's patents are exhausted when the chip manufacturer sells its chips*. This will be a surprising result indeed for IP owners when someone else can do something without your knowledge, involvement, or consent, which exhausts your patent rights.

The implications of *Quanta* for universities are acute as many university technologies are early stage or platforms that will require licensing and commercialization along vertical "value chains" such as the computer hardware manufacturing value chain in *Quanta*. Universities will need to think carefully about all of the ways that their IP rights can be reconveyed by the licensee, including assignments, transfers, sub-licenses, and acquisitions of the licensee entity by another entity. Some commentators have claimed that *Quanta* prohibits IP owners from licensing the same patent at multiple points in the value chain—characterized by critics of value chain licensing as "double dipping." This is simply untrue. The Court did not disturb *General Talking Pictures Corp. v. Western Elec. Co.*,[236] but rather distinguished the facts of the LG-Intel agreements and thus found LG's reliance on the two related cases to be misplaced. The *Quanta* Court left the door open for IP owners to limit the sell right granted to licensees as one whose scope is actually defined by the downstream market.

6. Research Use Exceptions/Exemptions

The unauthorized making, using, or selling of patented inventions is normally an infringement of exclusive patent rights.[237] This is the heart of the exclusive rights of patent owners. Further, the unauthorized import of products embodying the patented invention, or resulting from the patented process, is also an infringement of exclusive patent rights.[238] Thus, absent an exception, all commercial *and* non-commercial research which either experiments "on" or "with" patented inventions—as discussed below—constitutes patent infringement. However, in the seminal research use exemption patent case of *Whittemore v. Cutter,* Justice Story

[236] 304 U.S. 175 (1938), 305 U.S. 124 (1938).

[237] 35 U.S.C. § 271.

[238] *Id.*

famously declared "that it could never have been the intention of the legislature to punish a man, who constructed [the patented] machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects." [239] Coupled with the long standing prohibition on the patentability of scientific principles or laws of nature, as evidenced by landmark English cases such as *Hornblower v. Boulton*[240] and *Neilson v. Harford*,[241] this emerging nineteenth century common law or judicial research use exception seemed to protect pure scientific inquiry from suits for patent infringement. Beginning in the 1980s, the common law research use exception was the subject of significant Federal Circuit decisions clarifying and arguably limiting its scope, even as a new statutory research use exception was created by Congress for the development of generic drugs.

a. R&D exceptions

Whittemore v. Cutter established a narrow research use exception for private, philosophical, or purely scientific experiments. Throughout the nineteenth and twentieth centuries, this "common law" or judicially created exception was interpreted expansively by universities and non-profit research organizations to become a kind of patent law version of the "fair use" doctrine in copyright law. [242] However, the Federal Circuit re-established the narrow scope of this exception in a trilogy of cases beginning in 1984 with *Roche Products, Inc. v. Bolar Pharmaceuticals*,[243] a case that is more famous for leading to the statutory regulatory review exceptions (sometimes, in fact, called "*Bolar* exceptions") discussed in the next subsection. In *Roche*, the Federal Circuit held that the unauthorized use by Bolar Pharmaceuticals ("Bolar") of Roche Product, Inc.'s ("Roche") patented drug for purposes of satisfying Food and Drug Administration (FDA) data requirements for approval of the sale of a follow-on drug that would commence directly upon the expiration of Roche's patent on the pioneer drug was not excused under the common law research use exception. The court found that regardless of whether Bolar's activities could be characterized as true scientific experiments, they were solely undertaken "with a view to the adaption of the patented invention to the experimentor's business [as] a violation of the rights of the patentee to exclude others from using his patented invention."[244]

The second case in the trilogy was *Embrex v. Service Engineering*, decided in 2000. [245] In

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[239] 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813) (No. 17,600).

[240] 8 T. R. 95 (K.B. 1799) (finding Watt's patent for a steam engine to claim a manufacture and not a philosophical principle, the latter which would have been prohibited).

[241] Webster's Patent Cases 295 (Exch. 1844) (holding that a patent for interposing a heated receptacle between a blower and a furnace such that the air sent into the furnace would be warm, not cold, was not invalid as simply a scientific principle; whereas a patent for only a scientific principle (with no particular application) would be invalid).

[242] The fair use doctrine is codified in the Copyright Act at 17 U.S.C. § 107.

[243] 733 F.2d 858 (Fed. Cir. 1984).

[244] 733 F.2d at 863. The *Roche* court also relied on a precedential opinion from the Court of Claims to suggest that where the unauthorized use of the invention advances the alleged infringer's legitimate business interests, then the activities fall outside of the common law research use exception. *Id*. (quoting Pitcairn v. United States, 547 F.2d 1106, *cert. denied,* 434 U.S. 1051 (1978)).

[245] 216 F.3d 1343 (Fed. Cir. 2000).

Embrex, the Federal Circuit affirmed the lower court's decision to look through "the guise of scientific inquiry" based on Service Engineering's directed research by a university professor that nonetheless was done "expressly for commercial purposes." [246] The court also seemed to more clearly distinguish a *de minimis* exemption from the common law scientific research exception deriving from Justice Story. [247]

Despite these clear judicial pronouncements, many universities and non-profit research organizations continued to interpret the exception to cover virtually all of their research activities. In essence, they treated the common law research use exception as if it were a broad non-commercial and/or educational purposes exception similar to the fair use doctrine in the Copyright Act.[248] The *Madey v. Duke* decision in 2002 clearly swept away this interpretation. [249] Unfortunately, the facts of the *Madey* case were not well suited to be the test case for such an important area of IP and university/nonprofit research activities. The dispute centered on the soured relationship between Madey, a faculty researcher at Duke University ("Duke"), and the administration at Duke. The essential element was that Madey owned some patents arising from his earlier work at Stanford University that claimed a free electron laser technology used in his lab at Duke. After leaving Duke over a dispute involving control and use of the lab, he brought a patent infringement suit against Duke to prohibit it from using the claimed technology. Duke raised a number of defenses, including the common law research use exception. [250] Overturning the trial court's finding that Duke's use was covered by the common law research exception, the Federal Circuit focused on the reality that universities have become substantial economic players who have business objectives similar to other economic actors. [251] Because the Supreme Court declined to review the Federal Circuit's decisions in any of the cases in this trilogy, the Federal Circuit's interpretation of the common law research use exception constitutes the definitive scope of this doctrine for universities and nonprofits. Accordingly, the scope of this exception is extremely narrow and almost irrelevant for purposes of protecting any formal R&D activities of research universities from allegations of patent infringement.

b. Regulatory review exceptions.

The United States appears to have been the first major nation to adopt a statutory provision specifically directed to a regulatory review exception. Congress was already debating various bills aimed at resolving the conflict between pioneer and generic drug manufacturers when the Federal Circuit decided *Roche*. Expressly noting this congressional debate and inviting Congress to pass legislation specifically directed at the regulatory review exception issue in its opinion, the Federal Circuit declined to judicially create such an exception. [252] Shortly thereafter, Congress

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[246] 216 F.3d at 1349.

[247] *Id.* ("This court has construed both the experimental use and *de minimis* exceptions very narrowly.").

[248] However, even the fair use doctrine is often interpreted too broadly by those in academic settings.

[249] 307 F.3d 1351 (Fed. Cir. 2002).

[250] Duke's use of the Government License defense is discussed in Part III.B.3.c(ii) *supra*; its use of the Government Use Statute is discussed in Part III.J *infra*.

[251] 307 F.3d at 1362-63 and fn 7.

[252] Madey v. Duke, 307 F.3d 1351 (Fed. Cir. 2002).

passed the Drug Price Competition and Patent Term Restoration Act of 1984 (better known as the "Hatch-Waxman Act").[253] Among many other provisions, the Act added § 271(e)(1) to the U.S. Patent Act's definition of infringement. [254]

While many had believed that this statutory provision was intended to narrowly remove from the definition of infringement only the use of patented compounds (*i.e.*, drugs) in clinical trials by generic drug manufacturers to show bioequivalence for purposes of the new abbreviated regulatory approval mechanism for generics, the U.S. Supreme Court gave a much more expansive interpretation to the clause in its 2005 decision in *Merck KGaA v. Integra Lifesciences I, Ltd*.[255] Thus, instead of limiting the reach of § 271(e)(1) to research *on* patented compounds in the context of clinical trials, the Supreme Court interpreted the exception to cover "all uses of patented inventions that are reasonably related to the development and submission of *any* information under the [Food, Drug and Cosmetics Act]." Further, "[t]his necessarily includes preclinical studies of patented compounds that are appropriate for submission to the FDA in the regulatory process."[256] The Court could not have literally meant what it said in the first statement above, because then the unauthorized use of all patented lab equipment, software, etc. would seem to come within the § 271(e)(1) exception. At the same time, the Court claimed that it made no ruling as to the status of biotechnology research tools in a footnote to its opinion. [257]

Outside of these two particular uncertainties in the opinion, the Court focused on constructing the §271(e)(1) research exception in both chronological and subject matter breadth dimensions. Thus, the Court found that the exception explicitly includes uses of patented inventions to perform the early stage research required to file an "investigational new drug application" (IND), as well as the later stage research involved in clinical trials leading to submission of a "new drug application" (NDA). At the same time, the Court rejected the Federal Circuit's construction that seemed to restrict the exception to only research that produces safety data in the preclinical phase. Instead, the Court asserted that because research leading to data on the pharmacological, toxicological, pharmokinetic, and biological qualities of a drug can be required in an IND, then the research and collection of any data related to these qualities can properly fall under the exception. Further, the Court explained that, in certain circumstances, the §271(e)(1) exception can cover "(1) experimentation on drugs that are not ultimately the subject of an FDA submission or (2) use of patented compounds in experiments that are not ultimately submitted to the FDA."[258] The Court then held that "the use of patented compounds in preclinical studies is protected under §271(e)(1) as long as there is a reasonable basis for believing that the experiments will produce 'the types of information that are relevant to an IND or NDA.'" [259] Ultimately, then, this means that the regulatory review exception in the U.S. is quite broad. Accordingly, universities who engage in toxicology, animal, or any other clinical studies to

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[253] 98 Stat. 1585 (1984).

[254] 35 U.S.C. § 271(e)(1).

[255] 125 S. Ct. 2372 (2005).

[256] *Id.*

[257] *Id.* at 2382, FN 7.

[258] *Id.* at 2382.

[259] *Id.* at 2383-84. Note that the Court shifts over the course of its opinion from referencing "patented inventions" generally to the far more limited "patented compounds" as the touchstone for what is being covered by the exception. This adds to the uncertainty created by the ruling.

generate data that might later be used in an IND or NDA will be covered for the exception for these activities. It does not matter whether such studies are done as part of corporate sponsored research or other funding sources.

D. Federal Laws and Policy Pertaining to Ownership and Use of Data Arising From Federally Funded Research

Data in and of itself—meaning the facts amassed during research ("raw data")—is neither patentable nor copyrightable. Accordingly, raw data are only protectable by trade secret, physical control, or contractual arrangements such as non-disclosure, non-use, and/or confidentiality agreements. Thus, how universities protect raw data arising from their research activities is largely a matter of state law, to be discussed in Part IV below. However, once raw data are packaged into reports, charts, databases, etc., the overall package may be copyrightable. Such copyright will still not extend to the raw data, but will rather be "thin copyright" covering only the format and any original expression fixed in the package. [260] The federal government has an established history of requirements pertaining to the use and dissemination of "data"—which includes both raw data and packaged data—arising under various funding agreements with extramural contractors.

1. Ownership and use rules for data arising under federal contracts

The rules for ownership and use of data developed under federal funding agreements vary as between DoD and other federal agencies. When the FAR was promulgated in 1983, it was only one part—albeit the core part—of the larger Federal Acquisition Regulations System (FARS) which covers all executive agencies and includes agency-specific regulations that implement or supplement the FAR.[261] FARS was implemented to replace the FPR and agency-specific procurement regulations such as DoD's Defense Acquisition Regulation (DAR). DoD promulgated its Defense Federal Acquisition Regulation Supplement (DFARS) in March 1984.[262] Because the various agencies were not yet ready to issue uniform patent, copyright, and data policies in 1983 when the FAR issued, and because DoD had not finalized its own separate data and copyrights policy by the time it issued DFARS in early 1984, both the FAR and DFARS originally only reserved sections for these policies without issuing any content in them. However, in March 1984 DoD joined GSA and NASA to issue a final rule with a cursory general data provision for inclusion in the FAR. [263] By October of that year DoD had promulgated its separate data provisions.[264] Later that same month, however, Congress passed the Department of Defense Authorization Act, 1985, which added §§ 2320-2321 to Title 10 (Armed Forces) of the U.S.

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[260] *See* Feist Publications v. Rural Tel. Service, 111 S.Ct. 1282, 1289-90 (1991).

[261] *See* DoD *et al.*, Final Rule, Establishing the Federal Acquisition Regulation, 48 F ED. REG. 42102 (Sep. 19, 1983).

[262] DoD, Final Rule, DoD FAR Supplement, 49 F ED. REG. 11302 (Mar. 26, 1984).

[263] DoD *et al.*, Final Rule, Federal Acquisition Regulation, Item IX—Patents, Data, and Copyrights, 49 F ED. REG. 12972, 129744 (Mar. 30, 1984).

[264] DoD, Final Rule, Amendments to DoD FAR Supplement, Item III—227.4, Technical Data, Other Data, Computer Software, Copyrights, 49 F ED. REG. 38549, 38575-86 (Oct. 1, 1984).

Code, setting out specific requirements for rights and restrictions on technical data arising under DoD procurement contracts.[265] Later that same month, the Small Business and Federal Procurement Competition Enhancement Act of 1984 added a similar "rights in technical data" provision to the FAR.[266] After various other legislative and regulatory amendments, the data provisions of the FAR were codified at 48 C.F.R. Part 27, under the authority of 41 U.S.C. § 418a, while those of the DFARS were codified at 48 C.F.R. Part 227.71-72, under the authority of 41 U.S.C. § 2320. Both sets of provisions govern only data arising under procurement contracts. Data generated under grants or cooperative agreements is governed by policies set out in OMB Circular A-110 ("Circular A-110), as discussed below. Because most federally funded university research is done under grants or cooperative agreements, most data arising under federally funded research will be governed by the policies of Circular A-110. However, because some federally funded research at universities may be done under federal procurement contracts, the FAR and DFARS data sections will be reviewed briefly first, before turning to Circular A-110.

a. Treatment of data under the FAR

"Data" is defined as "recorded information, regardless of form or the media on which it may be recorded. The term includes technical data and computer software. The term does not include information incidental to contract administration, such as financial, administrative, cost or pricing, or management information."[267] Data produced under federal contract governed by the FAR is broken down into "Unlimited Rights Data" and "Limited Rights Data."[268] The former is generally allocated to the federal government, while the latter may be retained by the contractor, with some use rights granted to the federal government. The FAR also breaks out a category of "Form, Fit & Function Data."[269] The FAR is structured to allow contractors to retain title and confidentiality to computer programs and source code developed by the contractor unless such programs or code were the subject of the contract itself— *i.e.*, the product to be procured by the federal government under the contract.[270] Provisions for this are included in the data rights section of the FAR because some computer programs and source code are still protected only under trade secret law.

Copyrighted works containing data generated under a federal contract governed by the FAR are also addressed in Part 27.[271] For data first produced in the performance of the contract, the contractor must obtain permission of the funding agency before asserting any copyright to works

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[265] P.L. 98-525, Title XII, § 1216(a), 98 Stat. 2492 (Oct. 19, 1984) (adding §§ 2318-2323 to Title 10 (Armed Forces) of the U.S. Code).

[266] P.L. 98-577, Title III, § 301(a), 98 Stat. 3066 (Oct. 30, 1984) (adding § 418a to Title 41 (Public Contracts) of the U.S. Code).

[267] FAR § 27.401, 48 C.F.R. § 27.401.

[268] "Unlimited Rights Data" is governed by FAR § 27.404-1, 48 C.F.R. § 27.404-1; "Limited Rights Data" is governed by FAR § 27.404-2, 48 C.F.R. § 27.404-2.

[269] FAR § 27.401, 48 C.F.R. § 27.401.

[270] FAR § 27.404-2, 48 C.F.R. § 27.404-2.

[271] FAR § 27.404-3, 48 C.F.R. § 27.404-3.

containing the data. However, scientific or technical articles published in academic, technical or professional journals, symposia proceedings, or similar venues are generally exempt from that requirement so long as they are based on or reporting the data only for those purposes. At the same time, universities may negotiate to use Alternative IV of the FAR Standard Clauses which allows the university and colleges who are operating as the sole contractors for basic or applied research to retain title to any copyrightable works arising under the contract without further request to the funding agency. [272]

b. Treatment of data under the DFARS

There is no general definition of "data" under the DFARS, but rather it defines "technical data" as: "recorded information, regardless of the form or method of the recording, of a scientific or technical nature (including computer software documentation). The term does not include computer software or data incidental to contract administration, such as financial and/or management information." [273] "Form, fit, and function data" is defined as: "technical data that describes the required overall physical, functional, and performance characteristics (along with the qualification requirements, if applicable) of an item, component, or process to the extent necessary to permit identification of physically and functionally interchangeable items." [274] The major distinction in the DFARS technical data policy is as between whether DoD is procuring commercial or noncommercial items. For commercial items, DoD is to acquire only the technical data customarily provided to the public with the commercial item or process, with some limited exceptions.[275] The DFARS provides a standard clause for procurement of technical data in commercial items that grants DoD specific license rights in technical data such that DoD may use, modify, reproduce, release, perform, display, or disclose data only within the federal government.[276] However, the data "may not be used to manufacture additional quantities of the commercial items and except for emergency repair or overhaul, may not be released or disclosed to, or used by, third parties without the contractor's written permission." [277] Universities are least likely to be involved in these sorts of procurement contracts with DoD.

For noncommercial item procurement—a more likely route for university contracting with DoD—the policy is that DoD is to acquire only the technical data, and rights in that data, necessary to satisfy agency needs. [278] Solicitations and contracts for such procurement must

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[272] 48 C.F.R. § 27.404-3(a), 409(b)(5).

[273] 48 C.F.R. § 252.227-7013(a)(14) (definitions for the technical data provisions of DFARS Part 227 are actually set out in DFARS Part 252, Standard Clauses).

[274] *Id.*

[275] 48 C.F.R. § 227.7102-1(a). The exceptions are that the federal government can acquire the following types of technical data even if they are not customarily provided to the public with the item or process: (1) form, fit, or function data; (2) technical data required for repair or maintenance of commercial items or processes, of for the proper installation, operating, or handling of a commercial item, either as a stand alone unit or as part of a military system. *Id.*

[276] 48 C.F.R. § 227.7102-2.

[277] *Id.* These restrictions do not apply to the technical data listed as exceptions in § 227.7102-1(a), as set out in note 275 *supra*.

[278] 48 C.F.R. § 227.7103-1.

specify the technical data to be delivered, procedures for acceptance, and require identification in advance by the contractor of any technical data to be delivered with restrictions on the federal government's rights. The federal government's rights in technical data procured under noncommercial item contracts differ according to whether the DoD exclusively funded the work, the contractor exclusively funded the work, or both DoD and contractor funds were used. [279] Where DoD exclusively funded the work, the federal government will usually obtain "unlimited rights," which are defined as "rights to use, modify, reproduce, perform, display, release, or disclose technical data in whole or in part, in any manner, and for any purpose whatsoever, and to have or authorize others to do so." [280] Where the contractor exclusively funded the work, the federal government will usually obtain "limited rights," which are defined as "rights to use, modify, reproduce, release, perform, display, or disclose technical data, in whole or in part, within the federal government." [281] However, these rights are further limited in that the "Government may not, without the written permission of the party asserting limited rights, release or disclose the technical data outside the Government, use the technical data for manufacture, or authorize the technical data to be used by another party, except that the Government may reproduce, release or disclose such data or authorize the use or reproduction of the data by persons outside the Government if reproduction, release, disclosure, or use is: (i) Necessary for emergency repair and overhaul; or (ii) A release or disclosure of technical data (other than detailed manufacturing or process data) to, or use of such data by, a foreign government that is in the interest of the Government and is required for evaluational or informational purposes; (iii) Subject to a prohibition on the further reproduction, release, disclosure, or use of the technical data; and (iv) The contractor or subcontractor asserting the restriction is notified of such reproduction, release, disclosure, or use." [282] Where both DoD and the contractor provide funding for the work, then the federal government will usually obtain "Government purpose rights," which are defined as rights to: "(i) Use, modify, reproduce, release, perform, display, or disclose technical data within the Government without restriction; and (ii) Release or disclose technical data outside the Government and authorize persons to whom release or disclosure has been made to use, modify, reproduce, release, perform, display, or disclose that data for United States government purposes." [283] Further, DoD procurement contracts for noncommercial items will usually also include a copyright license for any copyrightable aspects of the technical data provided. [284]

2. Ownership and use rules for data arising under federal grants or cooperative agreements

Data arising under federal grants or cooperative agreements to universities is governed by Circular A-110.[285] The university may copyright any work that was developed or purchased

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[279] 48 C.F.R. § 227.7103-5.

[280] 48 C.F.R. § 252.227-7013(a)(15).

[281] 48 C.F.R. § 252.227-7013(a)(13).

[282] *Id.*

[283] 48 C.F.R. § 252.227-7013(a)(12).

[284] 48 C.F.R. § 227.7103-4.

[285] Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education,

using the federal funding.[286] However the funding agency reserves a irrevocable, non-exclusive, royalty free ("NERF") license to reproduce, publish, or otherwise use the work for federal purposes, and to authorize others to do so. The federal government also has the right to: (1) obtain, reproduce, publish or otherwise use the data first produced under an award; and (2) authorize others to receive, reproduce, publish, or otherwise use data arising under the grant or cooperative agreement for federal purposes.[287] Where research findings relying on "research data" were published under a university grant or cooperative agreement, and the funding agency used that data to develop an agency action that has the force and effect of law, then the agency has the right to request such data from the university and release it under a proper request and the procedures of the Freedom of Information Act.[288] Circular A-110 also contains a provision on "Property trust relationship" that governs property—real, personal, and intangible—acquired or improved using federal funds.[289] Any such property must be held in trust by the university as trustee for the beneficiaries of the project or program under which the property was acquired or improved. In 2008, OSTP issued a Final Notice of Standard Terms and Conditions for Research Grants ("Standard Terms") that incorporates the terms of Circular A-110.[290] The Standard Terms are now required for the 10 federal agencies and 98 institutional recipients of research funds who participate in the Federal Demonstration Partnership.

Beyond the regulations in Circular A-110, some federal agencies—primarily NIH—have initiated policies focused on data sharing among the scientific community. Because the sharing of data associated with research findings play an important role in the scientific community, data sharing has long been necessary for scientific experimentation and confirmation of the results of others.[291] The computational analysis of data now drives many fields of science, such as bioinformatics and the empirical environmental sciences.[292] A 1997 National Academies committee report stated that "[g]overnmental science agencies . . . should adopt as a fundamental

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Hospitals, and Other Non-Profit Organizations, 2 C.F.R. Part 215.

[286] 2 C.F.R. § 215.36(a).

[287] 2 C.F.R. § 215.36(c).

[288] 2 C.F.R. § 215.36(d). "Research data" is defined as "the recorded factual material commonly accepted in the scientific community as necessary to validate research findings, but not any of the following: Preliminary analyses, drafts of scientific papers, plans for future research, peer reviews, or communications with colleagues. This 'recorded' material excludes physical objects (*e.g.*, laboratory samples). Research data also do not include: (A) Trade secrets, commercial information, materials necessary to be held confidential by a researcher until they are published, or similar information which is protected under law; and (B) Personnel and medical information and similar information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, such as information that could be used to identify a particular person in a research study." *Id*. "Published" is defined as either when: "(A) Research finding are published in a peer-reviewed scientific or technical journal; or (B) A Federal agency publicly and officially cites the research findings in support of an agency action that has the force and effect of law." *Id.*

[289] 2 C.F.R. § 215.37.

[290] 73 FED. REG. 4563 (Jan. 25, 2008).

[291] *See*, *e.g.*, National Research Council, Sharing Publication-Related Data and Materials: Responsibilities of Authorship in the Life Sciences 17 (2003) [hereinafter Sharing Data & Materials], *available at* http://newton.nap.edu/catalog/10613.html#toc.

[292] National Research Council, Bits of Power: Issues in Global Access to Scientific Data 1-17 (1997).

operating principle the full and open exchange of scientific data. By 'full and open exchange' the committee means that the data and information derived from publicly funded research are made available with as few restrictions as possible, on a nondiscriminatory basis, for no more than the cost of reproduction and distribution." [293]

The Human Genome Project and its follow-on projects exemplify how large funders of public science can drive international collaborative research efforts to create common data resources for widespread use. [294] Beginning in the mid 1990s, both the Wellcome Trust in the U.K. and NIH in the United States supported data-sharing of human genome sequence as it was generated. The Wellcome Trust provided the critical leadership in this regard, sponsoring a meeting of international scientists and funders in 1996 that gave rise to the "Bermuda Principles."[295] These principles state that funded centers generating human genome sequence should make that information freely available in order to encourage its broad use in research, and maximize the benefits to society. [296] The Bermuda Principles also state that primary genomic sequence information should be "released as soon as possible," and that assemblies greater than 1 kilobase should be released on a daily basis. [297] NIH made its commitment to the Bermuda Principles clear in its Request for Proposals for large-scale sequencing centers, using its funding power to receive assurances from grantees that they would act in accordance with the Bermuda Principles.[298] Free access to the genome became a touchstone across the public genomics community, thereby prompting pre-publication disclosure policies and the acceleration of public funding to complete the sequence before private competitors appropriated it as a private resource.[299]

NIH also used its funding power to promote a public consortium on single nucleotide polymorphisms (SNPs). In its 1998 request for grant applications on "Methods for Discovering and Scoring Single Nucleotide Polymorphisms," NIH required applicants responding to the RFA to develop and propose specific plans for sharing the data, materials, and software generated through the grant. Dissemination via individual laboratory web sites would not be sufficient, and NIH expressed a preference for "a common, public database." As an enforcement mechanism,

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[293] *Id.* at 10.

[294] For detailed accounts of how this was accomplished, see Rebecca S. Eisenberg & Richard R. Nelson, *Public vs. Proprietary Science: A Fruitful Tension* , 131 DAEDALUS 89, 94-99 (2002); *see also* Robert Cook-Deegan, *The Science Commons in Health Research: Structure, Function, and Value* , 32 J. TECH. TRANSFER 133, 136-45, 149-52 (2007).

[295] The Human Genome Program of the U.S. Department of Energy Office of Science, Summary of Principles Agreed at the First International Strategy Meeting on Human Genome Sequencing (Bermuda, Feb. 25-28, 1996) [hereinafter Bermuda Principles], *available at* http://www.ornl.gov/sci/techresources/Human_Genome/research/bermuda.shtml#1.

[296] *Id.*

[297] *Id.*

[298] Testimony of Francis S. Collins, Director, National Human Genome Research Institute, at a Hearing on the Human Genome Project before the House Committee on Science, Subcommittee on Energy and the Environment, June 17, 1998, *available at* http://www.hhs.gov/asl/testify/t980617a.html. *See also* Eisenberg & Nelson, *supra* note 294, at 97-98 (stating that "[t]he public sponsors of the Human Genome Project stressed the importance of prompt and unrestricted access to the sequence, which they ensured by requiring grantees to deposit new sequence data in the publicly accessible Genbank database within twenty-four hours").

[299] Eisenberg & Nelson, *supra* note 294, at 96-98.

the RFA explained that the proposed sharing plan, after negotiation with the applicant when necessary, would be made a condition of the award. Evaluation of renewal applications included assessment of the effectiveness of data, material, and software release. [300] The private sector separately determined it was in their common interests to create a shared SNP database, deeming this data pre-competitive, called the "SNP Consortium." [301] The Consortium members decided to make this SNP data freely available to the public. NIH also houses an important SNP database.[302] Sharing within the International Haplotype Map project has also been driven by funder involvement. [303]

In 2003, NIH began to use its funding power to require more active forms of data sharing in all of its program areas. Starting in October 2003, investigators seeking $500,000 or more in NIH grants in any single year were expected to include a plan for data sharing or justify why data sharing was not possible. [304] In guidance for grantees seeking to implement the 2003 NIH data sharing policy, NIH clarified how grantees should treat proprietary data:

> Issues related to proprietary data also can arise when cofunding is provided by the private sector (e.g., the pharmaceutical or biotechnology industries) with corresponding constraints on public disclosure. NIH recognizes the need to protect patentable and other proprietary data. Any restrictions on data sharing due to cofunding arrangements should be discussed in the data-sharing plan section of an application and will be considered by program staff. While NIH understands that an institution's desire to exercise its intellectual property rights may justify a need to delay disclosure of research findings, a delay of 30 to 60 days is generally viewed as a reasonable period for such activity. [305]

Beyond the NIH policy, a 2007 report by the GAO found that DoE, NASA, NOAA, and NSF all had data sharing policies in the area of climate change. [306] DoE has also made data sharing a priority in other fields of research, such as genomics

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[300] National Institutes of Health, RFA: HG-98-001 "Methods for Discovering and Scoring Single Nucleotide Polymorphisms," Release Date: January 9, 1998 *available at* http://grants.nih.gov/grants/guide/rfa-files/RFA-HG-98-001.html.

[301] *See* Oak Ridge National Laboratory, Human Genome Project, SNP Fact Sheet *available at* http://www.ornl.gov/sci/techresources/Human_Genome/faq/snps.shtml#consortium; Cook-Deegan, *supra* note 294, at 151-52. The website for the original SNP Consortium has now been folded into the website for the International HapMap Project *available at* http://snp.cshl.org/.

[302] *See* the database's web portal at http://www.ncbi.nlm.nih.gov/sites/entrez?db=snp.

[303] *See* International HapMap Project website, *available at* <www.hapmap.org/index.html>; *see also* Rebecca S. Eisenberg & Arti K. Rai, *Harnessing and Sharing the Benefits of State-Sponsored Research: Intellectual Property Rights and Data Sharing in California's Stem Cell Initiative* , 21 BERKELEY TECH. L.J. 1187, 1191 (2006) (noting that "[w]ithin genomics, public research sponsors like NIH and the U.K.'s Wellcome Trust have applied normative pressure to achieve widespread data dissemination").

[304] National Institutes of Health (NIH), Final NIH Statement on Sharing Research Data (February 26, 2003), NOT-OD-03-032.

[305] NIH Data Sharing Policy and Implementation Guidance (Updated: March 5, 2003) http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm.

[306] United States Government Accountability Office Report to Congressional Requesters, "Climate Change Research: Agencies Have Data-Sharing Policies but Could Do More to Enhance the Availability of Data from Federally Funded (September 2007).

E. Federal Law and Policy Pertaining to Copyrightable Works Arising in the University Academic Environment

Universities produce an enormous amount of copyrightable works. These works take the form of everything from academic scholarship to teaching materials to promotional brochures and other administrative materials. Two main questions arise pertaining to university copyrightable works. The first is whether and how faculty and other academic researchers keep title to their scholarly works in light of the work made for hire provision of the Copyright Act. [307] The second is whether and how federal agencies can control the allocation and use of copyrighted works arising under funding agreements.

The Copyright Act's "work made for hire" doctrine vests authorship and ownership of employee-created works in the employer. [308] Certain kinds of commissioned works by independent contractors can also be works made for hire if explicitly stated in writing and if conforming to one of nine enumerated independent contractor relationships. [309] The work made for hire rule under the Copyright Act is quite different from the "hired to invent" common law rule that assigns certain inventions to employers: [310] a work made for hire is not an assignment or transfer of the ownership rights of the copyright. Rather it establishes that the employer—even if a corporation or other non-natural legal person—is the true and sole "author" of the work. [311] Accordingly, in a work made for hire situation, the employer need never give credit or attribution to the employee(s) for the work that the latter created. [312]

Although faculty are employees of a university, their works of scholarly authorship have traditionally not been treated by either faculty members or universities as works made for hire. However, there is no statutory basis for this "teacher exception" that would automatically exempt faculty works from the work made for hire doctrine without a separate written agreement disclaiming the works as such by the university. To the extent that a judicial or common law teacher exception existed under the 1909 Copyright Act, it does not appear to have been carried forward into the Copyright Act of 1976, which more clearly defined the term "work made for hire."[313]

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[307] 17 U.S.C. §§ 101, 201.

[308] 17 U.S.C. § 201(b).

[309] *Id.*

[310] *See infra* Part IV.B.3.

[311] This goes back to an earlier conception of works of authorship in which the party who had authorized the work was then the "author." *See, e.g.*, PAMELA O. LONG, OPENNESS, SECRECY, AUTHORSHIP: TECHNICAL ARTS AND THE CULTURE OF KNOWLEDGE FROM ANTIQUITY TO THE RENAISSANCE (Johns Hopkins Univ. Press 2001).

[312] Further, a determination that a work is a work made for hire also cuts off the reversion rights granted to natural authors under which they can take back any rights assigned, licensed, or otherwise transferred to another party beginning in the 35th year of the copyright term, and continuing for five years from that point. 17 U.S.C. § 203. This reversion right cannot be waived by the author, for their own protection. It was introduced in an effort to allow authors and composers to be able to renegotiate onerous deals that they may have signed when they were unknown or inexperienced.

[313] P.L. 94-553, 90 Stat. 2541 (Oct. 19, 1976). Some have argued that the legislative history of the 1976 Act is silent on the point because Congress had no intention of eliminating the teacher exception. *See* Elizabeth Townsend, *Legal and Policy Responses to the Disappearing "Teacher Exception," or Copyright Ownership in the 21st Century*

The case that is often cited for the proposition that such an exception survived— *Weinstein v. University of Illinois*—actually established the opposite.[314] In *Weinstein*, the U.S. Court of Appeals for the Seventh Circuit (Seventh Circuit) noted that the 1976 Act likely eliminated whatever judicial or common law teachers exception existed under the 1909 Act. It then explained that the University of Illinois, like many other academic institutions, instituted a new copyright policy after the 1976 Act changes to preserve the status quo that faculty members' academic writings would not be considered to be works made for hire. The mechanism of this policy response was critical. The 1976 Act made all works created in the scope of employment works made for hire "unless the parties have expressly agreed otherwise in a written instrument signed by them."[315] Full-time faculty members are employees, and when they are required to publish as part of their academic appointment (*e.g.*, for tenure and promotion review), then even their academic scholarly works are likely to be interpreted as works done within the scope of their employment. This may be true even though the works are not done "for" the university, nor are the topics, content, or manner of research/writing dictated or controlled by the university.[316] According to the *Weinstein* court, the University of Illinois therefore instituted its new policy and incorporated it into each professor's contract such that it would serve as the written instrument establishing that the parties had agreed otherwise as to what would constitute works made for hire.

The court then proceeded to parse *this policy* and was not ruling on whether a judicial or common law teacher exception still existed under the 1976 Act itself. While the court made several references to the longstanding tradition of allowing academics to retain copyright to their scholarly works, it did so simply as part of interpreting the policy because the court had determined that the *intention* of the policy was to retain the pre-1976 Act status quo. Overall, the policy disclaimed faculty works as works made for hire, but made three exceptions to this (works falling under these then *would* be deemed works made for hire): (i) works created under the terms of a university agreement with an outside party that required the university to hold or transfer ownership of the work; (ii) works expressly commissioned in writing by the university; and (iii) works created as a specific requirement of employment or as an assigned duty. The

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University, 4 MINN. INTELL. PROP. REV. 209 (2003).

[314] 811 F.2d 1091 (7th Cir. 1987).

[315] 17 U.S.C. § 201(b).

[316] "The [work made for hire] statute is general enough to make every academic article a 'work for hire' and therefore vest exclusive control in universities rather than scholars." 811 F.2d at 1094. The year after *Weinstein* was decided, the Seventh Circuit discussed the teacher exception in dicta in Hays v. Sony Corp., 847 F.2d 412 (7th Cir. 1988). While the court ventured that "we might, if forced to decide the issue, conclude that the exception had survived the enactment of the 1976 Act," it did not decide the matter in this case. Further, the court made it clear in this opinion that it believed that its earlier decision in *Weinstein* was in the camp of those who "widely believed that the 1976 Act abolished the teacher exception." 847 F.2d at 416 (citing *Weinstein*, 811 F.2d at 1093-1094; Dreyfuss, *The Creative Employee and the Copyright Act of 1976* , 54 U. CHI. L. REV. 590, 597-98 (1987); Simon, *Faculty Writings: Are They "Works for Hire" Under the 1976 Copyright Act?* , 9 J. COLLEGE & UNIVERSITY L. 485, 495-99 (1982)). Both the *Weinstein* and *Hays* courts concede that as a matter of strict literal statutory interpretation and based on the requirement that professors publish as part of their academic appointments, faculty academic writings seem to fall within the definition of a work made for hire. The *Weinstein* and *Hays* courts believe this outcome is bad on policy and pragmatic grounds—given the long settled expectations and reliances of the parties—but do not determine a way to avoid the outcome or issue a holding that the teacher exception survived the enactment of the 1976 Act.

University of Illinois argued that the work at issue—an article on a clinical program that the faculty member taught in—fit into category (iii) and therefore was a work made for hire. While the trial court had accepted this argument and held that the article was a work made for hire, the Seventh Circuit overturned this on the grounds that such an interpretation of the policy would allow the exception to swallow the rule. To read the scope of (iii) to mean that academic articles created by faculty members were "specific requirements of employment" because the faculty member was required to publish as part of his general faculty appointment would negate the goal of the policy and leave faculty in the position that the 1976 Act left them in, namely with all of their writings potentially being works made for hire. The court's references to preserving "longstanding practices" were made to underscore the goal of the policy—to preserve the pre-1976 Act status quo by contractually establishing the parameters of what would be designated as works made for hire. Accordingly, the holding of the case was only that the work in question did not fall under category (iii) of the policy, and therefore, *under the main provision of the policy* it was not a work made for hire (because the main provision disclaimed faculty works as works made for hire unless they fit into one of the three exception categories).

Accordingly, there is likely no "teacher exception" to the work made for hire doctrine, which means that *all* works created by regularly employed faculty under any of their three main areas of obligation to the academic institution—teaching, research, and service—are likely to be works made for hire, *unless* there is an express, written agreement between the university and the faculty member establishing a different set of terms for determining when a work is a work made for hire. Many academic institutions have established the requisite written agreement to alter this default and "retain" the pre-1976 Act understanding of a teacher exception. Faculty members at institutions that do not have such a policy incorporated into each faculty member's contract should not assume that their scholarly works will be upheld as their own. Further, a general policy by the university disclaiming such works as works made for hire may be insufficient unless it is also directly contained in the faculty member's appointment letter or other employment agreement. A reference to the policy from the appointment letter or employment agreement may be insufficient for these purposes, as is the mere existence of such policies in a faculty handbook with no mention to the same in the appointment letter or employment agreement.

The case law varies widely as to what other works produced in universities are works made for hire.[317] Regardless of whether a teacher exception still exists, copyrightable works such as software and computer programs that are not traditional academic scholarship but which the faculty member considers to be part of her scholarly work will be deemed works made for hire if they have a commercial nature. [318] College-level faculty may be able to retain title to their class and teaching materials, even if prepared for classes they were hired to teach, on the grounds that either the materials: (i) do not fit within the scope of employment; or (ii) do fit within the scope of employment but there is a written agreement establishing other allocation rules. [319]

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[317] Works created by staff or regular employees that are administrative, promotional, or otherwise non-academic are generally works made for hire. *See, e.g.*, Forasté v. Brown University, 248 F.Supp.2d 71 (D. R.I. 2003); Manning v. Board of Trustees Community College, 109 F.Supp.2d 976 (C.D. Ill. 2000).

[318] *See, e.g.*, Rouse v. Walter & Associates, L.L.C., 513 F.Supp.2d 1041 (S.D. Iowa 2007). This case did not decide whether the teachers exception still existed, because it was decided on the grounds that the commercial nature of the work was dispositive to judge it a clear work made for hire even if such an exception still existed.

[319] *See, e.g.*, Bosch v. Ball-Kell, 2006 WL 2548053, 80 U.S.P.Q.2d 1713 (C.D. Ill. 2006); *but see contra*

The second main copyright issue facing universities is the increased interest on the part of federal agencies to require the free dissemination of copyrightable works arising from federally funded research. Part of this issue is addressed under OMB Circular A-110 as discussed in Part III.D.2. In particular, as the costs of academic journal subscriptions have increased dramatically in the past decade or so, academic publications that contain material describing the outcomes of federally funded research are no longer readily accessible by the general public. Free abstracting and citation services such as that provided by NIH's PubMed had attempted to alleviate this. [320] But in the absence of licenses or rights to articles in proprietary science journals, these services cannot provide free full-text versions of all such articles. NIH issued rules in 2005 requesting all funding recipients to submit to PubMed "an electronic version of the author's final manuscript upon acceptance for publication, resulting from research supported, in whole or in part, with direct costs from NIH."[321] The author's final manuscript is "defined as the final version accepted for journal publication, and includes all modifications from the publishing peer review process." In 2007, the Consolidated Appropriations Act, 2008, made NIH's manuscript submission policy mandatory for FY 2008. [322] In 2009, the Omnibus Appropriations Act, 2009, made the policy mandatory on a permanent basis. [323] Recent Senate proposals would extend these manuscript submission policies to the other large federal agencies funding research. [324]

Vanderhurst v. Colorado Mountain College District, 16 F.Supp.2d 1297 (D. Colo. 1998). Because Bosch v. Ball-Kell was a decision based on a motion for summary judgment, it did not need to resolve the work made for hire question. Thus it did not specify whether a teacher exception still exists for class materials (or otherwise). It also over- interpreted the Seventh Circuit's references to the "longstanding traditions" related to the teacher exception in *Weinstein* and *Hays*. Teachers in grades lower than the college level will generally have their teaching materials deemed works made for hire. *See, e.g.*, Shaul v. Cherry Valley-Springfield Central School District, 363 F.3d 177 (2nd. Cir. 2004). However, evidence that teaching materials were created outside of the scope of employment alters the analysis. Pavlica v. Behr, 397 F.Supp.2d 519 (S.D.N.Y. 2005).

[320] *Available at* http://www.ncbi.nlm.nih.gov/pubmed/.

[321] National Institutes of Health, Final Policy Statement, Policy on Enhancing Public Access to Archived Publications Resulting from NIH-Funded Research, NOT-OD-05-022 (Feb. 3, 2005) *available at* http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-022.html.

[322] P.L. 110-161, Div. G, Title II, § 218, 121 Stat. 1844 (Dec. 29, 2007) (providing that "The Director of the National Institutes of Health shall require that all investigators funded by the NIH submit or have submitted for them to the National Library of Medicine's PubMed Central an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication: Provided, That the NIH shall implement the public access policy in a manner consistent with copyright law.").

[323] P.L.111-8, Div. F, § 217, 123 Stat. 524 (Mar. 11, 2009) (providing that "The Director of the National Institutes of Health ('NIH') shall require in the current fiscal year and thereafter that all investigators funded by the NIH submit or have submitted for them to the National Library of Medicine's PubMed Central an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication: Provided, That the NIH shall implement the public access policy in a manner consistent with copyright law.").

[324] *E.g.*, Federal Research Public Access Act of 2009 (S. 1373), available at <http://thomas.loc.gov/cgi-bin/query/z?c111:S.1373.>, §1. This bill would require major funding agencies to develop policies to make all grantees' published work publicly available. Specifically, it would require: (i) free online access to all peer-reviewed publications stemming from agency funding within six months of publication; and (ii) the online posting of authors' post-acceptance but pre-publication manuscripts, including changes made through the peer-review process. The bill excludes conference presentations, "preliminary data analysis," classified research, and research resulting in

F. Federal Criminal Statutes for Unauthorized Disclosure of Trade Secrets: Rules Governing Federal Employees and the Economic Espionage Act of 1996

While the basic doctrine, creation, and enforcement of trade secrets is situated in state law, [325] there are two federal criminal statutes pertaining to the misappropriation or unauthorized disclosure of trade secrets and other sensitive, confidential information. Chapter 93 of Title 18 (Crimes and Criminal Procedures) of the U.S. Code contains § 1905, which establishes criminal sanctions for the improper disclosure of confidential information. [326] It provides that any officer or employee of the United States, or of any department or agency, who "publishes, divulges, discloses, or makes known in any manner or to any extent not authorized by law any information coming to him in the course of his official duties or by reason of any examination or investigation made by, or return, report or record made to or filed with, such department or agency or officer or employee thereof" such information that "concerns or relates to the trade secrets, processes, operations, style of work, or apparatus, or to the identity, confidential statistical data, amount or source of any income, . . . shall be fined under this title, or imprisoned not more than one year, or both; and shall be removed from office or employment." [327]

Chapter 90 of the same title of the U.S. Code codifies the Economic Espionage Act of 1996 (EEA).[328] It creates federal criminal sanctions for: (i) misappropriation of U.S. citizen/entity trade secrets for the benefit of foreign governments, instrumentalities, or agencies; [329] and (ii) misappropriation of a trade secret that is related to or included in a product intended for interstate or foreign commerce. [330] The EEA defines a trade secret as "all forms and types of financial, business, scientific, technical, economic, or engineering information, including patterns, plans, compilations, program devices, formulas, designs, prototypes, methods, techniques, processes, procedures, programs, or codes, whether tangible or intangible, and whether or how stored, compiled or memorialized physically, electronically, graphically, photographically, or in writing if—(A) the owner thereof has taken reasonable measures to keep such information secret; and (B) the information derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable through proper means by, the public." [331] It also provides that the U.S. Attorney General can seek civil injunctions against the violation of the EEA.[332] By its own terms, the EEA does not preempt or displace any state trade secret

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patentable discoveries. It also excludes authors who do not submit their work for publication. Articles and manuscripts covered by the bill would have to be available in a digital archive that permits free public access, interoperability, and long-term preservation, and agencies would have to submit annual reports of performance with the relevant congressional committees.

[325] *See infra* Part IV.A.

[326] 18 U.S.C. § 1905 (2006).

[327] *Id.*

[328] P.L. 104-294, title I, § 101(a), 110 Stat. 3448 (Oct. 11, 1996) (*codified as amended at* 18 U.S.C. §§ 1831-1839).

[329] 18 U.S.C. § 1831.

[330] 18 U.S.C. § 1832.

[331] 18 U.S.C. § 1839.

[332] 18 U.S.C. § 1836.

laws.[333] It applies to activities outside the United States where: (1) the offender is a natural person who is a citizen or permanent resident alien of the United States, or an organization organized under the laws of the United States or a State or political subdivision thereof; or (2) an act in furtherance of the offense was committed in the United States. [334] Courts imposing sentences under the EEA must order, in addition to any other sentence, that the person forfeit to the United States: "(1) any property constituting, or derived from, any proceeds the person obtained, directly or indirectly, as the result of such violation; and (2) any of the person's property used, or intended to be used, in any manner or part, to commit or facilitate the commission of such violation, if the court in its discretion so determines, taking into consideration the nature, scope, and proportionality of the use of the property in the offense." [335]

G. National Security Export Controls and "Deemed Exports"

The export of goods, services, and data are governed by two separate regulatory systems. The Department of State Directorate of Defense Trade Controls (DDTC) manages defense-oriented items through the International Traffic in Arms Regulations (ITAR), [336] promulgated under the Arms Export Control Act of 1976 (AECA). [337] The DoC Bureau of Industry and Security manages "dual-use" items—those things having both military and commercial uses—through the Export Administration Regulations (EAR), [338] originally promulgated under the lapsed Export Administration Act of 1979, [339] and currently authorized by Executive Order 13222 issued under Executive Branch powers granted by the International Emergency Economic Powers Act. [340]

Under ITAR, much of the research that universities engage in will be exempted from export controls and licensing requirements so long as that research is "fundamental research": "basic and applied research in science and engineering where the resulting information is ordinarily published and shared broadly within the scientific community, as distinguished from research the results of which are restricted for proprietary reasons or specific U.S. Government access and dissemination controls."[341] However, university research will not be considered "fundamental research" if: "(i) The University or its researchers accept other restrictions on publication of scientific and technical information resulting from the project or activity"; or "(ii) The research is funded by the U.S. Government and specific access and dissemination controls protecting information resulting from the research are applicable." [342] If the university research is not considered "fundamental research," then any oral, visual, or documentary transmission of

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[333] 18 U.S.C. § 1838.

[334] 18 U.S.C. § 1837.

[335] 18 U.S.C. § 1834.

[336] 22 C.F.R. §§ 120-130.

[337] P.L. 90-629, 82 Stat. 1320 (Oct. 22, 1968) (*codified as amended at* 22 U.S.C. § 2778 *et seq.*).

[338] 15 C.F.R. §§ 730-774.

[339] P.L. 96-72, 93 Stat. 503 (Sep. 29, 1979).

[340] P.L. 95-223, 91 Stat. 1625 (Dc. 28, 1977) (*codified as amended at* 50 U.S.C. §§ 1701-1707).

[341] 22 C.F.R. § 120.11(a)(8).

[342] 22 C.F.R. §§ 120.11(a)(8)(i)-(ii).

technical data related to it by "U.S. persons" [343] to "foreign persons" [344] will require an export license from the Department of State.

Because of the high volume of foreign persons studying or researching at U.S. universities, there are many situations in which such persons might have access to technical data related to items listed on the U.S. Munitions List. Accordingly, universities will have to (a) determine what technical data in the university relates to items on the U.S. Munitions List, (b) determine whether the information is within the definition of "fundamental research," and (c) determine whether foreign persons will have access to the technical data. Given the substantial amount of federal and private funding that may restrict access and/or publication of university research results, some university research may wind up falling outside of "fundamental research." In these cases, the university will either need to restrict access to such research results for foreign persons or secure export licenses for the results from the Department of State (and possibly need to secure clearance to do so from the funding source). Further, transmission of such technical data as part of a technology transfer deal with an outside licensee that is a foreign person (in the broad sense of a "legal person" that includes partnerships, corporations, etc.) may also require an export license, unless the data falls within the fundamental research definition.

There is also a set of exemptions for export license requirements under ITAR for institutes of higher education. Under the first, accredited U.S. institutions of higher education are permitted, without a license, to permanently export, and temporarily export and return to the United States, articles fabricated only for fundamental research purposes otherwise controlled by Category XV (a) or (e) in 22 C.F.R. § 121.1 when all of the following conditions are met:

> (i) The export is to an accredited institution of higher learning, a governmental research center or an established government funded private research center located within countries of the North Atlantic Treaty Organization (NATO) or countries which have been designated in accordance with section 517 of the Foreign Assistance Act of 1961 as a major non-NATO ally (and as defined further in section 644(q) of that Act) for purposes of that Act and the Arms Export Control Act, or countries that are members of the European Space Agency or the European Union and involves exclusively nationals of such countries;
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> (ii) All of the information about the article(s), including its design, and all of the resulting information obtained through fundamental research involving the article will be published and shared broadly within the scientific community, and

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[343] *U.S. person* means a person (as defined in § 120.14 of this part) who is a lawful permanent resident as defined by 8 U.S.C. 1101(a)(20) or who is a protected individual as defined by 8 U.S.C. 1324b(a)(3). It also means any corporation, business association, partnership, society, trust, or any other entity, organization or group that is incorporated to do business in the United States. It also includes any governmental (federal, state or local) entity. It does not include any foreign person as defined in § 120.16 of this part." 22 C.F.R. § 120.15.

[344] "Foreign person means any natural person who is not a lawful permanent resident as defined by 8 U.S.C. 1101(a)(20) or who is not a protected individual as defined by 8 U.S.C. 1324b(a)(3). It also means any foreign corporation, business association, partnership, any natural person who is not a lawful permanent resident as defined by 8 U.S.C. 1101(a)(20) or who is not a protected individual as defined by 8 U.S.C. 1324b(a)(3). It also means any foreign corporation, business association, partnership, trust, society or any other entity or group that is not incorporated or organized to do business in the United States, as well as international organizations, foreign governments and any agency or subdivision of foreign governments (e.g., diplomatic missions)." 22 C.F.R. § 120.16.

> is not restricted for proprietary reasons or specific U.S. government access and dissemination controls or other restrictions accepted by the institution or its researchers on publication of scientific and technical information resulting from the project or activity . . .; and
>
> (iii) If the article(s) is for permanent export, the platform or system in which the article(s) may be incorporated must be a satellite covered by [22 C.F.R. § 125.4(d)(1)(iii)] and be exclusively concerned with fundamental research and only be launched into space from countries and by nationals of countries identified in this section.[345]

Under the second exemption, defense services for the items identified in the first exemption that are exported by accredited U.S. institutions of higher learning are exempt from the ITAR licensing requirements when the export is:

> (i) To countries identified in [22 C.F.R. § 123.16(b)(10)(i)] and exclusively to nationals of such countries when engaged in international fundamental research conducted under the aegis of an accredited U.S. institution of higher learning; and
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> (ii) In direct support of fundamental research as defined in [22 C.F.R. § 120.11(8)] being conducted either at accredited U.S. institutions of higher learning or an accredited institution of higher learning, a governmental research center or an established government funded private research center located within the countries identified in [22 C.F.R. § 123.16(b)(10)(i)]; and
>
> (iii) Limited to discussions on assembly of any article described in [22 C.F.R. § 123.16(b)(10)] and/or integrating any such article into a scientific, research, or experimental satellite.[346]

However, the foregoing does not cover: (i) Any level of defense service or information involving launch activities including the integration of the satellite or spacecraft to the launch vehicle; (ii) Articles and information listed in the Missile Technology Control Regime (MTCR) Annex or classified as significant military equipment; or (iii) The transfer of or access to technical data, information, or software that is otherwise controlled by the ITAR rules. subchapter.[347]

The EAR operates similar to ITAR in that "fundamental research" is exempted from licensing requirements. However, the definition of "fundamental research" varies a bit in the details from that used in ITAR. The rough idea is the same—"fundamental research" means "basic and applied research in science and engineering, where the resulting information is ordinarily published and shared broadly within the scientific community." [348] Such research is to be distinguished from "proprietary research and from industrial development, design, production, and product utilization, the results of which ordinarily are restricted for proprietary reasons or

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[345] 22 C.F.R. § 123.16(b)(10).

[346] 22 C.F.R. § 125.4(d)(1).

[347] 22 C.F.R. § 125.4(d)(2).

[348] 15 C.F.R. § 734.8(a).

specific national security reasons as defined in §734.11(b) of this part." [349] However, the express provisions for what university based activities will still come within the ambit of "fundamental research" despite some commercially oriented restrictions is broader than that for ITAR. [350] In particular, the following will not in and of themselves take research activities outside of "fundamental research": (x) prepublication review rights for funders to determine that proprietary information they may have given the university researchers is not being improperly disclosed; and (y) prepublications review rights by the funder solely to determine that a publication will not compromise patent rights, so long as the review causes no more than a temporary delay in publication. [351] However, the transfer of otherwise controlled information by a funder to the university does not exempt that transfer from licensing requirements just because it will be used for fundamental research at the university, so long as the information will be prohibited from further transmission or publication under the transfer agreement. [352] Similarly, if the university researchers accept other restrictions or limitations on their rights to publish scientific or technical information resulting from the funded research, whether this is from industry or federal government funders, then the research will not be considered "fundamental research" until or unless any such restrictions expire or are lifted. [353] Any release of technology or source code subject to the EAR to a "foreign national" [354] will be considered a "deemed export" because the release is deemed to be an export to the home country or countries of the foreign national.[355] "Release" of technology or source code is defined as: "(i) Visual inspection by foreign nationals of U.S.-origin equipment and facilities; (ii) Oral exchanges of information in the United States or abroad; or (iii) The application to situations abroad of personal knowledge or technical experience acquired in the United States." [356] Educational information is not subject to the EAR if it is released by instruction in catalog courses and associated teaching laboratories of academic institutions.[357]

The ITAR and EAR regulatory systems have become highly relevant to U.S. university campuses.[358] DoD recently issued further clarifying guidance on its intention to minimize the risks that fundamental research funding awards to universities might result in restricted or classified results.[359] At the same time, agency guidance and university experience and protocols

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[349] *Id.*

[350] 15 C.F.R. § 734.8(b).

[351] 15 C.F.R. §§ 734.8(b)(2)-(3).

[352] 15 C.F.R. §§ 734.8(b)(4).

[353] 15 C.F.R. §§ 734.8(b)(5)-(6).

[354] "Foreign national" does not include persons lawfully admitted for permanent residence in the United States or persons who are protected individuals under the Immigration and Naturalization Act (8 U.S.C. 1324b(a)(3)). 15 C.F.R. § 734.2(b)(2)(ii).

[355] *Id.*

[356] 15 C.F.R. § 734.3.

[357] 15 C.F.R. § 734.9.

[358] *See, e.g.*, GAO, Export Controls: Agencies Should Assess Vulnerabilities and Improve Guidance for Protecting Export-Controlled Information at Universities (GAO-07-70, Dec. 2006).

[359] DoD, The Office of the Under Secretary of Defense, Memorandum for Secretaries of the Military Departments: Fundamental Research (May 24, 2010).

with regards to this highly sensitive area for both academic freedom and national security are still underdeveloped and many traps for the unwary exist. For purposes of this report, the issues arising for university research under ITAR and EAR directly impact universities' abilities to: in-license IP, data, materials, and source code; allow foreign nationals to work on certain research projects; and out-license IP, data, materials, and source code to foreign firms, including possibly U.S. entities controlled or owned by foreign firms. This section provides only the briefest outline of these highly complicated areas of regulatory law. Further attention to this developing area for university IP and technology transfer is warranted.

H. Federal Policy Pertaining to the Transfer of Biological Materials

There is no direct federal law pertaining to the transfer of biological materials. Indirectly, prohibitions on the commercial sale of human tissues and organs provides some limitations on the way in which such materials could be transferred among researchers. Accordingly, much of the transfer of biological materials is taken care of through private contracting, as discussed below in Parts V.B.3 and V.C. However, NIH has established a voluntary policy for transfers as described below.

In the life sciences, the transfer of biological materials among researchers—including those in universities—has relied on a "lease-license" model in which title to the materials is often withheld by the provider so that it can limit third party access and potential liability, as well as control downstream IP, through a Material Transfer Agreement or MTA. [360] Materials that may often be potential biohazards if not handled properly need to be controlled as to subsequent downstream distribution. But, in part because of the heightened risk associated with potential third party liability for biohazard materials, the negotiation of MTAs has become a difficult and time-consuming process, many times ending with no deal and thus no materials for the prospective recipient researcher. [361] While this may just be a reality that the parties have to live with, a number of researchers and institutions in the field believe that the real obstacle lies in the lack of a standard form of MTA. [362] In other industries that use the lease-license distribution model, standard forms—such as end-user license agreements in software—have emerged from the parties themselves. This had not happened in the life sciences, and so NIH, in conjunction with the Association of University Technology Managers (AUTM) and representatives of universities, law firms, and industry, launched an initiative to create a uniform biological MTA (the UBMTA) in the 1990s. [363]

The final model UBMTA, issued in 1995, consists of a Master Agreement to be adopted by

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[360] *See* Sean M. O'Connor, *The Use of MTAs to Control Commercialization of Stem Cell Diagnostics & Therapeutics*, 21 Berkeley Technology Law Journal 1017 (2006).

[361] *See* John P. Walsh, Charlene Cho, Wesley M. Cohen, *View From the Bench: Patents and Material Transfers* , 309 SCIENCE 2002 (23 September 2005); John P. Walsh, Charlene Cho, Wesley M. Cohen, *Roadblocks to Accessing Biomedical Research Tools* (presentation at CSIC/OECD/OEPM Conference, "Research Use of Patented Inventions" Madrid, Spain, 18-19 May 2006) *available at* http://www.oecd.org/dataoecd/40/12/36816897.pdf.

[362] *See* Department of Health and Human Services, Uniform Biological Material Transfer Agreement: Discussion of Public Comments Received; Publication of the Final Format of the Agreement, 60 F.R. 12771, 12771 (March 8, 1995) (citing 2 THE NEW BIOLOGIST 495-497 (June 1990); 248 S CIENCE 952-957 (May 25, 1990)).

[363] *See* Department of Health and Human Services, Uniform Biological Material Transfer Agreement: Discussion of Public Comments Received; Publication of the Final Format of the Agreement, 60 F ED. REG. 12771 (Mar. 8, 1995).

institutions who voluntarily became signatories to the UBMTA initiative, and a shorter Implementing Letter form to be used by and between signatory institutions to record specific biological material transfers.[364] However, while 286 research institutions have signed onto the UBMTA initiative to date,[365] it does not seem to have had the broad streamlining effect on biological material transfers in the research community that was intended. Part of this may be because the initiative expressly did not cover for-profit organizations that might "choose to adopt this agreement as well" but were not part of the Public Health Service's (PHS) final recommendations as to target signatories/users.[366] But even in the recommended target signatory audience of public and nonprofit organizations, becoming a signatory to the Master UBMTA Agreement was neither required by PHS, nor a condition of further PHS funding.[367] Further, even among signatories, the UBMTA "would not be mandatory" so that organizations could "retain the option to handle specific material with unusual commercial or research value on a customized basis."[368]

I. OMB Rules Regarding Use and Accounting of Federal Funds by Universities

Outside of the particulars of Bayh Dole and other federal laws and policies governing allocation and use of IP, data, and materials arising under federal funding, the Office of Management and Budget (OMB) has promulgated a set of rules governing the use and accounting of federal funds themselves. OMB Circular A-21, "Cost Principles for Educational Institutions," contains a range of rules governing how universities can use Federal funds for direct and indirect costs.[369] For purposes of this report, the relevant sections of OMB A-21 are provisions in the Appendix to Part 220 for IP costs, both for procuring IP protection and for in-licensing costs. Section 34, "Patent Costs," of the Appendix provides that the following costs are allowed to be charged to the federal funding provided under a grant or cooperative agreement: (1) costs of preparing disclosures, reports, and other documents required by the funding agreement and of searching the art to the extent necessary to make such disclosures; (2) the costs of preparing, filing, and prosecuting U.S. patent applications where either the federal government is taking title or the Government License is mandated; and (3) general counseling services relating to patent and copyright matters, such as advice on patent and copyright laws, regulations, clauses, and employee agreements (but as subject to other sections of the Appendix governing the use of federal funds for professional service costs, and royalties and other costs for use of patents). However, similar costs arising from IP procurement activities not mandated under the funding agreements are generally unallowable. Specifically, the following are not allowed: (a) the costs of preparing disclosures, reports, and other documents and of searching the art to the extent necessary to make disclosures *not* required by the award; and (b) the costs in connection with

[364] *Id.* Both documents are available at http://www.autm.net/aboutTT/aboutTT_umbta.cfm.

[365] *See* AUTM, Resources: Signatories to the March 8, 1995 Master UBMTA Agreement, *available at* http://www.autm.net/aboutTT/aboutTT_umbtaSigs.cfm.

[366] Department of Health and Human Services, Uniform Biological Material Transfer Agreement: Discussion of Public Comments Received; Publication of the Final Format of the Agreement, 60 F ED. REG. 12771 (Mar. 8, 1995).

[367] *Id.* at 12771-72

[368] *Id.* at 12772.

[369] 2 C.F.R. Parts 215, 220.

filing and prosecuting any *foreign* patent application, or any U.S. patent application where the funding agreement award does *not* require conveyance of title to the federal government or the Government License (but again as subject to the section of the Appendix governing use of federal funds for royalties and other costs for use of patents).

Section 44 of the Appendix, "Royalties and other costs for use of patents," provides the general rule that royalties on a patent or copyright, or amortization of the cost of purchasing a copyright, patent, or rights thereto, that are necessary for the university's performance under the funding agreement are allowed to be taken from the federal funds awarded. However, there are four exceptions to this general rule. Such costs are *not* allowable if: (i) the federal government has a license or the right to free use of the patent or copyright (such as under a Government License arising from a prior funding agreement with another institution); (ii) the patent or copyright has been adjudicated to be invalid, or has been administratively determined to be invalid; (iii) the patent or copyright is considered to be unenforceable; or (iv) the patent or copyright is expired. This non-allowance of costs for royalty payments on patents that the federal government already has a license to underscores the need for federal agencies to specifically grant authorization and consent for university funding recipients to act on the federal government's behalf at least with regard to practicing patents that the federal government has a Government License to under prior funding agreements with other institutions (see Part III.B.3.c(ii) above). Section 44 also cautions universities that want to allocate costs to federal funding awards for payments of royalties, or purchases of title or rights, for patents or copyrights when "less-than-arm's-length bargaining" has occurred, including in any of the following circumstances: (x) royalties are to be paid to persons, including corporations, affiliated with the institution; (y) royalties are to be paid to unaffiliated parties, including corporations, under an agreement entered into in contemplation that a sponsored agreement award would then be made; (z) royalties are to be paid under an agreement entered into after a federal funding award is made to the university. Finally, in any case involving a patent or copyright formerly owned by the university, the amount of royalty allowed should not exceed the cost which would have been allowed had the university retained title thereto.

J. Government Use Statute – 28 U.S.C. § 1498

A number of countries have a "Crown Right" doctrine by which the government is free to practice, or have practiced on its behalf, patented inventions owned by its subjects. [370] In most of these countries, compensation must be paid to the patent owner. Thus, such rights are different from most uses of the term "compulsory license," which usually denotes a power by the sovereign to grant other commercial parties the right to practice the patent owner's claimed inventions in competition with the patent owner. The Government Use Statute in the United States (codified at 28 U.S.C. § 1498) is a kind of Crown Right, and not a compulsory license, because it only authorizes the federal government to practice the invention, or have the invention practiced on its behalf, for government purposes. Thus, any use of the Government Use Statute can only result in goods or services delivered to the public by, or directly on behalf of, the federal government. March-In Rights under Bayh-Dole are closer to the customary definition of compulsory licenses.

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[370] *See supra* Part II.A.

The Government Use Statute is essentially an *exemption* from normal liability for patent infringement, rather than an *exception* to patent infringement, in that it redirects the normal channel of patent infringement actions from federal district courts to the Court of Federal Claims. The actions are still considered to be infringements, but the patent owner's remedies are limited to those provided by the statute and in only one venue. [371] Most critically, the patent owner may not seek injunctive relief against either the federal government or its contractors. However, whereas patent owners are always restricted to sue the federal government in the Court of Federal Claims, they can bring an initial standard patent infringement suit against contractors in federal district courts (so long as they are not making any claims against the contractor under the Government Use Statute). [372] The contractors then must raise the Government Use Statute as an affirmative defense. [373] Such an affirmative defense can be the grounds for dismissal on a proper motion, but this is distinct from dismissal for lack of subject matter jurisdiction, which is not authorized by the statute. The patent owner must then bring the claim to the Court of Federal Claims and direct it against the federal government for compensation. The key to successful use of the Government Use Statute defense is that the contractor must show clear "authorization and consent" language in its agreement with the federal government. [374] The standard clause for this language is set out in the FAR in the same section as the Standard Patent Rights Clauses for federal funding and contract agreements. [375]

While the origins and applications of the Government Use Statute were oriented primarily towards manufacture of military hardware, the statute has been invoked as a kind of research use exemption by federally funded university and non-profit researchers. In *McMullen Associates, Inc. v. State Board Of Higher Education* the United States District Court for the District of Oregon considered the requirements for a basic science research grant in oceanography to Oregon State University (OSU) to qualify as work "for" the federal government under the Government Use Statute. [376] The plaintiff patent owner contended that the Government Use Statute applied only in true federal procurement contract situations where the contractor was supplying the federal government with specific goods and services. The court reviewed the Supreme Court's holding on an earlier version of the Government Use Statute and concluded that the purpose of the statute was to encourage private entities to "manufacture crucial products and to perform vital services" for the federal government by shifting the risk and burden of patent infringement to the federal government. [377] In light of this purpose, the court found that basic research in oceanography has been recognized by the legislative and executive branches as

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[371] Of particular note, the Government Use Statute does not provide for increased damages for willful infringement—which the activities almost certainly will be where the government has given authorization and consent to a contractor for the activities.

[372] If the patent owner pleads for a remedy against the contractor on the basis of the compensatory remedies of the Government Use Statute, the suit should be immediately dismissed as improperly brought before the district court.

[373] *See* Madey v. Duke University, 307 F.3d 1351, 1359 (Fed. Cir. 2002) (citing Sperry Gyroscope Co. v. Arma Engineering Co., 271 U.S. 232 (1926); Crater Corp. v. Lucent Technologies, 255 F.3d 1361 (Fed. Cir. 2001); Manville Sales Corp. v. Paramount Systems, Inc ., 917 F.2d 544 (Fed. Cir. 1990)).

[374] 28 U.S.C. § 1498.

[375] FAR § 52.227-1, 48 C.F.R. § 52.227-1.

[376] 268 F.Supp. 735 (D. Oregon 1969).

[377] 268 F.Supp. at 738.

serving vital interests of the federal government. At issue also was the grant of a ship to OSU, to be refitted and used only for the federal grant purposes, with the ship reverting to the federal government is not so used. Thus, the court further held that "where the Government finances the manufacture of a device and grants it to a private agency with the stipulation that it can only be used for specified purposes, and such use advances recognized vital interest of the U.S. government, the conclusion is inescapable that such manufacture and use were 'for' the U.S. Government."[378]

The U.S. Court of Appeals for the Ninth Circuit ("Ninth Circuit") upheld the District Court's decision.[379] However, the Ninth Circuit specifically stated that its affirmation did not include the District Court's statement that "an interpretation of section 1498 which includes all research grants is 'required.'"[380] Instead, the Ninth Circuit limited its holding to the facts where the patented articles were used in work of "vital importance of the government," the grant was "a financing device for work of special interest to the United States Navy," and the devices were used "only for research approved and financed by the government." [381]

Following *McMullen*, Duke University also invoked the Government Use Statute as one of its defenses in *Madey v. Duke* (discussed above for its holdings on the Government License and research use exceptions).[382] After Dr. Madey arrived at Duke, the university received a federal research grant from the Office of Naval Research (ONR). Later, Madey left Duke and sued it for patent infringement based on a patent he owned that was being practiced as part of the ONR and other research at Duke. In the subsequent lawsuit, Duke claimed that part of its infringing use was within the scope of the ONR grant, and thus covered under the Government Use Statute as an activity performed on behalf of the United States. While the trial court partially dismissed the case on these grounds, the Federal Circuit reversed this decision on appeal because the trial court: i) treated the Government Use Statute issue as jurisdictional; and ii) did not engage in proper fact finding to discover what portion of Duke's uses could be considered as performed under the ONR grant and whether there was evidence of authorization and consent of ONR for the infringement.[383] Madey argued that a federal research grant could not be a procurement contract for purposes of the Government Use Statute. However, the Federal Circuit disagreed with any categorical exclusion of research grants from the scope of "contracts" for purposes of the Government Use Statute defense. In particular, the court acknowledged that research grants can take the form of contracts and that these could be covered by the Government Use Statute. [384] On remand, the district court found that many of Duke's activities with Madey's patents were indeed being performed on behalf, and with the authorization and consent, of the federal government. [385]

In some cases where the federal government has exercised its rights under the Government

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[378] 268 F.Supp at 739.

[379] John J. McMullen Associates, Inc. v. State Board Of Higher Education, 406 F.2d 497 (9 th Cir. 1969), *cert. denied* June 9, 1969.

[380] 406 F.2d at 498.

[381] *Id.*

[382] *See supra* Parts III.B.3.c(ii) and III.C.6.a, respectively.

[383] Madey v. Duke, 307 F.3d 1351, 1358-59 (Fed. Cir. 2002).

[384] 307 F.3d at 1359.

[385] Madey v. Duke, 413 F.Supp.2d 601, 616-21 (M.D.N.C. 2006).

Use Statute, the private IP owner has asserted claims in litigation that such unauthorized use is a "taking" under the Fifth Amendment to the U.S. Constitution. However, the Federal Circuit has ruled that federal government use of privately owned IP under the Government Use Statute does not constitute a "taking" nor is it amenable to claims based on the Tucker Act. [386]

K. IP and Technology Transfer Issues Arising From Universities' Federal Tax Exempt Status and Bonds

Private and public nonprofit universities that have obtained tax exempt status under Internal Revenue Code (IRC) section 501(c)(3) are generally exempt from federal tax, but they may be subject to unrelated business income tax (UBIT) and must comply with a set of other requirements for preserving tax-exempt status. The IRC rules for these kinds of tax-exempt organizations legally constrain two sets of activities at universities that are relevant for this report: (a) accepting money for sponsored research; and (b) licensing inventions. A third, claiming equity stakes in companies spun out of technology transfer offices, is also important but is not treated in detail here. These activities need to be analyzed in relation to three sets of tax rules: (i) rules governing the ability of organizations to claim and maintain tax-exempt status; (ii) rules governing the issue of tax-exempt bonds for the construction of research facilities; and (iii) rules governing the taxation of UBIT.

There are signs that the Internal Revenue Service (IRS) may be trying to tighten up the constraints placed on universities regarding these tax rules. On October 1, 2008, the IRS announced it would send "compliance questionnaires" to "approximately four hundred U.S. colleges and universities" as part of the agency's "focused effort to study key areas in the tax-exempt community." [387] Among other things, the questionnaire sought to gather information from the schools about how they report revenues and expenses from their trade or business activities, classify their activities as exempt or taxable activities, and calculate and report income or losses on taxable activities. The questionnaire also sought to gather information regarding how the organization invests and uses its endowment funds and determines compensation of certain highly paid individuals.

1. Issues Regarding Tax-Exempt Status of Universities

Revenues received by universities for their patent licensing practices or sponsored research activities are unlikely to jeopardize the tax-exempt status of universities so long as these institutions are organized and operated for an "educational purpose" and/or "for the purpose of carrying on scientific research in the public interest." [388] Under IRC § 501(c)(3), entities "organized and operated exclusively for religious, charitable, scientific, testing for public safety,

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[386] Zoltek Corp. v. U.S., 442 F.3d 1345 (Fed. Cir. 2006).

[387] IRS Sends Compliance Questionnaires to 400 Colleges and Universities, IR-2008-112, Oct. 1, 2008, *available at* http://www.irs.gov/irs/article/0,,id=187328,00.html.

[388] IRS Reg. §§ 1.501(c)(3)-1(d)(5)(v), 26 C.F.R. §§ 1.501(c)(3)-1(d)(5)(v): "The fact that any organization (including a college, university, or hospital) carries on research which is not in furtherance of an exempt purpose described in section 501(c)(3) will not preclude such organization from meeting the requirements of section 501(c)(3) so long as the organization meets the organizational test and is not operated for the primary purpose of carrying on such research."

literary or educational purposes" can qualify as tax-exempt institutions. In general, an organization can claim tax exemption only it "it engages primarily in activities which accomplish one or more of such exempt purposes." [389] Various regulations promulgated by the IRS provide the official rules interpreting this language and detailing requirements for organizations claiming any of these purposes (the "IRS Regulations"). The rules define "educational purpose" broadly, and include colleges or universities that have "regularly scheduled curriculum, a regular faculty, and a regularly enrolled body of students in attendance at a place where the educational activities are regularly carried on." [390] This section is not intended to be an exhaustive account of the IRS regulations and rulings in this area. Rather, it sets out the general framework that governs the relevant law and policy.

Most universities define their tax exempt purpose as "scientific" as well as "educational" in order to be able to characterize income related to scientific research as tax exempt under the IRC. Therefore, such universities must qualify as organizations that "engage primarily in activities which accomplish" scientific purposes. The IRC does not explicitly state what "scientific" means in regard to tax-exempt activities, or define what sorts of research activities are related to scientific purposes. Therefore, the IRS Regulations are the principal authority for resolving questions of whether: (i) an organization can claim exemption as a scientific organization; and (ii) particular research activities qualify as being "related" to exempt purposes for purposes of UBIT. IRS Regulations define "scientific" for purposes of tax-exemption under § 501(c)(3) as the "carrying on of scientific research in the public interest." [391] Thus, so long as the organization is operated with the *primary purpose* of conducting scientific research in the public interest, then it can preserve its status as a tax exempt organization. [392]

Scientific research

Because "scientific" is not defined with precision in the regulations, courts have taken recourse to dictionary definitions. In *IIT Research Institute v. United States* , the Court of Claims considered the issue of whether IIT Research Institute could claim that revenues related to research contracts were "substantially related" to the scientific purpose claimed by the organization.[393] The court defined research as "scientific" if it: (1) involved the use of observation or experimentation to formulate or verify facts or natural laws; (2) could only have been performed by an individual with advanced scientific or technical expertise; (3) added to knowledge within a particular scientific field; (4) involved the application of mathematical reasoning; or, (5) was an attempt to systematize or classify a body of scientific knowledge by

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[389] IRS Reg. §§ 1.501(c)(3)-1(c), 26 C.F.R. §§ 1.501(c)(3)-1(c). This is the so-called "operational test."

[390] IRS Reg. §§ 1.501(c)(3)-1(d)(3)(ii), 26 C.F.R. §§ 1.501(c)(3)-1(d)(3)(ii).

[391] IRS Reg. §§ 1.501(c)(3)-1(d)(5)(i)-(iii), 26 C.F.R. §§ 1.501(c)(3)-1(d)(5)(i)-(iii) (ratified by IRS Revised Rules 76-296).

[392] IRS Reg. §§ 1.501(c)(3)-1(d)(5)(v), 26 C.F.R. §§ 1.501(c)(3)-1(d)(5)(v): "The fact that any organization (including a college, university, or hospital) carries on research which is not in furtherance of an exempt purpose described in section 501(c)(3) will not preclude such organization from meeting the requirements of section 501(c)(3) so long as the organization meets the organizational test and is not operated for the primary purpose of carrying on such research."

[393] 9 Cl. Ct. 13 (1985).

collecting information and presenting it in a useful form. [394]

The IRS has advised that given the range of acceptable definitions of the terms "scientific" and "research," the application of these terms in specific cases can also be determined in a negative way. Thus, the IRS Regulations set out activities that clearly fall *outside* of the meaning of "scientific research": "Scientific research does include activities of a type ordinarily carried on as an incident to commercial or industrial operations, as, for example, the ordinary testing or inspection of materials or products or the designing or construction of equipment, buildings, etc."[395] Universities bear the burden of proving that an activity constitutes "scientific research," but further clarification of what constitutes "scientific research" remains fairly ambiguous from various IRS "private letter" rulings.

Carried on in the public interest

Research that qualifies as scientific may still fall outside of the "carried on in the public interest" requirement. Under IRS Regulations, scientific research is deemed to meet the public interest requirement under any of the following situations:

a) the results of the research, including intellectual property, are made public on a non-discriminatory basis;
b) the research is performed for the United States, its agencies, or any State or political subdivision thereof; or
c) the research is directed to benefiting the public. [396]

The regulation then provides four examples under which scientific research "benefits the public" (the "(iii)(c) Rules"). Scientific research benefits the public when it is carried on for the purpose of:

(1) aiding in the scientific education of college or university students;
(2) obtaining scientific information which is published in a form available to the interested public;
(3) discovering a cure for a disease; and/or
(4) aiding community economic development by attracting or retaining industry in the community.

IRS Revised Rule 76-296 was published to provide an example of how problems involving commercially sponsored scientific research projects should be treated under these provisions. [397] In a later text, the IRS provided two illustrative scenarios. In the first, an exempt scientific research organization engaged in commercially sponsored scientific research projects would satisfy the (iii)(c) Rules where it informed the public of the research results by timely publication

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[394] 9 Cl. Ct. at 21. See also, Peter D. Blumberg, *From "Publish or Perish" To "Profit or Perish": Revenues from Technology Transfer and the § 501(c)(3) Tax Exemption* , 145 U. PA. L. REV. 89, 115 (1996).

[395] IRS Reg. §§ 1.501(c)(3)-1(d)(5)(ii), 26 C.F.R. §§ 1.501(c)(3)-1(d)(5)(ii).

[396] IRS Reg. §§ 1.501(c)(3)-d(5)(iii), 26 C.F.R. §§ 1.501(c)(3)-d(5)(iii).

[397] Rev. Rul. 76-296, 1976-2 C.B. 142.

of its findings, even if there were a reasonable delay so that the sponsor could establish its IP rights arising from the research. In the second scenario, a similarly situated exempt scientific research organization would be found to have not satisfied the (iii)(c) Rules where it kept secret or unreasonably delayed publishing the results of the project in order to serve some private interest of the commercial sponsor. The consequence would be that the second organization would then have all of the income it received from the project subject to UBIT. [398] Revised Rule 76-296 also suggests that a commercial sponsor of research qualifying as "scientific" under the rules may retain all rights associated with that research without destroying the exempt quality of the research so long as the publication requirement is met.

Many issues are still unclear with regard to what types of corporate sponsored research qualify both as "scientific" and also "carried on in the public interest." In *Midwest Research Institute v. U.S*,[399] Midwest Research Institute had engaged in a variety of corporate sponsored research activities and challenged the IRS decision to tax income from some of these activities. The court concluded that most of the activities were scientific research as distinguished from ordinary testing and that research was "carried on in the public interest." [400]

Exclusive licensing and tax exempt status

The IRS Regulations also state that "an organization will not be regarded as organized and operated for the purpose of carrying on scientific research in the public interest and, consequently, will not qualify under section 501(c)(3) as a scientific organization, if an organization (1) retains (directly or indirectly) the ownership or control of more than an insubstantial portion of the patents, copyrights, processes, or formulae resulting from its research and (2) does not make such intellectual property available to the public." [401] "Available to the public" is satisfied if the IP is offered to the public on a nondiscriminatory basis or in the form of an exclusive license only when such a license is the "only practicable manner" in which the IP can be utilized to benefit the public. In such cases, the IRS Regulations also make it clear that the research from which exclusive licenses are granted will be deemed to "benefit the public" (and thus be research in the public interest) if it is performed for the federal government and its agencies or if it qualifies under the "benefiting the public test" listed above. [402]

In theory, routine exclusive licensing practices could put the tax exempt status of a "scientific organization" in jeopardy if it seems that some or all of the exclusive licenses were not the "only practicable manner in which the IP can be utilized for the benefit the public" and if the organization is operated with the primary purpose of carrying on such research. The IRS Regulations do not explain what amount of unjustified exclusive licensing would qualify as not making the IP available to the public under the licensing test described above. Neither do they explain how the judgment regarding "only practicable manner" is to be made. Further, no

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[398] Quoted from IRS, CPE Text on "Scientific Research Under IRC 501(c)(3)" (1986).

[399] 554 F. Supp. 1379 (W.D. Mo. 1983), aff'd 744 F.2d 635 (8th Cir. 1984).

[400] *Id.* The IRS has taken issue with this decision however. *See* Internal Revenue Service, CPE Text on Exempt Organizations, "Scientific Research Under IRC 501(c)(3)" (1986).

[401] 26 C.F.R. §§ 1.501(c)(3)-1(d)(5)(iv).

[402] IRS Reg. §§ 1.501(c)(3)-1(d)(5)(iv)(b), 26 C.F.R. §§ 1.501(c)(3)-1(d)(5)(iv)(b).

decisions of precedential value appear to have been made interpreting the IRS Regulations dealing with an exclusive license as the only practicable means to utilize the invention to benefit the public.

2. Tax Exempt Bonds

Universities often rely on tax exempt bond issuances to raise funds to build or maintain their physical plant. The university and its bond purchasers benefit because the interest on the bond is not taxed. Investors can keep more of the gross interest paid on the bonds. Oversimplified, this means that universities can issue bonds to investors at lower interest rates than those of comparable taxable bond issuances, but investors could receive net interest from the tax exempt bonds that would be roughly the same as the post tax interest they would have received from a higher interest, but taxable, bond issuance. Thus, the university pays a lower interest rate to its purchasers—saving it money—while the investors receive the same interest return as they would have on a higher yield, but taxable, bond. However, if the university receives an amount exceeding a certain threshold of the bond issuance for "private business use" of the facilities built or maintained with the bond issuance proceeds, then the tax exempt status of the bond is lost.[403] For private universities operating under IRC § 501(c)(3) tax exemptions, this threshold is 10 percent of the bond issuance proceeds. [404] For public universities that are state agencies, this threshold is 5 percent of the bond issuance proceeds. [405] External research funding can be considered private business use, however, and so universities must take care in how they structure their external funding agreements. The IRS has created safe harbors for external funding agreements that cover only "basic research" such that funding agreements falling into the safe harbors will not be considered private business use of the tax exempt bond financed facilities.[406] Funding agreements that do not fall within these safe harbors—such as development oriented corporate sponsored research—will need to be closely monitored so that in the aggregate they do not exceed 5 percent of the bond issuance(s) used to finance the facilities used under the funding agreement.

These safe harbors fall into two main categories, each of which must be restricted to funding basic research: (i) corporate sponsored research; and (ii) industry or federally funded research. "Basic research" is defined as "original investigation for the advancement of scientific knowledge not having a specific commercial objective." [407] For corporate sponsored research to fall within the safe harbor, the funding agreement must establish that the corporate sponsor will pay the same, competitive price for a license to use any technology resulting from the research as any other non-sponsoring party, and that such price must be determined at the time the technology is developed (and thus not set in advance). [408] The university need not actually license the technology to any third parties, but the terms of any license with the sponsor must be the

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[403] IRC § 141(b).

[404] IRC § 141(b)(1).

[405] IRC § 141(b)(3).

[406] IRS, Rev. Proc. 2007-47, *available at* http://www.irs.gov/irb/2007-29_IRB/ar12.html#d0e1768.

[407] *Id.* at § 3.01.

[408] *Id.* at § 6.02.

same as what would be used with non-sponsoring third parties. In practice, some universities attempt to accommodate their corporate sponsors' reasonable interests in having some security that they will be able to get rights to the resultant technology through the inclusion of "first right to negotiate" clauses.[409]

For industry or federally funded research to fall within its safe harbor, the funding agreement must be one in which: (i) either single or multiple sponsors agree to fund "basic research;" (ii) the tax-exempt organization "determines the research to be performed and the manner in which it is to be performed;" (iii) the tax-exempt organization retains title to patents or products resulting from the research; and (iv) the sponsor or sponsors are entitled to no more than a nonexclusive, royalty-free license (NERF) to use the product of any of that research. [410] This does not preclude the sponsors from ultimately negotiating an exclusive royalty-free license (or presumably any other kind of license), but only that they may not have a right or option to one granted up front in the funding agreement. However, for consideration of the requirements of Bayh-Dole and the necessary inclusion of March-In Rights and the Government License in Federal funding agreements, the safe harbor language explicitly states that such federal government rights in the funding agreement will not push the arrangement out of the safe harbor so long as items (ii) and (iii) are met *and* "the license granted to any party other than the [university] to use the product of the research is no more than a nonexclusive, royalty-free license." [411] New language for this safe harbor promulgated in 2007 seems to have raised two technical problems—even as it fixed an earlier one.[412] First, the new language seems to ignore the fact that Bayh Dole also mandates that federal funding agreements also contain provisions that can allow the federal government to take title to subject inventions in certain circumstances. [413] This means then that the funding agreement cannot also guarantee that the university will retain exclusive title to any inventions arising from the funding agreement, as required for the safe harbor under (iii) above. It also means that the federal agency could not order the university to issue an exclusive license to other parties pursuant to a proper exercise of March-In Rights. [414]

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[409] *See, e.g.*, Master Agreement Dated November 9, 2007 Between BP TECHNOLOGY VENTURES INC. and THE REGENTS OF THE UNIVERSITY OF CALIFORNIA *available at* http://www.energybiosciencesinstitute.org/images/stories/pressroom/FINAL_EXECUTED_11-14.pdf.

[410] *Id.* at § 6.03.

[411] *Id.* at § 6.04. In fact, Rev. Proc. 2007-47 was promulgated to modify and supersede Rev. Proc. 97-14 to address uncertainties relating to the definition of a "sponsor." The definition included the federal government, and thus when the federal funding agencies reserved March-In Rights or the Government License in funding agreements, those provisions seemed to result in the funding agreements falling within the private business use test of IRC § 141(b).

[412] *Id.*

[413] *See supra* Part III.B.3.c.

[414] Some commentators have read § 6.04 to mean, apparently inadvertently, that universities cannot grant exclusive licenses at all. However, because § 6.04 is clearly titled and structured to only apply to the federal government's rights under federally funded research agreements—so as to explicitly establish that those rights as dictated by Bayh-Dole do not conflict with the agreement's qualification under the safe harbor—then it seems clear that the nonexclusive license limitation only applies to the federal government's rights, such as in the Government License or March-In Rights. However, even this more careful interpretation leads to problems as discussed in the text.

3. Unrelated Business Income Tax (UBIT)

Universities can receive "unrelated business income" (UBI), which the IRS defines as "income from a trade or business, regularly carried on, that is not substantially related to the performance by the organization of its exempt purpose or function." [415] In certain circumstances, the university may then have to pay UBI tax (UBIT). This report does not consider all of the myriad ways in which universities can be subject to UBIT, but rather only those which may arise from a university's management of its IP and technology transfer activities. Further, this report does not treat one of the most substantial IP related revenue streams for major universities—that generated from merchandising and use of university trademarks—because the focus of this report is on university IP and technology transfer issues arising from the research mission. Thus, this report restricts its UBIT analysis to income generated from licensing of technology based IP, data, and materials.

Analysis of whether a revenue stream constitutes UBI—as a threshold question that must be addressed before determining whether the university might be liable for UBIT—involves asking a series of questions: (i) is the activity related or unrelated to the attainment of the organization's exempt purpose?; (ii) is it a trade or business?; and (iii) is it regularly carried on? The IRS has stated that "because of the nature of research activities (ongoing, income producing activities), *they almost always constitute trade or business regularly carried on."* [416] This makes "relatedness" the critical issue for determining whether income from corporate sponsored research constitutes unrelated business activity and is thus subject to tax. Relatedness requires a "substantial causal relationship" between the activity that generates revenue and the exempt purpose of the organization. More specifically, the activity "must contribute importantly to the accomplishment" of the exempt purpose, "other than the university's need to produce income." [417] Further, the size and extent of the activity related to an exempt purpose must be proportional to supporting that purpose, especially where the activity is only partly related to the exempt purpose.[418]

Even where UBI exists, UBIT may not apply because many kinds of income are excluded from tax by IRC exceptions and exclusions. Of particular note, university research income, including that through any affiliated hospital, will generally not be subject to UBIT. [419] However,

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[415] IRS Reg. § 1.513-1(a), 26 C.F.R. § 1.513-1(a).

[416] IRS, CPE Text on "Scientific Research Under IRC 501(c)(3)" (1986) (emphasis added).

[417] IRS Reg. § 1.513-1(d)(2), 26 C.F.R. § 1.513-1(d)(2).

[418] IRS Reg. § 1.513-1(d)(3), 26 C.F.R. § 1.513-1(d)(3).

[419] IRC §§ 512(b)(7)-(9):

> (7) There shall be excluded all income derived from research for
>
> (A) the United States, or any of its agencies or instrumentalities, or
>
> (B) any State or political subdivision thereof; and there shall be excluded all deductions directly connected with such income.
>
> (8) In the case of a college, university, or hospital, there shall be excluded all income derived from research performed for any person, and all deductions directly connected with such income.
>
> (9) In the case of an organization operated primarily for purposes of carrying on fundamental research

the term "research" is not unlimited: IRS Regulations provide that it "does not include activities of a type ordinarily carried on as an incident to commercial or industrial operations, for example, the ordinary testing or inspection of materials or products or the designing or construction of equipment, buildings, etc." [420] A series of revenue rulings provide more detail on what will qualify for the research exception in the UBIT rules. One, for example, examined whether income received by a medical college for the testing of pharmaceutical products was subject to UBIT.[421] The IRS determined that the studies undertaken by the college were concerned with new applications of products or drugs in order to improve the ability to treat various diseases and conditions and were not, therefore, mere quality control programs or ordinary testing for certification purposes, as a final procedural step before marketing. Rather, these studies constituted "research" within the meaning of IRC § 512(b)(8) and thus that income derived by the college from the conduct of this research was from the performance of an activity substantially related to its exempt purpose and not UBI. However, any marketing, operating, or manufacturing activities conducted after a research phase is complete may result in UBIT.

The IRC also excludes "all royalties" from the calculation of UBI (including overriding royalties), whether measured by gross or taxable income from the property and all deductions directly connected with such income. [422] This provision generally pertains to all licensing revenue garnered from university patents, although these revenues must qualify as royalties and not either as profits from a joint venture or compensation for services rendered. For instance, when the exempt organization organization's involvement is characterized as "active," requiring ongoing services, *etc.*, the IRS will not characterize the payment as a royalty, excluded from UBIT. [423] However, there is an exception for royalties received from "controlled organizations" in which the university owns 50 percent or more of the beneficial interest in the organization. In such cases, the royalty income could be subject to UBIT. [424]

L. State Sovereign Immunity and IP Infringement by State Universities.

The doctrine of state sovereign immunity arises under the 11 th Amendment to the U.S. Constitution, which provides that the federal courts may not be used to sue a state by citizens of either another state within the U.S. or foreign states. [425] Further, while the 11th Amendment is silent about whether citizens may sue their *own* state in federal court, the Supreme Court has

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the results of which are freely available to the general public, there shall be excluded all income derived from research performed for any person, and all deductions directly connected with such income.

[420] IRS Reg. §§ 1.512(b)1-(f)(4), 26 C.F.R. § 1.512(b)1-(f)(4).

[421] IRS Letter Ruling 7936006, May 23, 1979.

[422] IRC § 512(b)(2); IRS Pub. 598 (Rev. Nov. 2007), Tax on Unrelated Business Income of Exempt Organizations ("Unrelated business taxable income does not include royalty income received from licensees by an exempt organization that is the legal and beneficial owner of patents assigned to it by inventors for specified percentages of future royalties").

[423] *See* IRS Letter Ruling 9527031.

[424] *See* IRS Pub. 598, p.14.

[425] U.S. Constitution, Amend. XI (1795) ("The Judicial power of the United States shall not be construed to extend to any suit in law or equity, commenced or prosecuted against one of the United States by Citizens of another State, or by Citizens or Subjects of any Foreign State.").

ruled that they may not.[426] At the same time, patent and copyright infringement suits may only be brought in federal courts.[427] Therefore, patent and copyright owners cannot directly sue states for infringement. Because many—but not all—state universities are state agencies,[428] patent and copyright owners cannot sue the state agency universities as this would be tantamount to suing the state. The history of the sovereign immunity doctrine as applied to IP infringing activities by state universities and their researchers has had an uneven history. Case law alternated between upholding state sovereign immunity against patent and copyright suits and abrogating it, until it appeared that the former had finally won out by the 1980s. In response, Congress passed both the Copyright Remedy Clarification Act (CRCA)[429] and the Patent and Plant Variety Protection Remedy Clarification Act (PRCA)[430] in the early 1990s that explicitly abrogated the doctrine for copyright and patent infringement. But in 1999, the Supreme Court invalidated the PRCA as unconstitutional in the landmark case of *Florida Prepaid Postsecondary Education Expense Board v. College Savings Bank*.[431]

There are complications to the sovereign immunity doctrine, however, that provide cautionary notes to any state research agency that might seek to rely on it as a kind of *de facto* research use exception.[432] First, states can be deemed to have waived their sovereign immunity where they: (i) bring a case in federal court;[433] (ii) successfully remove a case from state to federal court;[434] or (iii) voluntarily participate in an administrative proceeding with a federal agency.[435] Second, the *Ex Parte Young* doctrine, arising from the case of the same name,[436] allows actions for injunctive relief against named state officials in their capacity as individuals even where the state itself would enjoy sovereign immunity for the activity. In further

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[426] *See* Florida Prepaid Secondary Education Expense Board v. College Savings Bank, 527 U.S. 627, 634-35 (1999) (explaining that Article III of the U.S. Constitution was never meant to supersede the sovereign immunity that the states had before entering the Union).

[427] 28 U.S.C. § 1338(a) ("The district courts shall have original jurisdiction of any civil action arising under any Act of Congress relating to patents, plant variety protection, copyrights and trademarks. Such jurisdiction shall be exclusive of the courts of the states in patent, plant variety protection and copyright cases.").

[428] *See, e.g.*, Kovats v. Rutgers, The State University, 822 F.2 1303 (3 rd Cir. 1987).

[429] P.L. No. 101-553 (Nov. 15, 1990).

[430] P.L. No. 102-560 (Oct. 28, 1992).

[431] 527 U.S. 627 (1999).

[432] Standard research use exceptions are discussed in Part III.C.6 *supra*.

[433] *See* Clark v. Barnard, 108 U.S. 436 (1883); Tegic Communications Corp. v. Board of Regents of the University of Texas System, 458 F.3d 1335 (Fed. Cir. 2006); Regents of the Univ. of New Mexico v. Knight, 321 F.3d 1111 (Fed. Cir. 2003). Immunity is waived only for the subject matter of the particular case, narrowly defined, and any compulsory counterclaims.

[434] *See* Lapides v. Board of Regents of the University System of Georgia, 535 U.S. 613 (2002).

[435] *See* Vas-Cath, Inc. v. Curators of the University of Missouri et al ., 473 F.3d 1376 (Fed. Cir. 2007).

[436] 209 U.S. 123 (1908). Railway stockholders filed suit against the Minnesota State Attorney General complaining that a state statute establishing railway rates was unconstitutional. The district court enjoined the enforcement of the statute and when the Attorney General violated the injunction by attempting to enforce the statute anyway, the court found him in contempt and issued an injunction against him in his individual capacity. The Attorney General appealed on the basis of state sovereign immunity. Ultimately, the Supreme Court held that state officials did not enjoy the protection of sovereign immunity when they attempt to enforce unconstitutional laws.

development of the *Ex Parte Young* doctrine, the Supreme Court has stated that private parties can sue state officials in their individual capacity for prospective injunctive relief when the officials are violating federal law.[437] Similar to *Young*, this requires identification of the specific officials and a finding of a threat of ongoing violations of law, so that the injunction can prohibit such activities going forward. In particular, there must be "some connection with the enforcement of the act, or else the suit is merely making [the official] a party as a representative of the state, and thereby attempting to make the state a party."[438]

In *Pennington Seed, Inc. v. University of Arkansas et al .*,[439] Pennington sought an injunction against various officials of the University of Arkansas. The trial court found that the named officials had insufficient connection to the alleged infringing activities. Specifically, Pennington named the individuals then serving as the Chairman of the Board of Regents for the University of Arkansas System, the President of the University of Arkansas System, and the Chancellor of the University of Arkansas at Fayetteville as individual defendants. The court ruled that the fact that some of these officials oversaw university IP policy did not create a sufficient nexus to the actually infringing activities.[440] The Federal Circuit then affirmed the case on appeal.

Thus, while some commentators have suggested that the *Ex Parte Young* doctrine renders the state sovereign immunity doctrine unhelpful to state researchers, the picture is not so clear. Before *Pennington*, there may have been a sense that courts would allow suits for injunctive relief against high level state university officials who could then be enjoined to order that any IP infringing activities on campus cease. This was probably always an incorrect reading of *Young* and its progeny, and it is certainly wrong in light of *Pennington*. Accordingly, patent and copyright owners will have to sue the specific individuals who directly engage in allegedly infringing activities at state agency universities to get any injunctive relief under the *Ex Parte Young* doctrine.

IV. STATE LAWS AND REGULATIONS AFFECTING UNIVERSITY IP AND TECHNOLOGY TRANSFER

The fact that formal patent and copyright law in the United States are exclusively the province of federal law may lead the unwary to ignore state laws and regulations that have significant impact on who actually owns any particular IP, as well as how those rights may be conveyed or licensed to others. First, trade secret law—the primary means for protecting valuable know-how and show-how—is primarily governed by state law. Second, as state governments have increasingly stepped in to help finance certain areas of research at universities and other research organizations within the state, some of them have promulgated regulations governing the disposition of IP and other proprietary rights arising from such funding—

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[437] *See, e.g.*, Frew v. Hawkins, 540 U.S. 431 (2004).

[438] Ex Parte Young, 209 U.S. 123, 157 (1908).

[439] 457 F.3d 1334 (Fed. Cir. 2006).

[440] Additionally, because the suit was brought in Missouri, yet the university and officials were located in Arkansas, the court dismissed the individual defendants for lack of personal jurisdiction. Thus, even though Pennington did name one university professor as a defendant—and presumably one who truly was engaged in the allegedly infringing activities—its claims against that individual were dismissed as well, but only on jurisdictional grounds.

essentially state versions of Bayh-Dole and the FAR. At the same time, states have long financed research at their state public universities either directly through appropriations for research activities, or indirectly through appropriations for the university physical plant, faculty and staff researcher salaries, etc. Third, in the case of public universities that are organized as full state agencies—and not independent legal entities partly supported by the state—laws and regulations pertaining to the ethics and conduct of state employees and use and disposition of state assets apply to all university personnel including faculty researchers. Independent of IP issues, state law provides the primary law governing the ownership of human tissues collected to be used as research materials. However, a review of the state law cases involving informed consent for the collection and use of human tissues is beyond the scope of this report.

A. Trade Secret Law

Nearly every state has passed a version of the Uniform Trade Secret Act. [441] While trade secret law is primarily the province of state law, the Economic Espionage Act of 1996 provides federal criminal sanctions for some misappropriations of trade secrets. [442] The primary difference between trade secrets and the federal IP systems of copyright, patent, and trademark is that there is no examination or registration process for trade secrets. Those who want to claim the existence and ownership of trade secrets have to take reasonable steps to define and protect the subject matter through physical access barriers and legally enforceable arrangements for confidentiality and non-use by those who gain access to the material from the purported owner. If they do so, and the subject matter otherwise meets the definition of a trade secret, then the owner can sue anyone who allegedly has misappropriated the trade secret for injunctive and damages relief. The primary goal for trade secret owners is to prevent public disclosure of the trade secrets as any such disclosure—even if wrongful and resulting from the misappropriation of the trade secrets—will destroy the trade secrets. The owner may still be able to recover some or all of its damages resulting from the misappropriation, disclosure, and destruction of the trade secrets, but cannot get the trade secrets "reinstated." Thus, a trade secret owner must avail itself of immediate temporary restraining order (TRO) injunctions from courts if it believes that an improper disclosure of its trade secrets is imminent.

B. State Law Regarding IP Ownership, Assignment, Licenses, and Shop Rights

As discussed in the section on IP ownership and conveyances in Part III.C.1 above, the Patent Act primarily sets out only the rules for inventorship and gives initial title rights to the actual inventors. The Patent Act also provides that assignments and exclusive licenses must be in writing and encourages recordation of the transfer with the USPTO by expressly allowing a future purported assignee to receive title to the application or issued patent over an earlier *unrecorded* assignee under the *bona fide* purchaser rule. The Copyright Act wades further into initial title allocation, by expressly providing for the employer to be the sole original author and

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[441] The National Conference of Commissioners on Uniform State Laws, A Few Facts About The Uniform Trade Secrets Act, *available at http*://www.nccusl.org/Update/uniformact_factsheets/uniformacts-fs-utsa.asp. The text of the Uniform Trade Secret Act is available at http://www.law.upenn.edu/bll/archives/ulc/fnact99/1980s/utsa85.htm.

[442] *See supra* Part III.F.

copyright owner in cases of a properly structured work made for hire relationship. It also requires that assignments and exclusive licenses be in writing, and encourages recordation of the same with the Copyright Office. Nonetheless, these inventorship, authorship, and ownership rules in the federal IP laws still allow state statutory and common law rules to further regulate ownership and transfer of IP title and rights, so long as these rules do not conflict with the federal systems. Trade secret law, primarily the province of state statutory or common law, is also then subject to state law rules regarding ownership and transfer of title.

There are three major categories of state law to be considered for purposes of IP ownership, assignment, licensing, and shop rights: (i) statutory law; (ii) common law general contract, property, and tort rules; and (iii) common law default IP ownership and licensing rules in the absence of an express agreement—sometimes collectively called "shop rights."

1. State statutory IP assignment provisions

In some states, statutory law provides limits to the extent that employers can require assignment of employees' IP through contract. Sometimes referred to as "freedom to create" statutes,[443] they currently exist in California,[444] Minnesota,[445] North Carolina,[446] and Washington.[447] These statutory sections primarily seek to limit employer's use of contract clauses requiring new employees to assign over IP rights to inventions created even before the term of employment, as well as "trailer clauses" that require assignment of IP the employee might claim to have invented during some fixed time period *after* terminating employment with the employer. They also limit the ability of employers to contractually require assignments of inventions with no connection to the employee's job description, the employer's lines of business, and for which the employee did not use any employer resources.

From the opposite angle, Nevada now has an IP assignment statute that automatically assigns inventions to an employer so long as they were made during the term of employment and fell within the scope of the employee's job description.[448] Essentially, Nevada has created an "opt-out" system in which the default by statute is that employers own any IP developed by employees as part of their job description. The parties would have to execute an express writing to the contrary to opt out.

2. State contract and property law

Contractual arrangements regarding the allocation or transfer of property rights—primarily governed by state law—arguably constitute the overwhelming majority of the "law" that applies to and governs disposition of IP, data, and material rights. Legally enforceable contracts are

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[443] *See, e.g.*, ROBERT P. MERGES, ET AL., INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE 87 (rev. 4th ed., Aspen Publishers 2007).

[444] Cal. Labor Code § 2870.

[445] Minn. Stat. Ann. § 181.78.

[446] N.C. Gen. Stat. § 66-57.1, 66-57.2.

[447] Rev. Code Wash. § 49.44.140, 49.44.150.

[448] Nev. Rev. Stat. § 600.500.

themselves a form of law—sometimes referred to as "the law of the deal" or as "private ordering." Outside of any express statutory limits or requirements (such as those described above), parties are free to reallocate any initial allocation of IP title by contract. They can also enter into contracts to assign or license IP, as well as covenants not to sue. As seen in the cases discussed below, breach of express or implied contracts and related actions are often at the heart of university-inventor disputes. They also constitute the legally enforceable core of any technology transfer deal.

The free alienability of property rights across the IP spectrum is a bedrock principle of United States property and IP law. [449] Likewise, data and materials will generally be viewed as freely alienable personal property under state law. Under equally fundamental freedom to contract principles in the United States, contractual transfers of property rights will generally be upheld by courts absent clear fraud, duress, or coercion, or unless they take the form of "contracts of adhesion." [450] Individuals of sound mind over the age of 18 are generally presumed to have the full capacity to enter into legally binding contracts. Those with advanced education and/or sophistication are almost always seen as able to contract away rights to IP, regardless of whether they have any formal training in the law and/or IP. Courts have rarely, if ever, ruled that standard university IP assignment agreements or policies constitute duress, coercion, or contracts of adhesion. Only a showing of fraud, deception, or misrepresentation will generally lead a court to disregard such an agreement or policy.

Several important cases in the last decade or so underscore the foregoing principles. In *Chou v. Univ. of Chicago* (also discussed in Part III.C.1 for inventorship issues), the state common law actions for fraudulent concealment, breach of fiduciary duty, unjust enrichment, breach of express and implied contract, and academic theft and fraud were as important to the case as the correction of inventorship claim (even though that in many ways was the ultimate goal). [451] On appeal, the Federal Circuit sustained most of these state common law causes of action against either the faculty member who had supervised Chou and improperly attempted to keep her off the patent application as a co-inventor or the university itself. The only cause of action rejected by the trial court and the Federal Circuit was that for academic theft and fraud. Further, the closely related issue of whether Chou would retain ownership of the invention if she were found to be a co-inventor was resolved under state law, as is the case for most patent assignments.

Likewise, in *Fenn v. Yale* (also discussed in Part III.B.3 for Bayh-Dole issues), former faculty member John Fenn brought an action against Yale, alleging state law actions for conversion, theft, tortious interference with business relationship, and violations of Connecticut Unfair Trade Practices Act (CUTPA) in response to Yale's assertion of ownership of a patent resulting from his work while a faculty employee. [452] Yale counterclaimed with state law actions for accounting and assignment of patent, as well as damages for breach of contract and fiduciary duty, fraud, negligent misrepresentation, conversion, theft, and unjust enrichment. The court rejected Fenn's argument that Bayh-Dole trumped the state law claims, and so the case

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[449] The only meaningful exception is the prohibition in the Copyright Act on natural authors from waiving the 35 th year reversion right for any transfers of rights to works they authored and then licensed or assigned to others. 17 U.S.C. § 203.

[450] Contracts of adhesion are often misunderstood and over-invoked by commentators not trained in the law.

[451] 254 F.3d 1347 (Fed. Cir. 2001).

[452] Fenn v. Yale University, 393 F.Supp.2d 133 (D. Conn. 2004).

ultimately turned on state law principles. In a further ruling, the court found that Fenn had: (i) committed statutory civil theft and fraud against Yale in the form of larceny of the patent; and (ii) converted Yale's property rights in the patent to his own property. [453] This led the court to assess treble and punitive damages as well as attorneys fees and costs against Fenn. [454] In the aggregate, the court ruled that Fenn had to personally pay over $1M in damages and costs to Yale. It also ruled that it had the authority to, and did so, order the assignment of the patent from Fenn to Yale.

In *University of Pittsburgh v. Townsend* (also discussed in Part III.B.3.d for Bayh-Dole issues), the University of Pittsburgh ("Pitt") brought actions under state law sounding in: (a) tort, alleging that Townsend misappropriated or converted the property of the patent that issued on his invention developed while working at Pitt and a private company that had a cooperative R&D agreement with Pitt; (b) breach of contract, alleging that Townsend was contractually bound to assign his invention to Pitt and not the private company; (c) fraudulent concealment, alleging that Townsend intentionally misled Pitt about the inventions and his intentions whether he would assign it to Pitt or the private firm; and (d) breach of fiduciary duty, alleging that Townsend owed such a duty to Pitt because of his primary employment there and breached the duty by assigning his invention to the private instead. [455] Pitt even alleged unlawful conspiracy, fraud and misrepresentation, and unjust enrichment. However, in this case, the trial court ruled for the defendants on a motion to dismiss by finding that Pitt's own negligence and delay in securing the proper agreements and assignments from Townsend, and even in bringing the instant action, caused its claims to be time-barred by the appropriate statutes of limitations. The U.S. Court of Appeals for the Sixth Circuit affirmed the ruling.

Similarly, in *Board of Trustees of Leland Stanford Junior University v. Roche Molecular Systems, Inc.* (also discussed in Part III.B.3.d for Bayh-Dole issues), the Federal Circuit overturned the trial court's ruling that the statutory provisions of Bayh-Dole dictated that Stanford must own the researcher's invention and patent. [456] The Federal Circuit held that Bayh-Dole did not pre-empt state law-based assignment agreements and that the assignment to Roche's predecessor company effected an immediate assignment of the invention whereas the assignment agreement with Stanford merely obligated the researcher to assign the invention to Stanford at some later time. The Federal Circuit made it clear that ownership of a patent was not exclusively a matter of state law—as some earlier district court opinions had held—but that it was a mixed area of federal and state law. The court also suggested that Stanford might have a breach of contract claim against the researcher, who effectively breached the agreement by assigning inventions to the private firm that he had already committed to assign to Stanford upon Stanford's future election. But any remedy on that claim would not include a re-assignment of the patent to Stanford.

Shortly after the Federal Circuit's decision in *Stanford v. Roche*, the Delaware Court of Chancery issued an opinion upholding the supremacy of a university faculty member's agreement to assign inventions over a present conveyance assignment to an outside firm. [457]

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[453] Fenn v. Yale University, 2005 WL 327138 (D. Conn. 2005).

[454] *Id.*

[455] 542 F.3d 513 (6th Cir. 2008).

[456] 583 F.3d 832 (Fed. Cir. 2009).

[457] Cephalon, Inc. v. Johns Hopkins University, 2009 WL 4896227 (Del.Ch. 2009).

While the unpublished opinion in *Cephalon, Inc. v. Johns Hopkins University* seems at odds with the Federal Circuit's position in *Stanford v. Roche* at first blush, the specific facts easily distinguish the two cases. In *Cephalon v. Johns Hopkins*, the university made sure that the faculty researcher's consulting agreement with Cephalon contained a clause acknowledging the supremacy of the researcher's pre-existing contractual obligation to assign inventions to the university over any assignment obligations he might subsequently undertake with Cephalon (even if these preceded any *actual* assignment of a particular invention to the university). This sort of supremacy clause was absent in the case of the Stanford researcher's assignment agreement with the outside private firm. Accordingly, the private firm had no practical notice of the researcher's prior agreement to assign future inventions to Stanford and the court had no grounds to re-assign the patent from the firm to Stanford.

3. "Shop rights"—common law default rules regarding invention ownership

As mentioned throughout Parts II and III above, much of the current sense about how and when employees should be expected to assign inventions to their employers comes from the doctrine of "shop rights" that developed in nineteenth century case law. In the absence of express contractual arrangements to the contrary, this tripartite invention allocation scheme discussed by the Supreme Court in *U.S. v. Dubilier Condenser Corp.* still generally controls.[458] The first part is the true shop right: where an employee uses his employer's resources or time to invent, the employee may retain title but must grant a perpetual, non-exclusive, non-transferable license to the shop. It is important that the license not be transferable, and questions have arisen as to whether a shop right can survive the acquisition of the firm by another firm, or any other succession of ownership in which a material change of control takes place. [459] The second part is the "hired to invent" exception to the shop right: where the employee was specifically hired to invent the sort of thing ultimately invented, title to the invention will equitably vest in the employer. The challenge with this part is the evidentiary support required of employers to show that an employee was specifically hired to invent a kind of good or service. The third part has no specific name, but is where the employee invents on his own time and with his own resources, and was not hired to invent that kind of thing. In this case, the employee retains the title free and clear, with no license necessarily granted to the employer (unless the employee decides to grant one).

C. State and Local Research Funding Law Affecting IP Rights

While states have long supported basic research at state universities indirectly by allocating funds to the institutions for faculty researcher salaries and facilities, in the past decade they have

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[458] 289 U.S. 178 (1933). Note that even though *Dubilier* involved United States Government employees, it was decided before the Truman Executive Order was issued and so determined the rights of the parties based on common law rules as there was no written agreement of government policy in place at the time. See *supra* Part II. Thus, *Dubilier* does not currently control the disposition of rights in inventions created by government employees after the Truman Executive Order was issued. It does, however, still control for the disposition of rights in inventions created by employees of other organizations where no other written agreement or binding policy was in place.

[459] *See, e.g.*, Board of Trustees of Leland Stanford Junior University v. Roche Molecular Systems, Inc ., 583 F.3d 832 (Fed. Cir. 2009).

begun directly funding specific areas of research, such as human embryonic stem cells. For example, in 2004, California voters passed Proposition 71 establishing the California Institute of Regenerative Medicine (CIRM) and authorizing the sale of general obligation bonds to distribute 3 billion dollars over 10 years to fund stem cell research. [460] Advocates claimed that California would receive an adequate return on its investment through royalty payments on the scientific breakthroughs. However, as signed into law, Proposition 71 left these details to CIRM to work out on a case-by-case basis. Similarly, in 2005, the Washington State Legislature created the Life Sciences Discovery Authority to encourage development in the life sciences and enhance the competitive position of Washington State in the life science industry. [461] The legislation was similarly vague about the allocation of intellectual property. The uncertainty in ownership rights arising from state funding in any of these situations may actually limit commercialization. [462] Perhaps more critically, as such initiatives proliferate and begin to attach other restrictions on IP—e.g., CIRM's regulations governing IP—then conflicts could arise between federal, state, municipal, and even private sector funding initiatives and downstream IP requirements.

D. Nonprofit Organizations Law and State Agencies

Universities are legal entities and legal persons organized under state law. They are not an aggregate or association of their faculty, nor do they exist primarily for their faculty's benefit. Faculty may play a role in governance but they do not legally own or exert exclusive control (even in the aggregate) over the university entity. A core principle of state nonprofit corporations law is that neither employees, directors, board members, trustees, or any other individual directly involved in the governance or operations of a nonprofit organization may cause the organization to benefit the individual beyond the collection of fair market compensation. Any direction of further benefits or assets to the ownership or exclusive use of the individual is deemed "private inurement" and prohibited.

In the United States, universities are either corporations or state agencies. When structured as a corporation, they are normally incorporated under the nonprofit corporation statute of the state in which they are incorporated, and then usually seek tax exempt status with state and federal tax agencies. Nonprofit corporations—like their for profit corporation counterparts—are generally allowed to structure their governance and operations in any manner their incorporators and controlling board (whether named trustees, regents, or any other title) see fit, so long as it complies with relevant federal, state, and local law. State or federal agencies that seek to impose restrictions on such governance or operations will generally not be able to do so in any manner that forces the nonprofit corporation to act out of compliance with its controlling state nonprofit corporations statute, absent clear pre-emptive legislation passed by the relevant state legislature or by Congress. Federal or state agencies may be allowed to require nonprofit corporations to structure their governance or operations in ways that are permitted under the relevant state

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[460] http://www.cirm.ca.gov/.

[461] http://www.lsdfa.org/about/mission.html.

[462] *See* Michael Mireles, *States as Innovation System Laboratories: California, Patents, and Stem Cell Technology* , 28 CARDOZO LAW REVIEW 1133 (2006); Sean M. O'Connor, *IP Rights and Stem Cell Research: Who Owns the Medical Breakthroughs?*, 39 NEW ENGLAND LAW REVIEW 665 (2005).

nonprofit corporations statute.[463] However, they must have clear statutory authority to do so under the relevant state or congressional legislation, as nonprofit corporations are private legal persons. In the absence of clear statutory authority, state or federal agencies may have some latitude to condition the award of contracts, grants, or cooperative agreements on certain governance or operations arrangements of the recipient of funds. However, this is a limited power and must be expressly permitted by the enabling legislation governing that agency. Because much state and federal research funding is still considered to be a form of government procurement, and because of ever-present concerns that funding agencies will engage in arbitrary, capricious, or preferential funding decisions (with the latter based improperly on favoritism, nepotism, or cronyism), funding agencies are restricted in how they can exercise the "power of the purse" outside of clear statutory authority and proper rulemaking under binding agency administration statutes, such as the APA for federal agencies. When the university is established as a state agency it can be directly controlled by the state for which it operates as an agency. However, such control generally must also be clearly authorized by state statutes and regulations. Federal regulation of state agency universities can be a bit more complicated than federal regulation of nonprofit corporation universities because of state sovereign immunity issues.

E. Laws Governing State University Employees, IP, and Use of State Assets

Where state universities are state agencies, they have an extra level of legal issues for IP and technology transfer. On the one hand, they potentially benefit from the *de facto* protections against IP infringement suits by virtue of the constitutional doctrine of state sovereign immunity.[464] But on the other hand, they and their employees—including faculty members—must comply with fairly strict laws governing the behavior of state employees and use of state resources and assets. These generally prohibit the use of valuable assets arising from the work of a state employee to be used for the personal gain of that employee. Therefore, state universities will often have to require assignment of patentable inventions from researchers regardless of whether federal funding was involved. While some state university faculty members may feel that they are not "merely employees," of course legally they are. Further, state university faculty are state employees for purposes of state employee ethics laws. That they participate in governance of the university and their respective college, school, or department and are less directed in the performance of their jobs than more "traditional" employees are, does not change the fact that they are employees. Of course, state governments can make special statutory or regulatory exceptions for any class of state employee as long as such exceptions proceed through the appropriate channels and are not prohibited by any pre-emptive federal law or the state's constitution. This section does not review all such state laws, but instead focuses mainly on Washington State as a representative example.

As a threshold matter, it must be first determined whether a particular university is a state agency. Some "public" or "state" universities are independent legal entities which receive some funding from the state. Some, as for example in the case of the University of Pittsburgh, are

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[463] For example, in general, IRC and IRS governance requirements for nonprofit corporations who seek, or seek to maintain, tax exempt status do not require nonprofit corporations to structure themselves or engage in operations that would conflict with state nonprofit corporations statutes.

[464] *See supra* Part III.L.

considered "quasi-public" or "state-related" universities because of their essential independence as a legal entity, countered by their receipt of and reliance on significant amounts of state funding.[465] Federal courts have developed tests for determining whether any particular "public" university is a state agency, often in the case of determining whether the university qualifies as a branch or arm of the state for sovereign immunity purposes. [466] Notwithstanding the foregoing, in many states it is well established which universities are state agencies.

Once it is determined that a particular university is a state agency, then state statutory law must be checked to see: (i) if it has express provisions governing the actions of state employees; (ii) whether there are any carve-outs or exceptions for certain activities of any identifiable class of state employees such as university faculty members; and (iii) how state resources may be used and state assets disposed. In some cases, these statutory provisions will authorize state agency rulemaking. Any resultant regulations must also then be checked for their effect on any of the foregoing.

As an illustrative example, the remainder of this section will review the Washington State Ethics in Public Service Act, as amended by the 2005 "Ethics in Public Service—University Research Employees" act. The Ethics in Public Service Act was first passed in 1994 (the "Ethics Act").[467] Overall, the law appears to serve the admirable purpose of keeping state officers and employees free of corruption. As part of this, the law restricts state employees from receiving certain kinds of: (i) compensation for outside activities; [468] (ii) honoraria;[469] (iii) gifts;[470] and loans or other items of economic value. [471] For their part, state employees are restricted from using, loaning, or otherwise conveying state resources and assets, including the time of state personnel, to others for the employee's private gain. [472]

Prior to the 2005 amendments, the Washington State Attorney General's Office and the Washington State Ethics Board often interpreted the Ethics Act to mean that faculty researchers at the State's public research universities, including the University of Washington and Washington State University, could not receive any private gain from the commercialization of their inventions developed at these institutions. Thus, beyond the customary assignment of the faculty members' inventions as is done in most universities, Washington State public university faculty members were also restricted from entering into any significant relationships with outside firms that would commercialize their inventions (under license from the institution). Faculty researchers were censured or even penalized for seemingly minor infractions such as using their university office telephone or email for occasional communication with an outside party, including those commercializing the faculty member's invention under duly executed licenses

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[465] *See, e.g.*, University of Pittsburgh, Office of the Provost, History, *available at* http://www.provost.pitt.edu/more/ch1_history.htm. In many of these cases, the university started as a private school and then began receiving substantial state assistance later.

[466] *See, e.g.*, Kovats v. Rutgers, The State University, 822 F.2d 1303 (3 rd Cir. 1987).

[467] Wash. Session Laws, ch. 154, Laws of 1994 (need date) (*codified as amended at* RCW § 42.52).

[468] RCW § 42.52.120.

[469] RCW § 42.52.130.

[470] RCW §§ 42.52.140, 42.52.150.

[471] RCW § 42.52.170.

[472] RCW §§ 42.52.160, 42.52.170.

from the university.

All of the foregoing seriously hindered the ability of the outside licensee to commercialize the technology. As discussed elsewhere in this report, university research and technology outputs are not limited to patentable inventions. Rather, they frequently also encompass know-how/show-how (whether or not formally captured under state trade secrets), data, and materials. Most of these non-patentable components of the technology are critical to the effective use and commercialization of the technology overall, and often even of the patentable inventions. [473] Accordingly, licensees will often require the involvement of the faculty inventors to fully commercialize the licensed patents and understand the licensed know-how/show-how. Where licensees require such involvement, they are in almost all instances prepared to compensate the faculty inventors. With the involvement of the faculty members curtailed, Washington State research universities and many in the entrepreneurship and technology communities complained that promising university technologies were being inadequately licensed and commercialized.

Accordingly, in 2005 the Washington State Legislature passed the "Ethics in Public Service—University Research Employees" act (the "University Research Employee Act"). [474] The University Research Employee Act created a new definition for the "University research employee" that would include "a state officer or state employee employed by a university, but only to the extent the state officer or state employee is engaged in research, technology transfer, approved consulting activities related to research and technology transfer, or other incidental activities."[475] It rescinded an existing section of the Ethics in Public Service Act that had expressly restricted university employees from being interested in or accepting "any compensation, gratuity or reward" from a university contract or grant without "a written administrative process for identifying and eliminating conflicts of interest." [476] While this earlier statutory provision had not necessarily prohibited faculty inventors from entering into compensatory arrangements with external licensees of the university, it had made such arrangements harder. Further, the law tended to be interpreted conservatively against any borderline arrangements into which university research employees sought to enter. The key provision of the University Research Employee Act was a new section that granted rulemaking authority to the universities to craft appropriate policies that could allow faculty inventors to enter into compensated arrangements with external parties to the extent that those relationships facilitated technology transfer for state economic development. [477] The University Research

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[473] Note that an invention can be fully "enabled" for purposes of patentability, but not directly translate into a product, or even severable components of a product. Neither are they necessarily "technologies" or "technology platforms" in the sense that they can be practiced for commercial gain exclusively by themselves. A patent on a "computer system" can be an example of this: many other components and processes will be required to actually manufacture and deliver a full working computer; the system patent claims may capture only one particular way of assembling together these other components, using other processes as well, and not the full final machine.

[474] Wash. Session Laws, ch. 106, Laws of 2005 (Apr. 21, 2005) (*codified at* RCW §§ 42.52.010, 42.52.030, 42.52.200, 42.52.360, 42.52.220).

[475] RCW 42.52.010.21.

[476] RCW § 42.52.030.2 (2004) (*rescinded by* Wash. Sess. Law ch. 106, Laws of 2005 (Apr. 21, 2005)).

[477] RCW § 42.52.220, stating, "(1) Consistent with the state policy to encourage basic and applied scientific research by the state's research universities as stated in RCW 28B.140.005, each university may develop, adopt, and implement one or more written administrative processes that shall, upon approval by the governor, apply in place of the obligations imposed on universities and university research employees under RCW 42.52.030, 42.52.040,

Employee Act also amended the criteria and operations of the State Executive Ethics Board for purposes of enforcing the Ethics in Public Service Act. [478]

After passage of the University Research Employee Act, the various universities prepared draft regulations which were then ultimately approved by the Governor, and currently govern the conduct of state university researchers with regard to compensated arrangements with outside parties, including those who are commercializing inventions developed by the researcher. The changes appear to have been quite helpful to facilitating the effective commercialization of state university technologies. Anecdotally, however, there also appears to still be some confusion as to the full range of such permissible relationships, as well as related questions as to what degree university research employees can own equity or have other ownership interests in outside entities commercializing the employee's inventions. There are also questions as to how or whether a university research employee can be assigned ownership of inventions they created at the university, even where the university has expressly declared that it has no interest in retaining title to the invention, and the relevant federal agency, if any, has also approved the title transfer to the employee.

From this example can be gleaned the basic parameters of state employee ethics and asset disposition laws. Whereas a private university need only satisfy its trustees, regents or other governing body as to setting appropriate policies, state universities will often, if not always, be subject to state government rules that seek to control state employee corruption and protect the integrity of state institutions and assets. Unless these general statutory schemes have specific carve-outs, similar to those of the State of Washington, then they will often have the practical effect of restricting the state universities' freedom to allow university researchers to retain title to their inventions when created with state university facilities or even enter into many kinds of common compensatory arrangements to assist in the commercialization of their inventions.

V. THE ESSENTIAL ROLE OF "PRIVATE ORDERING" THROUGH CONTRACTS FOR UNIVERSITY IP AND TECHNOLOGY TRANSFER

A. Overview

While statutory, regulatory, and case law are often the exclusive focus of legal analyses for a particular topic, in many fields of activity the "private ordering" by various parties through written, verbal, customary, or implicit agreements provides the most direct rules for how the parties must behave in their relationship with each other. Private ordering occurs in a robust "free play" zone that is bounded by statutory, case, and regulatory law. Under strong freedom to contract principles in federal and state law, parties are free to create whatever relationship rules they wish so long as their agreements do not transgress any of the boundary laws or rules. Such legally enforceable agreements then become the "law of the deal" and in most cases have far

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42.52.080, 42.52.110, 42.52.120, 42.52.130, 42.52.140, 42.52.150, and 42.52.160. The universities shall coordinate on the development of administrative processes to ensure the processes are comparable. A university research employee in compliance with the processes authorized in this section shall be deemed to be in compliance with RCW 42.52.030, 42.52.040, 42.52.080, 42.52.110, 42.52.120, 42.52.130, 42.52.140, 42.52.150, and 42.52.160."

[478] RCW § 42.52.360.2.

more direct impact on the parties' legal relationships than statutory, case, or regulatory law.

While the private ordering zone can be extensive and admit a wide variety of particular agreements, in many industries and organizations there are established forms of deals with standard variations on common negotiated clauses. Sophisticated parties and their lawyers will use the full range of such clauses as bargaining chips that can be traded during negotiations to secure the most critical ones for their own position. Private ordering arrangements often govern the parties' relationship over time. When a long term relationship is contemplated, the agreements may include: complex dispute resolution mechanisms; provisions for creating new boards or governance structures to manage a joint project; ongoing exchanges of employees and assets; and/or complicated financial arrangements.

In the case of university IP and technology transfer, a number of standard private ordering arrangements are central to the allocation and use of IP, data, and materials in the research enterprise. Faculty researcher IP assignment agreements, funding agreements, technology transfer deals, and MTAs are all examples of such core private ordering arrangements. In some cases, such as federal funding agreements, the contract clauses are largely dictated by statutory or regulatory law. But in others, it is generally custom informed by statutory, case, and regulatory law that shapes the standard clause variants. The remainder of this section analyzes key private ordering issues in the three major areas of university IP and technology transfer activity: (i) arrangements governing research inputs; (ii) arrangements governing research and technology transfer outputs; and (iii) arrangements governing inter-institutional research projects.

B. Arrangements Governing Research Inputs

1. IP assignments from faculty and staff

As discussed in Part IV.B above, state law governs much of the allocation and transfer of patent title. While the Patent Act gives the statutory rules for determining inventorship, and grants original title in any patent applications and patents to those inventors, these same inventors may assign away their title either before or after conception, reduction to practice, or issuance of a patent (if any). Such assignments will generally be governed by state common law and/or contract law. However, a recipient of an express assignment of patent title must timely record it with the USPTO or else risk losing the title to a subsequent bona fide purchaser of the title. If no express, written agreement exists, then any such assignment can only come through the equitable "hired to invent" exception to the default shop rights rule of the common law. [479]

Universities, like any other employers, have the general capacity to determine under what terms employees, including faculty, are employed. By express terms in an employment agreement or appointment letter, the university can require employees to assign all rights and title to any inventions made while in the employ of the university. [480] The presence of federal funding does not automatically create or modify any university arrangements with faculty by act of law under Bayh-Dole. As discussed above in Part III.B.3, Bayh-Dole directly impacts the clauses of the funding agreement between the federal agency and the university, which in turn

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[479] *See supra* Part IV.B.3.

[480] Subject to any state law restrictions such as the "freedom to create" statutes in California, Minnesota, North Carolina, and Washington. *See supra* Part IV.B.1.

indirectly impacts the nature of the contractual arrangements the university must have with researcher inventors. But, the specific terms of the researcher assignment agreements are left to the university. However, not too much should be read into this. It does not alter the *de facto* requirement for universities to secure IP assignments from researchers operating under federal funding. Rather, because of the range of relationships that such researchers might have with the university (title, status, employee vs. independent contractor), and the specific governance policies a particular university might have, Bayh-Dole and its implementing regulations left it to each university to determine the exact mechanism to secure the necessary federal government rights, in addition to whatever rights the university sought for itself. At the same time, universities may establish a process in which employees must disclose *all* inventions they have produced during the term of their employ and then appropriate university personnel can determine which inventions are covered by assignments or obligations to assign of the employee, and which may instead be waived directly to the employee as they are neither subject inventions implicating federal government rights nor otherwise encumbered by other obligations or rights of the university.

State universities that are state agencies will also usually be subject to state laws governing state employee ethics and disposition of state assets.[481] Private universities have greater freedom to set the IP assignment and university asset use rules for their faculty because they are not subject to the state employee restrictions of state university faculty members. "State related" or "quasi-public" universities may also have greater freedom in this regard than state universities that are state agencies. However, such universities need to look at the exact nature of their relationship with the state, and any governing statutory or regulatory law, to determine whether any state employee or state contractor laws apply to them or their employee faculty members.

Two tax-related issues also limit all nonprofit universities' authority to allow faculty to control the disposition of valuable assets created at the university and using university resources and facilities. The first is the tax-exempt status of the university; the second is the extensive use of tax-exempt bonds by universities. As discussed above in Part III.K, the maintenance of tax-exempt status for both the institution and the interest on certain bonds requires the university to limit the use of its assets and facilities primarily to further the charitable, educational, or scientific mission of the university (as applicable). Such resources and assets may not be used for private inurement or personal gain of individuals employed or affiliated with the university. These factors thus also push universities to require assignments of IP developed by university personnel using university resources. However, universities are still free to structure assignment agreements with faculty and staff that do not require assignment of all IP, so long as the arrangements do not amount to prohibited private inurement or personal gain.

At the same time and where applicable, "freedom to create" statutes, as discussed above in Part IV.B.1, limit the extent of assignments a university can demand from its employees. Universities may also have procedures for determining which IP they will assert title to, and which they will not, subject to specific statutory allocation rules such as under Bayh-Dole. The university can then waive or assign rights to unencumbered IP back to the employee inventor. Further, students who are paying tuition for a degree or certificate are not considered employees or independent contractors. Thus, universities generally do not have the same latitude to require IP assignments from students, nor will they be required to secure such assignments under the

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[481] *See supra* Part IV.E.

relevant laws and regulations discussed above. However, when students step into paid positions at a university that can establish them as an employee or independent contractor for those specific activities, or become involved in sponsored research funded from either public or private sources, then the university is both able to and in some instances may be required to procure IP assignments from them.

With regard to inventions, there are three different kinds of things that can be owned and/or conveyed along the path to an issued patent. The first is the invention as a potentially patentable idea or trade secret. The second is the patent application that has been filed with the USPTO. The third is the patent that finally issues. Universities could require assignment of any or all of these. In many cases, trade secrets or other know-how and show-how will constitute an important part of the technology or implementation of the invention. Universities may then also include assignments of such information in the overall IP assignment agreement

The treatment of faculty ownership and/or assignment of copyright is widely misunderstood, despite its central role to most research faculty. As discussed above in Part III.E, there is no "teachers exception" to the work made for hire statutory provision in the Copyright Act of 1976, although there is some case law suggesting that some courts might still read such a provision into the current law. Thus, many universities rely on contractual disclaimers of their work made for hire rights to scholarly works by faculty members that are sufficient to contract around the default rule in the 1976 Act.

2. Funding agreements

Funding agreements from federal and state agencies, private foundations, and industry sponsors may contain important requirements or restrictions on the downstream use or transfer of IP, data, or materials arising under the agreement. In some cases, these agreements will be less negotiable than others. Universities need to take particular care when multiple funding sources may converge on a single research project, or closely related research projects.

a. Federal or state government funding agreements

As discussed in Parts III.B and IV.C above, both federal and state research funding agreements can contain significant IP requirements for universities. These funding agreements are also generally less negotiable than agreements from private funding sources due to statutory or regulatory requirements such as those governing federal funding agreements under Bayh-Dole,[482] or California state stem cell research funding under CIRM's regulations. [483] Nonetheless, many deal terms—such as the amount of research funding provided, scope and nature of work to be performed by the university, etc.—will vary considerably from one funding agreement to the next. Further, even federal agencies have some latitude to negotiate further restrictions on downstream licensing and use in funding agreements, including: (i) additional triggers for transfer of subject inventions to the Government; (ii) extra restrictions on licensing; and (iii) disclosure and public distribution of some or all of copyrightable works. [484] However, if the

[482] *See supra* Part III.B.

[483] *See supra* Part IV.C.

[484] Pending legislation may extend the current requirement for public distribution of copyrightable works reporting

federal agency seeks to add provisions for (i), then it has to report on why it is doing so and why this is justified.

For data and materials, federal and state agencies likely have greater latitude in requiring or restricting downstream uses, licenses, and transfers. For federal agencies, there may be some minimal requirements established under the FAR for data arising under a contract (but not under a grant or cooperative agreement). However, federal agencies may be able to add similar requirements (or more) in grants or cooperative agreements. There is no specific regulation in the FAR for biological materials. However, federal agencies are free to require transfer of materials to the Government when they are created specifically under a procurement contract. They may also be free to require such transfer under grants and cooperative agreements. Even if the materials stay with the university, a federal agency may be able to require or restrict downstream uses and transfers.

b. Private foundation funding agreements

Private foundation research funding agreements have traditionally had few if any IP allocation provisions. Recently, however, some foundations have become more active in their expectations as to how funding recipients should translate research results into publicly available products or services, or even simply publications. Notably, the Bill and Melinda Gates Foundation has limited in some cases how research funding recipients transfer or license IP rights so that nonprofits, governments, and to some degree the public, have access to the IP. [485] The exact terms of any funding agreements with private foundations will thus be critical to universities as they attempt to transfer or license IP arising under the agreements.

c. Industry sponsored research agreements

Industry or corporate sponsored research funding differs from that of governments or private foundations because the sponsor in most cases wants to own any resultant IP, data, and materials. The research in fact is often designed to advance R&D on particular products or services that the company will market. But there are many obstacles to a university's ability to assign—or pre-assign—any resultant IP, data, or materials, even if it is otherwise inclined to do so. First, it may have received other funding for the same (or a closely related) research project that will limit its freedom to transfer the IP. Second, the research may be occurring in a facility financed by tax-exempt bonds that will limit the nature and extent of any remunerative use of the facility. Third, the university's own tax-exempt status may be jeopardized if it appears that the university is letting its facilities and personnel be used as "labs for hire" in too many situations. Third, for state universities there may be state law limits to how and when state assets may be disposed. However, in many of these situations the university can still offer rights of first refusal or first rights to negotiate to the corporation. A good example of a first right to negotiate is contained in the collaborative Energy Biosciences Institute agreement between BP and the University of

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on results of NIH funded research to works arising from research funded by any Federal agency. *See supra* Part III.E.

[485] See, e.g., Clay Holtzman, *Gates Foundation global access requirement gives researchers a boost and a burden* , PUGET SOUND BUSINESS JOURNAL (March 13, 2009) *available at http://www.bizjournals.com/seattle/stories/2009/03/16/focus4.html.*

California, Berkeley.[486]

3. Incoming MTAs

As described in Part III.H above, MTAs can provide the largest practical obstacle to ongoing academic research. Unique biological materials can be hard to replicate in another lab and so labs that do not have them will need to request them from the labs that created them. Potential liability for the recipient's use is a major concern. Accordingly, materials providers will usually seek to include indemnification and limitations on liability clauses in the MTA. New inventions arising from the recipient's use that could then be used to block the provider's continuing use of its own materials are also a concern. Thus, materials providers often seek a grant back assignment of any IP developed by the recipient through use of the materials. Recipients often resist this and universities—especially state universities—may be unable to comply without running afoul of other agreements or tax exempt issues. The parties can compromise by having the recipient agree to grant back a license to the provider for any new IP.

Due in large part to all of the foregoing issues, materials providers often seek to retain title to their materials even after the materials are transferred to the recipient. [487] That is, they lease rather than sell the materials. This leaves ownership with the provider and gives it a higher degree of control over uses of the materials as well as the right to demand return or destruction of the materials if the recipient engages in certain uses or activities prohibited by the MTA. Or, the return or destruction right can be triggered by early or planned termination of the MTA. In some cases the materials will be delivered as a *service* instead so that the recipient does not even have legal possession or a bailment on the materials. This service model is quite similar to that used for much software distribution: the "purchaser" of software usually only acquires usage rights under an "end-user license agreement" (EULA), while prohibiting a long list of otherwise lawful activities such as reverse engineering or decompiling the code, further distributing the software, or modifying the code. Likewise, MTAs will limit the recipient to the use of the materials intended by the agreement and expressly prohibit or limit other kinds of activities. Common examples of restrictions include that the recipient may: only evaluate the materials and not use them for any R&D; use the materials only for non-commercial or academic research; not release the materials, or any derivatives, into the environment; and not introduce the materials, or any derivatives, into humans or other living organisms.

4. Incoming data & IP licenses

There are four major areas of consideration for IP and data owners who seek to license others: (i) how to disclose the IP or data and grant the requested rights; (ii) how to value the IP or data and then arrange for appropriate compensation in the license; (iii) how to allocate liabilities and risks; and (iv) how to establish termination triggers and remedies to protect against unauthorized

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[486] Master Agreement Dated November 9, 2007 Between BP TECHNOLOGY VENTURES INC. and THE REGENTS OF THE UNIVERSITY OF CALIFORNIA *available at* http://www.energybiosciencesinstitute.org/images/stories/pressroom/FINAL_EXECUTED_11-14.pdf.

[487] *See* Sean M. O'Connor, *The Use of MTAs to Control Commercialization of Stem Cell Diagnostics & Therapeutics*, 21 Berkeley Technology Law Journal 1017 (2006).

activities by the licensee.[488] For (i), the licensor will first need to make sure that some kind of confidentiality or nondisclosure agreement is in place so that any unpatented information can be maintained as a secret as to third parties. When patents are involved, the licensor will need to determine which of the severable "make," "use," and "sell" rights will be licensed. In the case of licenses to a university, the licensor will likely grant only the "make" and/or "use" rights as the university will not usually be selling products covered by the patent. The licensor will also have to decide whether the license is sublicensable, assignable, or transferable in any other way. For (ii), the parties will have to negotiate the valuation of the IP and license, as well as the exact form of compensation. For (iii), the parties will have to negotiate the legal risks. IP-specific risks vary depending on the transaction, but can be highest for assignments and exclusive licenses. First, does the licensor have proper, unencumbered title to the IP? Second, is the IP valid and enforceable? Third, will the license give the university sufficient freedom to operate in the relevant technology space? For (iv), the parties need to consider how the relationship will end. Breach and termination rights and remedies provide end-of-relationship rules that can help the parties disengage civilly whether things go as planned or not. IP-specific breach and termination issues include: what constitutes material breach; whether material breach automatically terminates the agreement or whether there will be a notice and cure period; and the status of payments and rights after termination.

C. Arrangements Governing Research and Technology Transfer Outputs

Switching from inputs that are in-licensed by universities, to the development and use of research outputs generated by the research enterprise, many of the same basic private ordering issues are at play. Nonetheless, there are some distinct issues to be considered. First, many universities seek to preserve a noncommercial research use right for their own researchers in any assignment or exclusive license of IP, data, or materials. In the case of an assignment, this may take the form of a grant back license. Further, some universities will negotiate grant back licenses for new IP, data, or materials created by the licensee or assignee using the originally licensed or assigned IP, data, or materials. Second, the university may be prohibited from pre-assigning or even pre-licensing IP, data, or materials—especially to the private sector—without jeopardizing its tax-exempt status, bonds, federal funding agreements (where applicable), and possibly state funding agreements or state employee ethics rules (again where applicable). And third, when federal funding is involved, patents may not be assigned to third parties (except patent management firms) without consent of the funding agency, and they can never be licensed on a truly exclusive basis because of the Government License.[489] At the same time, universities may grant multiple "exclusive" or sole licenses to different firms for separate fields of use.

Licensing to start-ups presents challenges often not found in licensing to large established firms. First, because many start-ups will have little to no cash flow for a significant number of years, they may want to use stock or stock options as all or part of their licensing fees. This

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[488] *See* Sean M. O'Connor, *IP Transactions as Facilitators of the Globalized Innovation Economy* , in ROCHELLE DREYFUSS, DIANE L. ZIMMERMAN, AND HARRY FIRST, EDS., WORKING WITHIN THE BOUNDARIES OF INTELLECTUAL PROPERTY (Oxford University Press, 2010).

[489] Most universities will thus include a notice that any exclusive type license is subject to government rights under Bayh-Dole.

presents issues for universities that have policies—or in the case of state universities, laws or regulations—limiting or prohibiting the direct holding of equity stakes in for profit entities. [490] One solution can be to place any such equity stakes in the university's separate private foundation endowment fund. However, because universities generally share licensing revenues with inventors, where equity is accepted for license payments the university will have to redistribute portions of this equity to university inventors (and often the inventors' departments). But in many cases, start-ups will only be able to issue restricted stock which can only be transferred under specific processes established by the federal securities laws and Securities and Exchange Commission (SEC). Further, any party that receives stock with the intended purpose of holding it for others or to transfer it to others, rather than holding it for its own investment purposes, may then be deemed either an investment company or advisor, a broker-dealer, or an underwriter. Accordingly, universities that accept equity often place it into a fund until the issuing company registers the stock with the SEC such that it can be freely traded—often after the company's initial public offering (IPO).

Second, as discussed in Part III.C.4 above, in the wake of the Supreme Court's decision in *MedImmune v. Genentech*,[491] universities are experimenting with strategies to reduce the risks of lost revenues where a licensee decides to challenge the underlying patents just as the licensee begins earning revenues on covered products and hence would start paying royalties. Stanford's approach is to include an automatic trigger clause that doubles the royalty rate following any challenge of the patent by the licensee, and then triples it if the challenge is ultimately unsuccessful. Other universities are including termination clauses that terminate the license upon any challenge by the licensee. [492] Some have employed a mechanism proposed by one of us to structure an up-front conveyance of stock and options designed to track the success of the company generally, and the product development based on the university technology specifically, such that even if the company later challenges the patent, the university still already holds a certain amount of stock and options. Some universities might be employing a strategy advocated by Rochelle Dreyfuss and Lawrence Pope in which the university demands warrants or letters of credit from the licensee as up-front payments which convey valuable, essentially irrevocable instruments to the university that would stand even if the licensee later challenges the patents.

Because many university technology-based start-ups will either be founded by the university inventor, or seek to involve him or her, universities also have been considered their policies around such faculty involvement. In the case of state universities, such consulting and ownership can be constrained by state employee ethics laws, with direct ownership stakes essentially prohibited in most cases. But even if ownership or a substantial role in the firm is allowed, conflicts of interest may still arise. First, the university researcher will be conflicted if he or she participates in the negotiation of the technology transfer license on behalf of the outside start-up. Further, as an inventor he or she may be called upon by the university and its TLO to help advise

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[490] University endowment funds will in almost all cases hold equity stakes in for profit companies either directly, or indirectly through investments in professionally managed funds (which will then invest in for profit companies). But in most cases, these endowment funds will be established as formal and separate private foundations which can then professionally manage the corpus.

[491] 549 U.S. 118 (2007).

[492] This may *not* be in the form of a "no-challenge" provision however, which has been struck down by the Supreme Court.

as to the packaging and licensing of the technology on behalf of the university, which would exacerbate the conflict. Second, he or she may become conflicted in her university research by his or her financial stake in the start-up, especially if this in the form of equity. [493] Third, even the *appearance* of conflicts can be as problematic as actual conflicts for universities and their researchers given the special place and mission in society for universities.

The last major issue for universities to consider when out-licensing research results is where materials will be conveyed. In such cases, the university is strongly encouraged to use MTAs itself. While MTAs can be unpopular—including to the universities when they are on the recipient side—the same reasons that make MTAs vital for industry materials providers generally apply to universities. Further, universities may have extra needs to protect university (or state) assets from potential liability claims. While state universities might have some protections under the doctrine of sovereign immunity from such suits, quasi-public, or state-related universities and private universities will not. In particular, universities will want to ensure that if they have any liability, it is for problems with the materials as delivered by the university to the recipient. The university will want to limit any liability for the recipient's use of the materials, especially if such uses were unexpected or unauthorized. Other than this issue, the same dynamics as described above for universities as recipients of incoming MTAs will apply equally for universities as materials providers.

D. Arrangements Governing Inter-institutional Research Projects

A final critical area of private ordering for universities with regard to their IP, research, and technology transfer, is the necessity in many cases of collaborative research between its faculty and those of other institutions. Such collaboration will raise a host of issues usually addressed through an inter-institutional agreement (IIA). These issues include: IP allocation; material transfers; data sharing and use; and cost and revenue sharing.

The main IP issue for collaborative research is whether new IP will be jointly or singly owned. In determining this, the different institutions will have to consider how the IP will be secured, maintained, and then licensed out. Joint ownership often seems reasonable and fair, but it gives rise to administrative challenges. First, one institution must be tasked with the right and responsibility to secure patent rights arising from the joint research. If not, then the rights might be allowed to dissipate when neither institution takes the initiative. But even if one institution has the primary rights and responsibility to secure the rights, if it fails to do so in a timely fashion, then the other institutions must have rights to step in and take over. Second, the institution that actually secures the IP must have a right to collect some share of the costs from the other institutions. And third, because each co-owner of IP can assign or license their rights independent of the other absent an express agreement to the contrary, the institutions must contractually establish conditions under which the joint IP will be assigned or licensed.

The institutions might decide to try to avoid these issues by assigning the IP to only one institution, with the others receiving grant back licenses and rights to share in any revenues from licensing deals entered into by the "lead" institution. However, this can raise problems if there

[493] In fact, conflicts of interest based on ongoing cash or equity compensation have led major organizations such as the Association of American Medical Colleges (AAMC) to call for limits to outside consulting and equity participation by university medical researchers with outside commercializing entities, whether start-ups or major pharmaceutical companies.

are any restrictions on the assignment of the IP by any of the participating universities (per the issues raised above in Part III.C.2). In the event that the institutions desire the rights of co-ownership but need to allocate the IP to only one institution, they can devise a license to mimic the rights and obligations of co-ownership. The non-owning institution can receive an irrevocable license, with sublicense rights, to give it the same freedom to operate and licensing power as the IP-owning institution. However, the institutions will still need to work out the co-ownership issues described above, because if the IP-owning institution fails to secure or maintain the IP, then the non-owning institution will lose the value of the IP as well. Related to this, the non-owning institution will want a right to enforce the IP directly, or at least be able to step in and do so if the IP-owning institution does not. In the end, even though arrangements that track co-ownership are used quite frequently, they add to the complexities and administrative burdens of both the deal and the ongoing relationship.

APPENDIX A: PRESIDENTIAL MEMORANDUM AND STATEMENT OF GOVERNMENT PATENT POLICY ISSUED BY PRESIDENT JOHN F. KENNEDY, OCTOBER 10, 1963

MEMORANDUM FOR THE HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES[494]

Over the years, through Executive and Legislative actions, a variety of practices has developed within the Executive Branch affecting the disposition of rights to inventions made under contracts with outside organizations. It is not feasible to have complete uniformity of practice throughout the Government in view of the differing missions and statutory responsibilities of the several departments and agencies engaged in research and development. Nevertheless, there is need for greater consistency in agency practices in order to further the governmental and public interests in promoting the utilization of federally financed inventions and to avoid difficulties caused by different approaches by the agencies when dealing with the same class of organizations in comparable patent situations.

From the extensive and fruitful national discussions of government patent practices, significant common ground has come into view. First, a single presumption of ownership does not provide a satisfactory basis for government-wide patent policy on the allocation of rights to inventions. Another common ground of understanding is that the Government has a responsibility to foster the fullest exploitation of the inventions for the public benefit.

Attached for your guidance is a statement of government patent policy, which I have approved, identifying common objectives and criteria and setting forth the minimum rights that government agencies should acquire with regard to inventions made under their grants and contracts. This statement of policy seeks to protect the public interest by encouraging the Government to acquire the principal rights to inventions in situations where the nature of the work to be undertaken or the Government's past investment in the field of work favors full public access to resulting inventions. On the other hand, the policy recognizes that the public interest might also be served by according exclusive commercial rights to the contractor in situations where the contractor has an established nongovernmental commercial position and where there is a greater likelihood that the invention would be worked and put into civilian use than would be the case if the invention were made more freely available.

Wherever the contractor retains more than a non-exclusive license, the policy would guard against failure to practice the invention by requiring that the contractor take effective steps within three years after the patent issues to bring the invention to the point of practical application or to make it available for licensing on reasonable terms. The Government would also have the right to insist on the granting of a license to others to the extent that the invention is required for public use by governmental regulations or to fulfill a health need, irrespective of the purpose of the contract.

The attached statement of policy will be reviewed after a reasonable period of trial in the light of the facts and experience accumulated. Accordingly, there should be continuing efforts to monitor, record, and evaluate the practices of the agencies pursuant to the policy guidelines.

This memorandum and the statement of policy shall be published in the Federal Register.

JOHN F. KENNEDY

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[494] 28 FED. REG. 10,943 (October 12, 1963); 3 C.F.R. 861 (1959-1963).

STATEMENT OF GOVERNMENT PATENT POLICY

Basic Considerations

A. The government expends large sums for the conduct of research and development which results in a considerable number of inventions and discoveries.

B. The inventions in scientific and technological fields resulting from work performed under government contracts constitute a valuable national resource.

C. The use and practice of these inventions and discoveries should stimulate inventors, meet the needs of the government, recognize the equities of the contractor, and serve the public interest.

D. The public interest in a dynamic and efficient economy requires that efforts be made to encourage the expeditious development and civilian use of these inventions. Both the need for incentives to draw forth private initiatives to this end, and the need to promote healthy competition in industry must be weighed in the disposition of patent rights under government contracts. Where exclusive rights are acquired by the contractor, he remains subject to the provisions of the antitrust laws.

E. The public interest is also served by sharing of benefits of government-financed research and development with foreign countries to a degree consistent with our international programs and with the objectives of U.S. foreign policy.

F. There is growing importance attaching to the acquisition of foreign patent rights in furtherance of the interests of U.S. industry and the government.

G. The prudent administration of government research and development calls for a government-wide policy on the disposition of inventions made under government contracts reflecting common principles and objectives, to the extent consistent with the missions of the respective agencies. The policy must recognize the need for flexibility to accommodate special situations.

Policy

SECTION 1. The following basic policy is established for all government agencies with respect to inventions or discoveries made in the course of or under any contract of any government agency, subject to specific statutes governing the disposition of patent rights of certain government agencies.

(a) Where

(1) a principal purpose of the contract is to create, develop or improve products, processes, or methods which are intended for commercial use (or which are otherwise intended to be made available for use) by the general public at home or abroad, or which will be required for such use by governmental regulations; or

(2) a principal purpose of the contract is for exploration into fields which directly concern the public health or the public welfare; or

(3) the contract is in a field of science or technology in which there has been little significant experience outside of work funded by the government, or where the government has been the principal developer of the field, and the acquisition of exclusive

rights at the time of contracting might confer on the contractor a preferred or dominant position; or

(4) the services of the contractor are

(i) for the operation of a government-owned research or production facility; or

(ii) for coordinating and directing the work of others,

the government shall normally acquire or reserve the right to acquire the principal or exclusive rights throughout the world in and to any inventions made in the course of or under the contract. In exceptional circumstances the contractor may acquire greater rights than a non-exclusive license at the time of contracting, where the head of the department or agency certifies that such action will best serve the public interest. Greater rights may also be acquired by the contractor after the invention has been identified, where the invention when made in the course of or under the contract is not a primary object of the contract, provided the acquisition of such greater rights is consistent with the intent of this Section 1(a) and is a necessary incentive to call forth private risk capital and expense to bring the invention to the point of practical application.

(b) In other situations, where the purpose of the contract is to build upon existing knowledge or technology to develop information, products, processes, or methods for use by the government, and the work called for by the contract is in a field of technology in which the contractor has acquired technical competence (demonstrated by factors such as know-how, experience, and patent position) directly related to an area in which the contractor has an established nongovernmental commercial position, the contractor shall normally acquire the principal or exclusive rights throughout the world in and to any resulting inventions, subject to the government acquiring at least an irrevocable non-exclusive royalty free license throughout the world for governmental purposes.

(c) Where the commercial interests of the contractor are not sufficiently established to be covered by the criteria specified in Section 1(b), above, the determination of rights shall be made by the agency after the invention has been identified, in a manner deemed most likely to serve the public interest as expressed in this policy statement, taking particularly into account the intentions of the contractor to bring the invention to the point of commercial application and the guidelines of Section 1(a) hereof, provided that the agency may prescribe by regulation special situations where the public interest in the availability of the inventions would best be served by permitting the contractor to acquire at the time of contracting greater rights than a non-exclusive license. In any case the government shall acquire at least a non-exclusive royalty free license throughout the world for governmental purposes.

(d) In the situation specified in Sections 1(b) and 1(c), when two or more potential contractors are judged to have presented proposals of equivalent merit, willingness to grant the government principal or exclusive rights in resulting inventions will be an additional factor in the evaluation of the proposals.

(e) Where the principal or exclusive (except as against the government) rights in an invention remain in the contractor, he should agree to provide written reports at reasonable intervals, when requested by the government, on the commercial use that is being made or is intended to be made of inventions made under government contracts.

(f) Where the principal or exclusive (except as against the government) rights in an invention remain in the contractor, unless the contractor, his licensee, or his assignee has taken effective steps within three years after a patent issues on the invention to bring the invention to the point of practical application or has made the invention available for licensing royalty free or on terms that are reasonable in the circumstances, or can show cause why he should retain the principal or

exclusive rights for a further period of time, the government shall have the right to require the granting of a license to an applicant on a non-exclusive royalty free basis.

(g) Where the principal or exclusive (except as against the government) rights to an invention are acquired by the contractor, the government shall have the right to require the granting of a license to an applicant royalty free or on terms that are reasonable in the circumstances to the extent that the invention is required for public use by government regulations or as may be necessary to fulfill health needs, or for other public purposes stipulated in the contract.

(h) Where the government may acquire the principal rights and does not elect to secure a patent in a foreign country, the contractor may file and retain the principal or exclusive foreign rights subject to retention by the government of at least a royalty free license for governmental purposes and on behalf of any foreign governments pursuant to any existing or future treaty or agreement with the United States.

SECTION 2. Government-owned patents shall be made available and the technological advances covered thereby brought into being in the shortest time possible through dedication or licensing and shall be listed in official government publications or otherwise.

SECTION 3. The Federal Council for Science and Technology in consultation with the Department of Justice shall prepare at least annually a report concerning the effectiveness of this policy, including recommendations for revision or modification as necessary in light of the practices and determinations of the agencies in the disposition of patent rights under their contracts. A patent advisory panel is to be established under the Federal Council for Science and Technology to

(a) develop by mutual consultation and coordination with the agencies common guidelines for the implementation of this policy, consistent with existing statutes, and to provide overall guidance as to disposition of inventions and patents in which the government has any right or interest; and

(b) encourage the acquisition of data by government agencies on the disposition of patent rights to inventions resulting from federally-financed research and development and on the use and practice of such inventions, to serve as the basis for policy review and development; and

(c) make recommendations for advancing the use and exploitation of government-owned domestic and foreign patents.

SECTION 4. Definitions: As used in this policy statement, the stated terms in singular and plural are defined as follows for the purposes hereof:

(a) *Government agency*—includes any Executive department, independent commission, board, office, agency, administration, authority, or other government establishment of the Executive Branch of the Government of the United States of America.

(b) *Invention or Invention or discovery*—includes any art, machine, manufacture, design, or composition of matter, or any new and useful improvement thereof, or any variety of plant, which is or may be patentable under the Patent Laws of the United States of America or any foreign country.

(c) *Contractor*—means any individual, partnership, public or private corporation, associations, institution, or other entity which is a party to the contract.

(d) *Contract*—means any actual or proposed contract, agreement, grant, or other arrangement, or sub-contract entered into with or for the benefit of the government where a purpose of the contract is the conduct of experimental, developmental, or research work.

(e) *Made*—when used in relation to any invention or discovery means that the conception or first actual reduction to practice of such invention in the course of or under the contract.

(f) *Governmental purpose*—means the right of the Government of the United States (including any agency thereof, state, or domestic municipal government) to practice and have practiced (made or have made, used or have used, sold or have sold) throughout the world by or on behalf of the Government of the United States.

(g) *To the point of practical application*—means to manufacture in the case of a composition or product, to practice in the case of a process, or to operate in the case of a machine and under such conditions as to establish that the invention is being worked and that its benefits are reasonably accessible to the public.

APPENDIX B: PRESIDENTIAL MEMORANDUM AND STATEMENT OF GOVERNMENT PATENT POLICY ISSUED BY PRESIDENT RICHARD M. NIXON ON AUGUST 23, 1971

THE WHITE HOUSE
Washington, August 23, 1971

MEMORANDUM FOR HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES

On October 10, 1963, President Kennedy forwarded to the Heads of Executive Departments and Agencies a Memorandum and Statement of Government Patent Policy for their guidance in determining the disposition of rights to inventions made under Government-sponsored grants and contracts. On the basis of the knowledge and experience then available, this Statement first established Government-wide objectives and criteria, within existing legislative constraints, for the allocation of rights to inventions between the Government and its contractors.

It was recognized that actual experience under the Policy could indicate the need for revision or modification. Accordingly, a Patent Advisory Panel was established under the Federal Council for Science and Technology for the purpose of assisting the agencies in implementing the Policy, acquiring data on the agencies' operations under the Policy, and making recommendations regarding the utilization of Government-owned patents. In December 1965, the Federal Council established the Committee on Government Patent Policy to assess how this Policy was working in practice, and to acquire and analyze additional information that could contribute to the reaffirmation or modification of the Policy.

The efforts of both the Committee and the Panel have provided increased knowledge of the effects of Government patent policy on the public interest. More specifically, the studies and experience over the past seven years have indicated that:

(a) A single presumption of ownership of patent rights to Government-sponsored inventions either in the Government or in its contractors is not a satisfactory basis for Government patent policy, and that a flexible, Government-wide policy best serves the public interest;

(b) The commercial utilization of Government-sponsored inventions, the participation of industry in Government research and development programs, and commercial competition can be influenced by the following factors: the mission of the contracting agency; the purpose and nature of the contract; the commercial applicability and market potential of the invention; the extent to which the invention is developed by the contracting agency; the promotional activities of the contracting agency; the commercial orientation of the contractor and the extent of his privately financed research in the related technology; and the size, nature and research orientation of the pertinent industry;

(c) In general, the above factors are reflected in the basic principles of the 1963 Presidential Policy Statement.

Based on the results of the studies and experience gained under the 1963 Policy Statement certain improvements in the Policy have been recommended which would provide: (1) agency heads with additional authority to permit contractors to obtain greater rights to inventions where necessary to achieve utilization or where equitable circumstances would justify such allocation of rights, (2) additional guidance to the agencies in promoting the utilization of Government-sponsored inventions, (3) clarification of the rights of States and municipal governments in inventions in which the Federal Government acquires a license, and (4) a more definitive data base for evaluating the administration and effectiveness of the Policy and the feasibility and

desirability of further refinement or modification of the Policy.

I have approved the above recommendations and have attached a revised Statement of Government Patent Policy for your guidance. As with the 1963 Policy Statement, the Federal Council shall make a continuing effort to record, monitor and evaluate the effects of this Policy Statement. A Committee on Government Patent Policy. operating under the aegis of the Federal Council for Science and Technology, shall assist the Federal Council in these matters.

This memorandum and statement of policy shall be published in the Federal Register.

RICHARD NIXON

STATEMENT OF GOVERNMENT PATENT POLICY[495]

Basic Considerations

A. The Government expends large sums for the conduct of research and development which results in a considerable number of inventions and discoveries.

B. The inventions in scientific and technological fields resulting from work performed under Government contracts constitute a valuable national resource.

C. The use and practice of these inventions and discoveries should stimulate inventors, meet the needs of the Government, recognize the equities of the contractor, and serve the public interest.

D. The public interest in a dynamic and efficient economy requires that efforts be made to encourage the expeditious development and civilian use of these inventions. Both the need for incentives to draw forth private initiatives to this end, and the need to promote healthy competition in industry must be weighed in the disposition of patent rights under Government contracts. Where exclusive rights are acquired by the contractor, he remains subject to the provisions of the antitrust laws.

E. The public interest is also served by sharing of benefits of Government-financed research and development with foreign countries to a degree consistent with our international programs and with the objectives of U.S. foreign policy.

F. There is growing importance attaching to the acquisition of foreign patent rights in furtherance of the interests of U.S. industry and the Government.

G. The prudent administration of Government research and development calls for a Government-wide policy on the disposition of inventions made under Government contracts reflecting common principles and objectives, to the extent consistent with the missions of the respective agencies. The policy must recognize the need for flexibility to accommodate special situations.

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[495] [Ed. note: Portions of this Statement of Government Patent Policy that were substantively modified from the Kennedy Statement of Government Patent Policy are indicated by bold face for additions and strike through for deletions.]

Policy

SECTION 1. The following basic policy is established for all Government agencies with respect to inventions or discoveries made in the course of or under any contract of any Government agency, subject to specific statutes governing the disposition of patent rights of certain Government agencies.

(a) Where

(1) a principal purpose of the contract is to create, develop or improve products, processes, or methods which are intended for commercial use (or which are otherwise intended to be made available for use) by the general public at home or abroad, or which will be required for such use by governmental regulations; or

(2) a principal purpose of the contract is for exploration into fields which directly concern the public health**, public safety,** or ~~the~~ public welfare; or

(3) the contract is in a field of science or technology in which there has been little significant experience outside of work funded by the Government, or where the Government has been the principal developer of the field, and the acquisition of exclusive rights at the time of contracting might confer on the contractor a preferred or dominant position; or

(4) the services of the contractor are

(i) for the operation of a Government-owned research or production facility; or

(ii) for coordinating and directing the work of others,

the Government shall normally acquire or reserve the right to acquire the principal or exclusive rights throughout the world in and to any inventions made in the course of or under the contract.

In exceptional circumstances the contractor may acquire greater rights than a non-exclusive license at the time of contracting, where the head of the department or agency certifies that such action will best serve the public interest. Greater rights may also be acquired by the contractor after the invention has been identified where the ~~inventions when made in the course of or under the contract is not a primary object of the contract, provided~~ **head of the department or agency determines that** the acquisition of such greater rights is consistent with the intent of this Section 1(a) and is **either** a necessary incentive to call forth private risk capital and expense to bring the invention to the point of practical application **or that the Government's contribution to the invention is small compared to that of the contractor. Where an identified invention made in the course of or under the contract is not a primary object of the contract, greater rights may also be acquired by the contractor under the criteria of Sections 1(c).**

(b) In other situations, where the purpose of the contract is to build upon existing knowledge or technology, to develop information, products, processes, or methods for use by the Government, and the work called for by the contract is in a field of technology in which the contractor has acquired technical competence (demonstrated by factors such as know-how, experience, and patent position) directly related to an area in which the contractor has an established nongovernmental commercial position, the contractor shall normally acquire the principal or exclusive rights throughout the world in and to any resulting inventions, ~~subj ect to the government acquiring at least an irrevocable non exclusive royalty free license throughout the world for governmental purposes~~.

(c) Where the commercial interests of the contractor are not sufficiently established to be

covered by the criteria specified in Section 1(b), above, the determination of rights shall be made by the agency after the invention has been identified, in a manner deemed most likely to serve the public interest as expressed in this policy statement, taking particularly into account the intentions of the contractor to bring the invention to the point of commercial application and the guidelines of Section 1(a) hereof, provided that the agency may prescribe by regulation special situations where the public interest in the availability of the inventions would best be served by permitting the contractor to acquire at the time of contracting greater rights than a non-exclusive license. ~~In any case the government shall acquire at least a non-exclusive royalty free license throughout the world for governmental purposes.~~

(d) In the situations specified in Sections 1(b) and 1(c), when two or more potential contractors are judged to have presented proposals of equivalent merit, willingness to grant the Government principal or exclusive rights in resulting inventions will be an additional factor in the evaluation of the proposals.

(e) Where the principal or exclusive ~~(except as against the government)~~ rights in an invention remain in the contractor, he should agree to provide written reports at reasonable intervals, when requested by the Government, on the commercial use that is being made or is intended to be made of inventions made under Government contracts.

(f) Where the principal or exclusive ~~(except as against the government)~~ rights in an invention remain in the contractor, unless the contractor, his licensee, or his assignee has taken effective steps within three years after a patent issues on the invention to bring the invention to the point of practical application or has made the invention available for licensing royalty-free or on terms that are reasonable in the circumstances, or can show cause why he should retain the principal or exclusive rights for a further period of time, the Government shall have the right to require the granting of a **nonexclusive or exclusive** license to a~~n~~ **responsible** applicant**(s)** on ~~a non-exclusive royalty free basis~~ **terms that are reasonable under the circumstances**.

(g) Where the principal or exclusive ~~(except as against the government)~~ rights to an invention are acquired by the contractor, the Government shall have the right to require the granting of a **nonexclusive or exclusive** license to a~~n~~ **responsible** applicant**(s)** ~~royalty free or~~ on terms that are reasonable in the circumstances **(i)** to the extent that the invention is required for public use by government regulations**,** or **(ii)** as may be necessary to fulfill health **or safety** needs, or **(iii)** for other public purposes stipulated in the contract.

(h) **Whenever the principal or exclusive rights in an invention remain in the contractor, the Government shall normally acquire, in addition to the rights set forth in Sections 1(e), 1(f), and 1(g),**

(1) at least a nonexclusive, nontransferable, paid-up license to make, use, and sell the invention throughout the world by or on behalf of the Government of the United States (including any Government agency) and States and domestic municipal governments, unless the agency head determines that it would not be in the public interest to acquire the license for the States and domestic municipal governments; and

(2) the right to sublicense any foreign government pursuant to any existing or future treaty or agreement if the agency head determines it would be in the national interest to do acquire this right; and

(3) the principal or exclusive rights to the invention in any country in which the contractor does not elect to secure a patent.

(i) Whenever the principal or exclusive rights in an invention are acquired by the

Government, there may be reserved to the contractor a revocable or irrevocable nonexclusive royalty-free license for the practice of the invention throughout the world; an agency may reserve the right to revoke such license so that it might grant an exclusive license when it determines that some degree of exclusivity may be necessary to encourage further development and commercialization of the invention. Where the Government ~~may~~ **has a right to** acquire the principal **or exclusive** rights **to an invention** and does not elect to secure a patent in a foreign country, **the Government may permit** the contractor ~~may file and retain the principal or exclusive foreign rights subject to retention by the government of at least a royalty free license for governmental purposes and on behalf of any foreign governments pursuant to any existing or future treaty or agreement with the United States~~ **to acquire such rights in any foreign country in which he elects to secure a patent, subject to the Government's rights set forth in Section 1(h)**.

SECTION 2. **Under regulations prescribed by the Administrator of General Services,** Government-owned patents shall be made available and the technological advances covered thereby brought into being in the shortest time possible through dedication or licensing **, either exclusive or nonexclusive,** and shall be listed in official Government publications or otherwise.

SECTION 3. The Federal Council for Science and Technology in consultation with the Department of Justice shall prepare at least annually a report concerning the effectiveness of this policy, including recommendations for revision or modification as necessary in light of the practices and determinations of the agencies in the disposition of patent rights under their contracts. ~~A patent advisory panel is to be established under the Federal Council for Science and Technology~~ **The Federal Council for Science and Technology shall continue** to

(a) develop by mutual consultation and coordination with the agencies common guidelines for the implementation of this policy, consistent with existing statutes, and to provide overall guidance as to disposition of inventions and patents in which the Government has any right or interest; and

(b) ~~encourage the acquisition of~~ **acquire** data ~~by~~ **from the** Government agencies on the disposition of patent rights to inventions resulting from federally financed research and development and on the use and practice of such inventions to serve as t~~he basis~~ **bases** for policy review and development; and

(c) make recommendations for advancing the use and exploitation of Government-owned domestic and foreign patents.

Each agency shall record the basis for its actions with respect to inventions and appropriate contracts under this statement.

SECTION 4. Definitions: As used in this policy statement, the stated terms in singular and plural are defined as follows for the purposes hereof:

(a) *Government agency*—includes any executive department, independent commission, board, office, agency, administration, authority, **Government corporation,** or other Government establishment of the executive branch of the Government of the United States of America.

(b) *States*—means the States of the United States, the District of Columbia, Puerto Rico, the Virgin Islands, American Samoa, Guam, and the Trust Territory of the Pacific Islands.

~~(b)~~ **(c)** *Invention, or Invention or discovery*—includes any art, machine, manufacture, design, or composition of matter, or any new and useful improvement thereof, or any variety of plant, which is or may be patentable under the Patent Laws of the United States of America or any foreign country.

~~(c)~~ **(d)** *Contractor*—means any individual, partnership, public or private corporation,

associations, institution, or other entity which is a party to the contract.

~~(d)~~ **(e)** *Contract*—means any actual or proposed contract, agreement, grant, or other arrangement, or sub-contract entered into with or for the benefit of the Government where a purpose of the contract is the conduct of experimental, developmental, or research work.

~~(e)~~ **(f)** *Made*—when used in relation to any invention or discovery means t~~hat~~ the conception or first actual reduction to practice of such invention in the course of or under the contract.

~~(f) *Governmental purpose*—means the right of the Government of the United States (including any agency thereof, state, or domestic municipal government) to practice and have practiced (made or have made, used or have used, sold or have sold) throughout the world by or on behalf of the Government of the United States.~~

(g) *To the point of practical application*—means to manufacture in the case of a composition or product, to practice in the case of a process, or to operate in the case of a machine and under such conditions as to establish that the invention is being worked and that its benefits are reasonably accessible to the public.

APPENDIX C: STANDARD FORM OF INSTITUTIONAL PATENT AGREEMENT ("IPA")

INSTITUTIONAL PATENT AGREEMENT[496]

This Agreement is made and entered into by and between the United States of America as represented by the _____hereinafter sometimes referred to as the "Agency," and _ , hereinafter referred to as the "Institution."

___WITNESSETH:

WHEREAS, in accordance with the President's Memorandum and Statement of Government Patent Policy dated August 23, 1971, and the provisions of 41 CFR 1-9.107-4(a)(6), it has been determined by the Agency that the Institution has a technology transfer program meeting the criteria of41 CFR 1-9.109-7 in that the Institution's patent policy as set forth in _ and its technology transfer practices have been reviewed and found acceptable; and

WHEREAS, the Institution is desirous of entering into an agreement whereby it may retain the entire right, title, and interest in and administer inventions made in the course of or under research supported by the Agency, subject to certain rights acquired by the Government:

NOW, THEREFORE, in consideration of the foregoing, the parties hereto agree as follows:

I. Scope of Agreement

This Agreement defines the rights of the parties hereto regarding the allocation of rights in Subject Inventions reported after the date of this Agreement and made under contracts entered into with the Agency, including contracts entered into prior to this Agreement, except contracts specifically excluded by the Agency.

II. Definitions

(a) "Subject Invention" means any invention or discovery of the Institution conceived or first actually practiced in the course of or under a contract with the Agency, and includes any art, method, process, machine, manufacture, design, or compositions of matter, or any new and useful improvement thereof, and any variety of plant, which is or may be patentable under the Patent Laws of the United States of America or any foreign country.

(b) "Contract" means any contract, [agreement, grant, or other arrangement] or subcontract entered into with or for the benefit of the Government, where a purpose of the contract is the conduct of experimental, developmental, or research work.

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[496] U.S. Senate, Hearings Before the Subcomm. on Monopoly and Anticompetitive Activities of the Select Comm. on Small Business, 95th Cong., May 22, 23, June 20, 21, and 26, 1978 (Part 2: Appendix: GSA submission for the record: Minutes of meetings of interagency committees on revision of the draft of the Government-wide IPA (notes omitted), pp. 1831-43).

(c) “States and domestic municipal governments” means the States of the United States, the District of Columbia, Puerto Rico, the Virgin Islands, American Samoa, Guam, and the Trust Territory of the Pacific Islands, and any political subdivisions and agencies thereof.

(d) “To bring to the point of practical application” means to manufacture in the case of a composition or product, to practice in the case of a process, or to operate in the case of a machine and under such conditions as to establish that the invention is being worked and that its benefits are reasonably accessible to the public.

(e) “Made” when used in relation to any invention or discovery, means the conception or first actual reduction to practice of such invention in the course of or under a contract.

III. Allocation of Principal Rights

(a) The Institution may retain the entire right, title, and interest throughout the world or in any country thereof in and to each Subject Invention disclosed pursuant to Section V., below, subject to the provisions of this Agreement. The Institution shall include with each Subject Invention disclosure an election whether it will retain the entire right, title, and interest in the invention throughout the world or in any country thereof subject to the rights acquired by the Government in Section IV of the Agreement: provided that the Institution may request an extension of the time for election. If the Institution elects not to retain rights in a Subject Invention, it shall supply the Agency with any written reports upon which this decision was made. such as marketing reports, patent searches, or other similar reports.

(b) The Institution agrees to convey to the Government, upon request, the entire domestic right, title, and interest in any Subject Invention when the Institution:

(i) does not elect under Section III(a) to retain such rights; or

(ii) fails to have a United States Patent Application filed on the invention in accordance with Section VI(a), or decides not to continue prosecution of such application; or

(iii) at any time, no longer desires to retain title.

(c) The Institution agrees to convey to the Government, upon request, the entire right, title, and interest in any Subject Invention in any foreign country when the Institution:

(i) does not elect under Section III(a) to retain such rights in the country; or

(ii) fails to have a patent application filed in the country on the invention in accordance with Section VII(a); except that if an application has been filed in a foreign country after the time specified in Section VII(a) but prior to such request by the Government, the Institution shall retain the entire right, title, and interest in the Subject Invention in the country involved; or

(iii) decides not to continue prosecution of such application or to pay any maintenance fees

covering the invention. To avoid forfeiture of the patent application or patent, the Institution shall notify the Agency not less than sixty (60) days before the expiration period for any action required by the foreign patent office.

(d) A conveyance, requested pursuant to Sections III(b) or (c) of this Agreement, shall be made by delivering to the Agency duly executed instruments (prepared by the Government) and such other papers as are deemed necessary to vest in the Government the entire right, title, and interest to enable the Government to apply for and prosecute patent applications covering the invention in this or the foreign country, respectively, or otherwise establish its ownership of such invention.

IV. Minimum Rights Acquired by the Government

(a) With respect to each Subject Invention to which the Institution retains principal or exclusive rights, the Institution hereby grants to the Government of the United States a nonexclusive, nontransferable, paid-up license to make, use, and sell each Subject Invention throughout the world by or on behalf of the Government of the United States (including any Government agency) ad States and domestic municipal governments, unless the Agency determines after the invention has been identified that it would not be in the public interest to acquire the license for States and domestic municipal governments.

(b) With respect to each Subject Invention to which the Institution retains principal or exclusive rights, the Institution agrees to grant to responsible applicants, upon request of the Agency, a license on terms that are reasonable under the circumstances;

(i) unless the Institution, its licensee, or its assignee, demonstrates to the Government that effective steps have been taken within three (3) years after a patent issues on such invention to bring the invention to the point of practical application or that the invention has been made available for licensing royalty-free or on terms that are reasonable in the circumstances or can show cause why the principal or exclusive rights should be retained for a further period of time; or

(ii) to the extent that the invention is required for public use by governmental regulations or as may be necessary to fulfill public health or safety needs, or other public purposes stipulated in the applicable contract.

Any requests made pursuant to this subparagraph (b) shall be by the head of the Agency or a duly authorized agent, and the Institution shall be given written notice of any proposed request not less than thirty (30) days prior to the issuance of a formal request and, if it so requests, shall be granted a hearing before the request is issued and otherwise made effective.

(c) Notwithstanding Section III(a) or any other provisions of this Agreement, the Institution agrees to license or assign Subject Inventions as directed by the Agency to comply with the terms of any applicable international agreement. At the request of the Institution, the Agency will, after an invention is identified, identify the specific obligations of the Institution with respect to such invention which might otherwise conflict with the provisions of this Agreement.

(d) Nothing contained in this section shall be deemed to grant to the Government any rights with respect to any invention other than a Subject Invention.

V. Invention Identification, Disclosure, ad Reports

(a) The Institution shall furnish the Agency:

(i) a complete technical disclosure for each Subject Invention promptly after conception or first actual reduction to practice, whichever occurs first in the course of or under the contract, but in any event immediately upon any on sale, public use, or publication of the invention known to the Institution. The disclosure shall identify the contract and inventor and shall be sufficiently complete in technical detail and appropriately illustrated in sketch or diagram to convey to one skilled in the art to which the invention pertains a clear understanding of the nature, purpose, operation, and, to the extent known, the physical, chemical, biological, or electrical characteristics of the invention. Such disclosure shall be furnished directly to the Agency in addition to any other requirement under the contract for the submission of progress or other reports and whether or not reference to the Subject Invention has been made in any such reports.

(ii) Complete information concerning the date and identity of any on sale, public use, or publication of the invention which may constitute a statutory bar under 35 USC 102, which was authorized by or known to the Institution or any contemplated action of this nature.

(iii) A final report within three months after completion of the work under any contract, listing all Subject Inventions or certifying that there were no such inventions.

(b) The Institution shall obtain patent agreements to effectuate the provisions of this Agreement from all persons in its employ who perform any part of the work under any contract except nontechnical personnel, such as clerical and manual laborers.

(c) The Institution agrees that the Government may duplicate and disclose Subject Invention disclosures and, subject to Section XI, all other reports and papers furnished or required to be furnished pursuant to this Agreement. Notwithstanding, the Agency will take reasonable care to ensure that such disclosures are not released to the public unless the Agency determines, after consultation with the Institution, that the proposed release will not adversely affect the Institution's opportunity to obtain patent protection.

(d) The Institution shall not bar or prohibit publication of disclosures of Subject Inventions on which patent applications have been filed.

VI. Filing of Domestic Patent Applications

(a) With respect to each Subject Invention in which the Institution elects to retain domestic rights pursuant to section III(a) of this Agreement the Institution shall have a domestic patent application filed within six (6) months after an election has been made pursuant to section III(a)

of this Agreement or such longer period as may be approved in writing by the Agency. However, if the Agency determines that there has been such use or publication of the invention so as to initiate a one-year statutory period which ends less than six months after the election, the Agency may require the application to be filed one month or less before the end of the statutory period. With respect to such invention, the Institution shall promptly notify the Agency of any decision not to file an application.

(b) For each Subject Invention on which a patent application is filed by or on behalf of the Institution, the Institution shall

(i) within six months after such filing, or within six months after submission of the invention disclosure if the patent application was filed prior to the contract, deliver to the Agency (A) a copy of the application as filed, including the filing date and serial number; (B) a copy of any assignment from the inventor or inventors to the Institution of all right, title and interest in the invention properly recorded in the United States Patent and Trademark Office; and (C) a duly executed and approved instrument on the form specified in Exhibit A which is attached hereto and by this reference made a part hereof;

(ii) include the following statement, appropriately completed, in the second paragraph of the specification of the application and any patents issued on the Subject Invention, "The Government has rights in this invention pursuant to Contract(s) (or Grant(s)) No(s). _____ awarded by (identify the Agency or Agencies)";

(iii) not less than thirty (30) days before the expiration of the response period for any action required by the United States Patent and Trademark Office, notify the Agency of any decision not to continue the prosecution of the application and deliver to the Agency upon request executed instruments granting the Government a power of attorney;

(iv) upon request, fully advise the Agency concerning all actions taken during the prosecution of any patent application and furnish copies of any relevant documents as requested; and

(v) provide the Agency with a copy of the patent within six months after a patent issues on the application.

VII. Filing of Foreign Patent Applications

(a) With respect to each Subject Invention in which the Institution elects to retain principal rights in a foreign country pursuant to section III(a) of this Agreement, the Institution shall have a patent application filed on the invention in such country, in accordance with applicable statutes and regulations, and within one of the following periods:

(i) eight months from the date of a corresponding United States application filed by or on behalf of the Institution; or if such an application is not filed, six months after an election is made pursuant to section III(a) of this Agreement;

(ii) six months from the date a license is granted by the Commissioner of Patents and Trademarks to file foreign applications when such filing has been prohibited by security reasons; or

(iii) such longer period as may be approved in writing by the Agency.

(b) The Institution shall notify the Agency of foreign applications filed and, upon request, shall furnish an English version of such foreign application without additional compensation.

VIII. Subcontracts

(a) Except as provided in (b), below, or when the subcontractor holds an Institutional Patent Agreement with the Agency, the Institution shall include in any subcontract where a purpose of that subcontract is the conduct of experimental, developmental, or research work either the "Patent Rights – Acquisition by the Government" clause found at 41 CFR 1-9.107-5(a) or the following clause:

Patent Rights

(a) The Contractor hereby agrees to report fully and promptly to _____ (Institution) any invention conceived or first actually reduced to practice in the course of or under this contract (hereinafter referred to as "Subject Invention(s)," and to assign all right, title, and interest in and to such invention to _____ (Institution) or its designee.

(b) In addition, the Contractor agrees to furnish the following materials, disclosures and reports:

(i) Upon request, such duly executed instruments (prepared by the _____ (Institution) or its designee) and such other papers as are deemed necessary to vest in the _____ (Institution) or its designee the rights granted under this clause and to enable the _____ (Institution) or its designee to apply for and prosecute any patent application, in any country, covering such invention.

(ii) Prior to final settlement of this contract, a final report listing all Subject Inventions or certifying that no inventions were conceived or first actually reduced to practice under the contract.

(c) The Contractor shall include in any subcontract either a clause identical to this clause or the "Patent Rights – Acquisition by the Government" clause found at 41 CFR 1-9.107-5(a) if a purpose of the subcontract is experimental, developmental, or research work. If a subcontractor refuses to accept either of these clauses or if, in the opinion of the Contractor, these clauses are inconsistent with the policy set forth in 41 CFR 1-9.107-3, the Contractor (i) shall promptly notify the Institution and (ii) shall not proceed with the subcontract without the written authorization of the Institution. It is understood that the Institution will seek direction from the _____ (insert name of appropriate Agency).

(d) The Contractor shall report any subcontracts containing a patent rights clause to the

Institution. The Contractor shall not be obligated to enforce the agreements of any Subcontractor hereunder relating to the obligations of the Subcontractor to the Government in regard to Subject Inventions.

[End of Clause]

(b) In the event of a refusal by a subcontractor to accept either of the clauses specified in (a), or if, in the opinion of the Institution, these clauses are inconsistent with the policy set forth in 41 CFR 1-9.107-3, the Institution (i) shall promptly submit a written notice to the Agency setting forth reasons for the Subcontractor's refusal and other pertinent information which may expedite disposition of the matter; and (ii) shall not proceed with the subcontract without the written authorization of the Agency.

(c) It is understood that the Government is a third party beneficiary of any subcontract clause granting rights to the Government in Subject Inventions, and the Institution hereby assigns to the Government all rights that it would have to enforce the Subcontractor's obligations for the benefit of the Government with respect to Subject Inventions. The Institution shall not be obligated to enforce the agreements of any subcontractor hereunder relating to the obligations of the Subcontractor to the Government in regard to Subject Inventions.

(d) Nothing in this Agreement is intended to preclude the Institution from granting a subcontractor rights or an option to rights in any inventions made by the subcontractor to the extent such rights are consistent with the provisions of this Agreement.

IX. Administration of Inventions in Which the Institution Elects to Retain Rights

(a) The Institution shall administer those Subject Inventions to which it elects to retain title in the public interest and shall, except as provided in subsection (b), below, make them available through licensing on a nonexclusive, royalty-free or reasonable royalty basis to all qualified applicants.

(b) The Institution may license a Subject Invention on an exclusive basis if it determines that an exclusive license is required in the public interest because it is necessary as an incentive for development of the invention or because market conditions are such as to require licensing on an exclusive basis in order to bring the invention to the point of practical application. Any exclusive license issued by the Institution under a U.S. patent or patent application shall be for a limited period of time and such period shall not, unless otherwise approved by the Agency, exceed five years from the date of the first commercial sale or use in the United States of America of a product or process embodying the invention, or eight years from the date of the exclusive license excepting that time before regulatory agencies necessary to obtain premarket clearance, whichever occurs first. Such license shall also provide that the licensee shall use all reasonable efforts to effect introduction into the commercial market as soon as practicable, consistent with sound and reasonable business practices and judgment. Any extension of the maximum period of exclusivity shall be subject to the approval of the Agency. Upon expiration of the period of exclusivity or any extension thereof, licenses shall be offered to all qualified applicants at a reasonable royalty rate not in excess of the exclusive license royalty rate.

(c) Royalties shall not normally be in excess of accepted trade practice. The Institution also agrees that no royalties shall be payable by its licensees or sublicensees with respect to any Subject Invention in procurements for or on behalf of the Government and to so provide in any instrument transferring rights to any party in any Subject Invention.

(d) The balance of the royalty income after payment of expenses, including payment to inventors, incidental to the administration of all inventions assigned to it pursuant to the provisions of this Agreement shall be utilized for the support of education or research.

(e) All licenses issued by the Institution to other than the Government of the United States under any patent application or patent on a Subject Invention shall be made expressly subject to the conditions of this Agreement. The Institution shall, upon request, promptly furnish copies of any license agreements entered into by it to the Agency.

X. Patent Management Organizations

The Institution shall not assign any Subject Invention to parties (other than the Agency) except that it may assign rights in the invention to the following patent management organizations -- _____ -- or any other patent management organization if subsequently approved by the Agency. Any reference to an Institution in this Agreement shall also include a patent management organization where applicable and an assignment to such organization shall specifically be made subject to all the terms and conditions of this Agreement.

XI. Reports on Development and Commercial Use

The Institution shall provide a written annual report to the Agency on or before December 31 st of each year covering the preceding year ending September 30 th, regarding the status of development and commercial use that is being made or intended to be made of each Subject Invention left for administration to the Institution and the steps that have been taken by the Institution to bring the invention to the point of practical application. Such reports shall include information regarding status of development, the date of first commercial sale or use, gross royalties received by the Institution, and such other data and information as the Agency may reasonably specify. To the extent data or information supplied pursuant to this section is considered by a licensee to be privileged or confidential and is so marked, the Agency agrees that to the extent permitted by law it will not disclose such information to persons outside the Government.

XII. Inventions by Federal Employees

Nothing in this Agreement shall preclude the Government from obtaining greater rights in a Subject Invention made by an inventor while a Federal employee.

XIII. Termination

This Agreement may be terminated by either party for convenience upon thirty (30) days written notice. Disposition of rights in, and administration of inventions made under contracts subject to this Agreement will not be affected by such termination; except that in the event the Government terminates this Agreement because of a failure or refusal by the Institution to comply with any of its obligations under sections V(a), VI, IX, and X of this Agreement, the Agency has the rights to require that the Institution's entire right, title and interest in and to the particular invention with respect to which the breach occurred be assigned to the United States of America, as represented by the Agency.

XIV. Communications

Requests for Agency approvals, extensions, or similar actions and other correspondence required by this Agreement should be addressed to _____. Except where specifically provided otherwise in this Agreement, the _____ or his designee shall act as the point of authority within the Agency to grant such approvals, extensions, or take such Agency actions as may be authorized in this Agreement.

IN WITNESS WHEREOF, each of the parties hereto has executed this Agreement as of the day and year below.

UNITED STATES OF AMERICA

By_____
Title_____
Date_____

(Corporate Seal)

_____
(Institution)

By_____
Title_____
Date_____

APPENDIX D: FINAL GSA PATENT POLICY REGULATIONS

Subpart 1-9.1-Patents[497]

§ 1-9.100 Scope of subpart.

This subpart sets forth policies, procedures, and contract clauses with respect to inventions made in the course of or under a contract or subcontract entered into with or for the benefit of the Government where a purpose is the conduct of experimental, developmental, or research work. The policies, procedures, and contract clauses may also be used in grants, agreements, and other arrangements as agencies deem appropriate.

§§ 1-9.101-1-9.106 *[Reserved]*

§ 1-9.107 Patent rights under contracts for research and development.

§ 1-9.107-1 General.

(a) *Introduction.* On August 23, 1071, the President Issued a Statement of Government Patent Policy (36 IM 16887, August 26, 1971) applicable to all executive departments and agencies, revising a prior Statement of Policy (28 FS 10943, October 12, 1963 **).** Essentially, the goals of 'this Statement are to provide criteria for determining the allocation of rights in inventions resulting from federally sponsored research and development contracts, to promote their expeditious development so that the public can benefit from early civilian use of the Inventions, and to ensure their continued availability. In applying this regulation, agency heads must weigh both the need for incentives to draw forth private initiatives, and the need to promote healthy competition in industry. Consistent with the FPR system, agencies may implement and supplement this subpart.

(b) *Applicable statutes.* Except to the extent that agencies are governed by specific statutes or by any treaty or agreement between the United States and any foreign country that are inconsistent with this subpart, agencies shall follow the provisions of this subpart, including the use of the prescribed clauses. Modifications to the prescribed clauses are permissible to the extent that these clauses are inconsistent with the requirements of statutes, treaties, or agreements.

(c) *Co-sponsored, cost sharing, or joint venture research.* The provisions of this subpart are not mandatorily applicable to co-sponsored, cost sharing, or joint venture research when the agency determines that in the course of the work under the contract the contractor will be required to make a substantial contribution of funds, facilities, or equipment to the principal purpose of the contract, However, agencies are encouraged to follow the provisions of this subpart to the extent practicable.

(d) *Background patent rights.* Nothing in this subpart is intended to preclude the use of

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[497] 40 FED. REG. 19814 (May 7, 1975).

appropriate contract provisions concerning rights in contractor's background patents.

§ 1-9.107-2- [Reserved]
§ 1-9.107-3 Policy.

(a) The Government shall normally acquire or reserve the right to acquire the principal or exclusive rights throughout the world in and to any inventions made in the course of or under a contract where:

(1) A principal purpose of the contract is to create, develop, or improve products, processes, or methods which are intended for commercial use (or which are otherwise intended to be made available for use) by the general public at home or abroad, or which will be required for such use **by** governmental regulations; or

(2) A principal purpose of the contract is for exploration into fields which directly concern the public health, public safety, or public welfare; or

(3) The contract is in a field of science or technology in which there has been little significant experience outside of work funded by the Government, or where the Government has been the principal developer of the field, and the retention of exclusive rights at the time of contracting. might confer on the contractor a preferred or dominant position; or

(4) The services of the contractor are:

(i) For the operation of a Government owned research or production facility; or

(ii) For coordinating and directing the work of others. In exceptional circumstances the contractor may retain greater rights than a nonexclusive license at the time of contracting where the head of the department or agency certifies that such action will best serve the public interest. Greater rights may also be retained by the contractor after the invention has been identified where the head of the department or agency determines that the retention of such greater rights is consistent with the intent of this paragraph (a) and is either a necessary incentive to call forth private risk capital and expense to bring the invention to the point of practical application or that the Government's contribution to the invention is small compared to that of the contractor. Where an identified invention made in the course of or under the contract is not directly related to a principal purpose of the contract, greater rights may also be retained by the contractor under the criteria of (c) below. In other situations, where the purpose of the contract is to build upon existing knowledge or technology to develop information, products, processes, or methods for use by the Government and the work called for by the contract is in a field of technology in which the contractor has acquired technical competence (demonstrated by factors such as know-how, experience, and patent position) directly related to an area in which the contractor has an established nongovernmental, commercial position, the contractor shall normally retain the principal or exclusive rights throughout the world in and to any resulting inventions.

(c) Where the commercial interests of the contractor are mot sufficiently established to be covered by the criteria specified in (b), above, the allocation of rights shall be made by the

agency after the invention has been identified, in a manner deemed most likely to serve the public interest as expressed in this policy, taking particularly into account the intentions of the contractor to bring the invention to a point of commercial application and the guidelines of (a) above, provided that the agency may prescribe by regulation special situations where the public interest in the availability of the inventions would best be served by permitting the contractor to retain at the time of contracting greater rights than a nonexclusive license.

(d) In the situations specified In (b) and (c) of this section, when two or more potential contractors are judged to have presented proposals of equivalent merit, willingness to grant the Government principal or exclusive rights in resulting Inventions will be an additional factor In the evaluation of the proposals.

(e) Where the principal or exclusive rights in an invention remain in the contractor, he should agree to provide written reports at reasonable intervals, when requested by the Government, on the commercial use that is being made or intended to be made of inventions made under Government contracts.

(f) Where the principal or exclusive rights in an invention remain in the contractor, unless the contractor, his licensee, or his assignee has taken effective steps within 3 years after a patent issues on the Invention to bring the invention to the point of practical application, or has made the invention available for licensing royalty-free or on terms that are reasonable in the circumstances, or can show cause why he should retain the principal or exclusive rights for a further period of time, the Government shall have the right to require the granting of a nonexclusive or exclusive license to a responsible applicant(s) on terms that are reasonable under the circumstances.

(g) Where the principal or exclusive rights to an invention are retained by the contractor, the Government shall have the right to require the granting of a nonexclusive or exclusive license to a responsible applicant(s) on terms that are reasonable in the circumstances (i) to the extent that the invention Is required for public use by governmental regulations, or (ii) as may be necessary to fulfill health or safety needs, or (iii) for other public purposes stipulated in the contract.

(h) Whenever the principal or exclusive rights in an invention remain in the contractor, the Government shall normally acquire:

(1) At least a nonexclusive, nontransferable, paid-up license to make, use, and sell the invention throughout the world by or on behalf of the Government of the United States (including any Government agency) and States and domestic municipal governments, unless the agency head or his designee determines that it would not be in the public interest to acquire the license for the States and domestic municipal governments; and

(2) The right to sublicense any foreign government pursuant to any existing or future treaty or agreement if the agency head or his designee determines it would be in the national interest to acquire the right; and

(3) The principal or exclusive rights to the invention in any country in which the

contractor does not elect to secure a patent.

(I) Whenever the principal or exclusive rights in an invention are acquired by the Government, there may be reserved to the contractor a revocable or irrevocable, nonexclusive, royalty-free license for the practice of the invention throughout the world; an agency may reserve the right to revoke such license so that it might grant an exclusive license when it determines that some degree of exclusivity may be necessary to encourage further development and commercialization of the invention. Where the Government acquires the principal or exclusive rights to an invention and does not elect to secure a patent in a foreign country, the contractor may retain such rights in any foreign country in which he elects to secure a patent, subject to the Government's rights set forth in (h) of this section.

(J) Nothing in this subpart shall be construed to confer immunity upon any person from the antitrust laws or from a charge of patent misuse, and no person shall be immune from the operation of State or Federal law by reason of the retention and use of rights pursuant to this subpart.

§ 1-9.107- Procedures.

(a) *Selection of Patent Rights clause.*

(1) Whenever a contract which is to be performed in the United States, its possessions, Puerto Rico, or the District of Columbia has as a purpose the conduct of experimental, developmental, or research work, the agency shall apply the policy in § 1-9.107-3 to the contracting situation and shall include in the contract a Patent Rights clause from §§ 1- 9.107-5 or 1-9.107-6. The clauses in § 1-9.107-5 shall be used as appropriate in contracts with industrial concerns or in contracts with nonprofit organizations calling for developmental work. The clauses specified In §§1-9.107-5 or 1-9.107-6 may be used in contracts calling for basic or applied research with nonprofit organizations. Solicitations shall provide offerors with an opportunity to show that the selected clause proposed for a contract is inappropriate for a particular procurement situation. In no event will contractors be asked to state their willingness to grant the Government principal or exclusive patent rights prior to a determination that proposals of equivalent merit have been presented.

(2) The Patent Rights clause in § 1-9.107-5(a), except as otherwise provided in § 1-9.107-6(a), shall be used whenever the agency determines that the experimental, developmental, or research work to be performed under the contract falls within § 1-9.107-3(a). This clause provides that the Government shall acquire title, under certain circumstances, to inventions made in the course of or under the contract subject to the reservation of nonexclusive license rights to the contractor. The contractor may retain greater rights than a nonexclusive license after an invention has been identified if the agency determines that the criteria of § 1-9.109-6 are met. When the agency head or his duly' authorized designee determines that exceptional circumstances exist as provided for in § 1-9.107-3 (a), paragraphs (b) and (1) of the clause prescribed in § 1-9.107-5(a) may be appropriately modified so that the contractor retains greater rights than a nonexclusive license concerning all or specific inventions.

(3) The Patent Rights clause in § 1-9.107-5(b) shall be used whenever the agency determines that the experimental, developmental, or research work to be performed under the contract does not come within § 1-9.107-3 (a) but is within § 1-9.107-3(b). This clause provides that title to any inventions resulting from the contract remains-in the contractor subject to the acquisition of certain specified rights by the Government.

(4) The Patent Rights clause in § 1-9.107-5(c), except as otherwise provided in § 1-9.107-6(b), shall be used whenever the agency determines that the experimental, developmental, or research work to be performed under the contract does not come within H9 1-9.107-3 (a) or (b), but is within § 1-9.107-3(c). The clause in § 1-9.107-5(c) provides that the allocation of rights in inventions resulting from the contract shall be deferred until after an invention has been identified. When the agency determines pursuant to its regulations that a special situation exists, paragraphs (b) and (i) of the clause prescribed in § 1-9.107-5(c) may be modified so that the contractor retains greater rights than a nonexclusive license.

(5) A short form Patent Rights clause in § 1-9.107-6 (a) or (b) may be used by the agency instead-of the clause in § 1-9.107-5 (a) or (c), respectively, where the contract calls for basic or applied research and the contractor is a nonprofit organization for other than the operation of a Government-owned research or production facility. These clauses are not appropriate for use where the agency head determines that the contractor is entitled to retention of greater rights upon a finding that exceptional circumstances as provided for in § 1-9.107-3 (a) are present or where the contract falls within the special situations criteria of § 1-9'.107-(c). In either event, a Patent Rights clause in § 1-9.107-5, appropriately modified, shall be used.

(b) *Record of decisions.* Agencies shall record the basis for the following actions: (1) Selection of a Patent Rights clause; (2) finding of exceptional circumstances in 9 1-9.107-3(a) or of special situations in § 1-9.107-3(c); (3) retention of greater rights pursuant to § 1-9.109-6; and (4) determinations under §§ 1-9.107-4 (c) and (d).

(c) *License for the Government, States, and municipal governments.* The policy set forth in § 1-9.107-3(h) (1) provides that the Government shall normally acquire a paid-up license in any invention resulting from the contract for the Government, States, and municipal governments. Paragraph (c) (1) in the Patent Rights clauses in § 1-9.107-5 sets forth such a license. When the agency determines that it would not be in the public interest in a particular contracting situation to acquire a license for the Government of the scope in paragraph (c) (1), this paragraph may be appropriately modified. The agency head or his duly authorized designee may determine at the time of contracting that it would not be in the public interest to acquire such a license for States and municipal governments or may reserve the right to make this determination after the invention has been identified. When the determination is made or the right to make the determination is reserved, paragraph (c) (1) of the Patent Rights clauses in § 1-9.107-5 shall be replaced with the appropriate paragraph in § 1-9.107-5(d).

(d) *Right to sublicense foreign governments.* Paragraph (c) of the Patent Rights clauses in § 1-9.107-5 does not provide the Government with the right to grant a sublicense in any inventions resulting from the contract to any foreign government pursuant to any treaty or agreement. The agency head or his duly authorized designee may determine at the time of contracting that it

would be in the national interest to acquire this right, or he may reserve the right to make this determination after the invention has been identified. When the agency head makes or reserves the right to make this determination, the appropriate sentence in § 1-9.107-5(e) shall be included as part of paragraph (c) in the Patent Rights clauses of § 1-9.107-5.

(e) *Minimum rights to contractor.* Paragraph (d) of the Patent Rights clauses of § 1-9.107-5 specify the minimum rights retained by the contractor in inventions made in the course of or under the contract. Where appropriate, the agency may modify this Minimum Rights provision, whereby, the contractor reserves:

(1) A *revocable,* nonexclusive, royalty-free license in the inventions, in which case paragraph (d) of § 1-9.107-5(a) shall be included in the Patent Rights clauses in § 1-9.107-5;

(2) A *revocable,* nonexclusive, royalty-free license in the inventions only upon request by the contractor for reservation of such a license, in which case paragraph (d) (1) of the Patent Rights clauses in § 1-9.107-5 shall be replaced with paragraph (d) (1) In § 1-9,107-5 (f);

(3) An *irrevocable,* nonexclusive, royalty-free license in the inventions, in which case paragraph (d) of the Patent Rights clauses in § 1-9.107-5 shall be replaced with paragraph (d) in § 1-9.107-5(g); or

(4) An *irrevocable,* nonexclusive; royalty-free license in inventions constructively reduced to practice prior to the effective date of the contract, in which case paragraph (d) (4) of § 1-9.107-5(h) shall be added to the Patent Rights clauses in § 1-9.107-5.

(f) *Subcontracts.* (1) The policy expressed in § 1-9.107-3 is applicable to prime contracts and to subcontracts regardless of tier. The appropriate Patent Rights clause prescribed by this subpart shall be included in all subcontracts having as a purpose the conduct of experimental, developmental, or research work. In general, the Patent Rights clause in the prime contract, with the exception of the withholding provision, will be appropriate for inclusion in such subcontracts. Whenever the prime contractor or a subcontractor considers the inclusion of the Patent Rights clause of the prime contract in a subcontract to be inconsistent with the policy expressed in § 1-9.107-3, or a subcontractor refuses to accept a Patent Rights clause in his subcontract, the matter shall be referred to the agency contracting officer for resolution prior to the award of the subcontract. Upon such referral, the same considerations and procedures followed by the contracting officer in selecting the Patent Rights clause included in the prime contract shall be used in selecting the Patent Rights clause to be included in the subcontract.

(2) Contractors shall not use their ability to award subcontracts as economic leverage to acquire rights for themselves in the inventions resulting from subcontracts.

(g) *Publication of invention disclosures.* The Patent Rights clauses of § 1-9.107-5 and § 1-9.107-6 specify in paragraph (e) (4) and (b) (2), respectively, that the Government may duplicate and disclose invention disclosures reported under the contract. However, the publication of the information in an invention disclosure by any party before the filing of a patent application may create a bar to the filing of foreign patent applications. The agency may restrict the publication of

such information by the contractor in order to protect the interests of the Government or the contractor in obtaining foreign patents by adding the paragraph prescribed by § 1-9.107-5(i) (2) as a consecutively numbered paragraph after paragraph (e) (4) of the clauses of § 1-9.107-5, and after paragraph (b)(2) of the clauses of § 1-9.107-6. Where the contractor has been authorized to file foreign patent applications, the Agency may desire to restrict its publication of the information in the related invention disclosure in order to protect the filing of such foreign applications by the contractor. In this event, the sentence in § 1-9.107-5 (i)(I) should be added to paragraph (e)(4) of the Patent Rights clauses in § 1-9.107-5, and to paragraph (b)(2) of Patent Rights clauses in § 1-9.107-6.

(h) *Deviations.* Any departures from the policy, procedures, and clauses of this subpart shall be subject to the provisions of § 1-1.009

§ 1-9.107-5 Clauses for domestic contracts (long form).

(a) *Patent Rights clause-Acquisition by the Government.* When the agency has determined that a contract falls within § 1-9.107-4(a) (2), the following clause shall be included in the contract.

PATENT RIGHTS-ACQUISITION BY THE GOVERNMENT

(a) *Definitions.* (1) "Subject Invention" means any invention or discovery of the Contractor conceived or first actually reduced to practice in the course of or under this contract, and includes any art, method, process, machine, manufacture, design, or composition of matter, or any new and useful improvement thereof, or any variety of plant, which is or may be patentable under the Patent Laws of the United States of America or any foreign country.

(2) "Contract" means any contract, agreement, grant, or other arrangement, or subcontract entered into with or for the benefit of the Government where a purpose of the contract is the conduct of experimental, developmental, or research work.

(3) "States and domestic municipal governments" means the States of the United States, the District of Columbia, Puerto Rico, the Virgin Islands, American Samoa, Guam, the Trust Territory of the Pacific Islands, and any political subdivision and agencies thereof.

(4) "Government agency" includes an executive department, independent commission, board, office, agency, administration, authority, Government corporation, or other Government establishment of the executive branch of the Government of the United States of America.

(5) "To the point of practical application" means to manufacture in the case of a composition or product, to practice in the case of a process, or to operate in the case of a machine and under such conditions as to establish that the invention is being worked and that its benefits are reasonably accessible to the public.

(b) *Allocation of principal rights.* (1) *Assignment to the Government.* The Contractor agrees to assign to the Government the entire right, title, and interest throughout the world in and to

each Subject Invention, except to the extent that rights are retained by the Contractor under paragraphs (b) (2) and (d) of this clause.

(2) *Greater rights determinations*. The Contractor or the employee-inventor with authorization of the Contractor may retain greater rights than the nonexclusive license provided in paragraph (d) of this clause in accordance with the procedure and criteria of 41 CFR 1-9.109-6. A request for determination whether the Contractor or the employee-inventor is entitled to retain such greater rights must be submitted to the Contracting Officer at the time of the first disclosure of the invention pursuant to paragraph (e) (2) (1) of this clause, or not later than 3 months thereafter, or such longer period as may *be* authorized by the Contracting Officer for good cause shown in writing by the Contractor. The Information to be submitted for a greater rights determination is specified in 41 CFR 1-9.109-4. Each determination of greater rights under this contract normally shall be subject to paragraph (c) of this clause and to the reservations and conditions deemed to be appropriate by the agency.

(c) *Minimum rights acquired by the Government.* With respect to each Subject Invention to which the Contractor retains principal or exclusive rights, the Contractor:

(1) hereby grants to the Government a nonexclusive, nontransferable, paid-up license to make, use, and sell each Subject Invention throughout the world by or on behalf of the Government of the United States (including any Government agency) and States and domestic municipal governments;

(2) Agrees to grant to responsible applicants, upon request of the Government, a license on terms that are reasonable under the circumstances:

(i) Unless the Contractor, his licensee, or his assignee demonstrates to the Government that effective steps have been taken within 3 years after a patent issues on such invention to bring the invention to the point of practical application, or that the invention has been made available for licensing royalty-free or on terms that are reasonable in the circumstances, or can show cause why the principal or exclusive rights should be retained for a further period of time; or

(ii) To the extent that the invention is required for public use by governmental regulations or as may be necessary to fulfill public health, safety or welfare needs, or for other public purposes stipulated in this contract;

(3) Shall submit written reports at reasonable intervals upon request of the Government during the term of the patent on the Subject Invention regarding:

(i) The commercial use that is being made or is intended to be made of the Invention; and

(ii) The steps taken by the Contractor or his transferee to bring the invention to the point of practical application or to make the invention available for licensing;

(4) Agrees to refund any amounts received as royalty charges on any Subject Invention in procurements for or on behalf of the Government and to provide for that refund in any

Instrument transferring rights to any party in the invention; and

(5) Agrees to provide for the Government's paid-up license pursuant to paragraph (c) (1) of this clause in any instrument transferring rights in a Subject Invention and to provide for the granting of licenses as required by (2) of this clause, and for the reporting of utilization information as required by paragraph (c) (3) of this clause whenever the instrument transfers principal or exclusive rights in any Subject Invention. Nothing contained in this paragraph (c) shall be deemed to grant to the Government any rights with respect to any invention other than a Subject Invention.

(d) *Minimum rights to the Contractor.* (1) The Contractor reserves a revocable, nonexclusive, royalty-free license in each patent application filed in any country on a Subject Invention and any resulting patent in which the Government acquires title. The license shall extend to the Contractor's domestic subsidiaries and affiliates, if any, within the corporate structure of which the Contractor is a part and shall include the right to grant sublicenses of the same scope to the extent the Contractor was legally obligated to do so at the time the contract was awarded. The license shall be transferable only with approval of the agency except when transferred to the successor of that part of the Contractor's business to which the Invention pertains

(2) The Contractor's nonexclusive domestic license retained pursuant to paragraph (d) (1) of this clause may be revoked or modified by the agency to the extent necessary to achieve expeditious practical application of the Subject Invention under 41 CFR 101-4.103-3 pursuant to an application for exclusive license submitted in accordance with 41 CFR 101-4.104-3. This license shall not be revoked in that field of use and/or the geographical areas in which the Contractor has brought the invention to the point of practical application and continues to make the benefits of the invention reasonably accessible to the public. The Contractor's nonexclusive license in any foreign country reserved pursuant to paragraph (d) (1) of this clause may be revoked or modified at the discretion of the agency to the extent the Contractor or his domestic subsidiaries or affiliates have failed to achieve the practical application of the invention in that foreign country.

(3) Before modification or revocation of the license pursuant to paragraph (d) (2) of this clause, the agency shall furnish the Contractor a written notice of its intention to modify or revote the license, and the Contractor shall be allowed 30 days (or such longer period as may be authorized by the agency for good cause shown in writing by the Contractor) after the notice to show cause why the license should not be modified or revoked. The Contractor shall have the right to appeal, in accordance with procedures prescribed by the agency, any decision concerning the modification or revocation of his license.

(e) *Invention, identification, disclosures, and reports.* (1) The Contractor shall establish and maintain active and effective procedures to ensure that Subject Inventions are promptly identified and timely disclosed. These procedures shall include the maintenance of laboratory notebooks or equivalent records and any other records that are reasonably necessary to document the conception and/or the first actual reduction to practice of Subject Inventions, and records which show that the procedures for identifying and disclosing the inventions are followed. Upon request, the Contractor shall furnish the Contracting Officer a description of these procedures so

that he may evaluate and determine their effectiveness.

(2) The Contractor shall furnish the Contracting Officer:

(i) A complete technical disclosure for each Subject Invention within 6 months after conception or first actual reduction to practice whichever occurs first in the course of or under the contract, but in any event prior to any on sale, public use, or publication of such invention known to the Contractor. The disclosure shall identify the contract and inventor and shall be sufficiently complete in technical detail and appropriately illustrated by sketch or diagram to convey to one skilled in the art to which the invention pertains a clear understanding of the nature, purpose, operation, and, to the extent known, the physical. chemical. biological, or electrical characteristics of the invention;

(ii) Interim reports[498] at least every 12 months from the date of the contract listing Subject Inventions for that period and certifying that:

(A) The Contractor's procedures for identifying and disclosing Subject Inventions as required by this paragraph (e) have been followed throughout the reporting period; and

(B) All Subject Inventions have been disclosed or that there are no such inventions; and

(iii) A final report within 3 months after completion of the contract work, listing all Subject Inventions or certifying that there were no such inventions.

(3) The Contractor shall obtain patent agreements to effectuate the provisions of this clause from all persons in his employ who perform any part of the work under this contract except nontechnical personnel, such as clerical employees and manual laborers.

(4) The Contractor agrees that the Government may duplicate and disclose Subject Invention disclosures and all other reports and papers furnished or required to be furnished pursuant to this clause.

(f) *Forfeiture* of *rights in unreported Subject Inventions.* (1) The Contractor shall forfeit to the Government all rights in any Subject Invention which he fails to disclose to the Contracting Officer within 6 months after the time he:

(i) Files or causes to be filed a United States or foreign application thereon; or

(ii) Submits the final report required by paragraph (e) (2) (ii) of this clause, whichever is later.

(2) However, the Contractor shall not forfeit rights in a Subject Invention if, within the time specified in (1) (i) or (1) (ii) of this paragraph (f), the Contractor:

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[498] Agency may specify form.

(i) Prepared a written decision based upon a review of the record that the invention was neither conceived nor first actually reduced to practice in the course of or under the contract; or

(ii) Contending that the invention is not a Subject Invention, he nevertheless discloses the invention and all facts pertinent to his contention to the Contracting Officer, or

(iii) Establishes that the failure to disclose did not result from his fault or negligence.

(3) Pending written assignment of the patent applications and patents on a Subject Invention determined by the Contracting Officer to be forfeited (such determination to be a final decision under the Disputes Clause) the Contractor shall be deemed to hold the invention and the patent applications and patents pertaining thereto in trust for the Government. The forfeiture provision of this paragraph (f) shall be in addition to and shall not supersede other rights and remedies which the Government may have with respect to Subject Inventions.

(g) *Examination of records relating to inventions.* (1) The Contracting Officer or his authorized representative until the, expiration of 3 years after final payment under this contract shall have the right to examine any books (including laboratory notebooks), records, documents, and other supporting data of the Contractor which the Contracting Officer reasonably deems pertinent to the discovery or identification of Subject Inventions if the Contractor refuses or the requirements of this clause.

(2) The Contracting Officer shall have the right to review all books (including laboratory notebooks), records and documents of the Contractor relating to the conception or first actual reduction to practice of inventions in the same field of technology as the work under this contract to determine whether any such inventions are Subject Interventions if the Contractor refuses or falls to;

(1) Establish the procedures of paragraph (e) (1) of this clause; or

(ii) Maintain and follow the procedures; or

(iii) Correct or eliminate any material deficiency in the procedures within thirty (30) days after the Contracting Officer notifies the Contract of such a deficiency.

(h) *Withholding of payment (Not applicable to Subcontracts).* (1) Any time before final payment of the amount of this contract, the Contracting Officer may, if he deems such action warranted, withhold payment until a reserve not exceed $50,000 or 1 percent of the amount of this contract, whichever is less, shall have been set aside if in his opinion the Contractor fails to:

(i) Establish, maintain, and follow effective procedures for identifying and disclosing Subject Inventions pursuant to paragraph (e) (1) of this clause; or

(ii) Disclose any Subject Invention pursuant to paragraph (e) (2) (i) of this clause; or

(iii) Deliver acceptable interim reports pursuant to paragraph (a) (2) (l) of this clause; or

(iv) Provide the information regarding subcontracts pursuant to paragraph (i) (5) of this clause.

The reserve or balance shall be withheld until the Contracting Officer has determined that the Contractor has rectified whatever deficiencies exist and has delivered all reports, disclosures, and other information required by this clause.

(2) Final payment under this contract shall not be made before the Contractor delivers to the Contracting Officer all disclosures of Subject Inventions required by paragraph (e) (2) (1) of this clause, and an acceptable final report pursuant to (e) (2) (iii) of this clause.

(3) The Contracting Officer may, in his discretion, decrease or increase the sums withheld up to the maximum authorized above. If the Contractor is a nonprofit organization the maximum amount that may be withheld under this paragraph shall not exceed $50,000 or 1 percent of the amount of this contract whichever is less. No amount shall be withheld under this paragraph while the amount specified by this paragraph is being withheld under other provisions of the contract. The withholding of any amount or subsequent payment thereof shall not be construed as a waiver of any rights accruing to the Government under this contract.

(i) *Subcontracts.* (1) For the purpose of this paragraph the term "Contractor" means the party awarding a subcontract and the term "Subcontractor" means the party being awarded a subcontract, regardless of tier.

(2) Unless otherwise authorized or directed by the Government Contracting Officer, the Contractor shall include this Patent Rights clause modified to identify the parties in any subcontract hereunder if a purpose of the subcontract is the conduct of experimental, developmental, or research work. In the event of refusal by a Subcontractor to accept this clause, or if in the opinion of the Contractor this clause is inconsistent with the policy set forth in 41CFR 1-9.107-3, the Contractor:

(i) Shall promptly submit a written notice to the Government Contracting Officer setting forth reasons for the Subcontractors refusal and other pertinent information which may expedite disposition of the matter; and

(ii) Shall not proceed with the subcontract without the written authorization of the Government Contracting Officer.

(3) The Contractor shall not, in any subcontract or by using a subcontract an consideration therefor, acquire any rights in his Subcontractor's Subject Invention for his own use (as distinguished from such rights as may be required solely to fulfill his contract obligations to the Government in the performance of this contract).

(4) All invention disclosures, reports, instruments, and other information required to be furnished by the Subcontractor to the Government Contracting Officer under the provisions of a Patent Rights clause in any subcontract hereunder may, in the discretion of the Government Contracting Officer, be furnished to the Contractor for transmission to the Government

Contracting Officer.

(5) The Contractor shall promptly notify 'the Government Contracting Officer in writing upon the award of any subcontract containing a Patent Rights clause by identifying the Subcontractor, the work to be performed under the subcontract, and the dates of award and estimated completion. Upon request of the Government Contracting Officer, the Contractor shall furnish a copy of the subcontract. If there are no subcontracts containing Patent Right Clauses, a negative report shall be included in the final report submitted pursuant to paragraph (c) (2) (iii) of this clause.

(6) The Contractor shall identify all Subject Inventions of the Subcontractor of which he acquires knowledge In the performance of this contract and shall notify the Government Contracting Officer promptly upon the identification of the inventions.

(7) It is understood that the Government is a third party beneficiary of any subcontract clause granting rights to the Government in Subject Inventions, and the Contractor hereby assigns to the Government all rights that he would have to enforce the Subcontractor's obligations for the benefit of the Government with respect to Subject Inventions. The Contractor shall not be obligated to enforce the agreements of any Subcontractor hereunder relating to the obligations of the Subcontractor to the Government in regard to Subject Inventions.

(b) *Patent Rights clause-Retention by the Contractor.* When the agency has determined that a contract falls within § 1-9.107-4(a) (3), the Patent Rights clause in § 1-9.107-5(a) shall be included in the contract, except that the name of the clause shall be changed to "Patent Rights--Retention by the Contractor", paragraph (b) of that clause shall be replaced by the following paragraph (b), and the following paragraphs (j) and (k) shall be added:

(b) *Allocation of principal rights.* (1) The Contractor may retain the entire right, title, and interest throughout the world or in any country thereof in and to each Subject Invention disclosed pursuant to paragraph (c) (2)-(1) of this clause, subject to the rights obtained by the Government in paragraph (c) of this clause. The Contractor shall include with each Subject Invention disclosure an election as to whether he will retain the entire right, title, and interest in the invention throughout the world or any country thereof.

(2) Subject to the license specified in paragraph (d) of this clause, the Contractor agrees to convey to the Government, upon request, the entire domestic right, title, and interest in any Subject Invention when the Contractor:

(i) Does not elect under paragraph (b) (1) of this clause to retain such rights; or

(ii) Fails to have a United States patent application filed on the invention in accordance with paragraph (j) of this clause, or decides not to continue prosecution of such application; or

(iii) At any time, no longer desires to retain title.

(3) Subject to the license specified in paragraph (d) of this clause, the Contractor agrees to

convey to the Government upon request the entire right, title, and interest in any Subject Invention in any foreign country if the Contractor:

(i) Does not elect under paragraph (b) (1) of this clause to retain such rights in the country; or

(ii) Fails to have a patent application filed in the country on the invention in accordance with paragraph (k) of this clause, or decides not to continue prosecution or to pay any maintenance fees covering the invention. To avoid forfeiture of the patent application or patent, the Contractor shall notify the Contracting Officer not less than 60 days before the expiration period for any action required by the foreign patent office.

(4) A conveyance requested pursuant to paragraph (b) (2) or (3) of this clause shall be made by delivering to the Contracting Officer duly executed instruments (prepared by the Government), and such other papers as are deemed necessary to vest in the Government the entire right, title, and interest to enable the Government to apply for and prosecute patent applications covering the invention in this or the foreign country, respectively, or otherwise establish its ownership of the invention.

(j) *Filing of domestic patent applications* .

(1) With respect to each Subject Invention in which the Contractor elects to retain domestic rights pursuant to paragraph (b) of this clause, the Contractor shall have a domestic patent application filed within 6 months after submission of the invention disclosure pursuant to paragraph (e) (2) (1) of this clause or such longer period as may be approved by the Contracting Officer for good cause shown in writing by the Contractor. With respect to the invention, the Contractor shall promptly notify the Contracting Officer of any decision not to file an application.

(2) For each Subject Invention on which a patent application is filed by or on behalf of the Contractor, the Contractor shall:

(i) Within 2 months after the filing or within 2 months after submission of the invention disclosure if the patent application previously has been filed, deliver to the Contracting Officer a copy of the application as filed including the filing date and serial number;

(ii) Include the following statement in the second. paragraph of the specification of the application and any patents issued on a Subject Invention, "The Government has rights in this invention pursuant to Contract No . (or Grant No.) awarded by (identify the agency);

(iii) Within 6 months after filing the application, or within 6 months after submitting the invention disclosure if the application has been filed previously, deliver to the Contracting Officer a duly executed and approved instrument on a form specified by the Government fully confirmatory of all rights to which the Government is entitled, and provide the agency an irrevocable power to inspect and make copies of the patent application filed;

(iv) Provide the Contracting Officer with a copy of the patent within 2 months after a patent is issued on the application; and

(v) Not less than 30 days before the expiration of the response period for any action required by the Patent and Trademark Office, notify the agency of any decision not to continue prosecution of the application and deliver to the agency executed instruments granting the Government a power of attorney.

(3) For each Subject Invention in which the Contractor initially elects not to retain principal domestic rights, the Contractor shall inform the Contracting Officer promptly in writing of the date and identity of any on sale, public use, or publication of the invention which may constitute a statutory bar under 35 U.S.C. 102, which was authorized by or known to the Contractor, or any contemplated action of this nature.

(k) *Filing of foreign patent applications*.

(1) With respect to each Subject Invention in which the Contractor elects to retain principal rights in a foreign country pursuant to paragraph (b) (1) of this clause, the Contactor shall have a patent application filed on the invention in that country, in accordance with applicable statutes and regulations, and within one of the following periods:

(i) Eight months from the date of a corresponding United States application filed by or on behalf of the Contractor, or if such an application is not filed, 6 months from the date the invention is submitted in a disclosure pursuant to paragraph (e) (2) (1) of this clause;

(ii) Six months from the date a license is granted by the Commissioner of Patents and Trademarks to file foreign applications where such filing has been prohibited by security reasons; or

(iii) Such longer period as may be approved by the Contracting Officer.

(2) The Contractor shall notify the Contracting Officer promptly of each foreign application filed and upon written request shall furnish an English version of the foreign application without additional compensation.

(c) *Patent Rights clause-Deferred.* When the agency has determined that a contract falls within § 1-9.107-4(a) (4), the Patent Rights clause in § 1-9.107-5 (a) shall be included in the contract, except that the name of the clause shall be changed to “Patent Rights-Deferred" and paragraph (b) of that clause shall be replaced with the following paragraph (b):

(b) *Allocation of principal rights.* (1) *Assignment to the Government.* After a Subject Invention is identified, the Contractor agrees to assign to the Government the entire right, title, and interest therein throughout the world except to the extent that greater rights are retained by the Contractor under paragraphs (b) (2) and (d) of this clause.

(2) *Greater Rights determinations.* The Contractor, or the employee-inventor with authorization of the Contractor, may retain greater rights than the nonexclusive license provided in paragraph (d) of this clause in accordance with the procedure and criteria of 41 CFR 1-9.109-6.

A request for a determination of whether the Contractor or the employee-inventor is entitled to retain such greater rights must be submitted to the Contracting Officer at the time of first disclosure of the invention pursuant to paragraph (e) (2) (1) of this clause, or not later than 3 months thereafter or such longer period as may be authorized by the Contracting Officer for good cause shown in writing by the Contractor. The information to be submitted for a greater rights determination is specified in 41 CFR 1-9.109-6. Each determination of greater rights under this contract normally shall be subject to paragraph (c) of this clause and to the reservations and conditions deemed to be appropriate by the agency.

(d) *License rights of States and municipal governments.*

(1) When the agency head or his duly authorized designee determines at the time of contracting that it would not be in the public interest to acquire a paid-up license in inventions made in the course of or under the contract for States and domestic municipal governments, paragraph (c)(1) of the Patent Rights clauses in § 1-9.107-5 shall be replaced with the following paragraph (c)(1):

(1) Hereby grant to the Government a nonexclusive, nontransferable, paid-up license to make, use, and sell each Subject Invention throughout the world by or on behalf of the Government of the United States (including any Government agency).

(2) When the agency head or his duly authorized designee decides to reserve the right to make the determination that it would not be in the public interest to acquire a paid-up license in a Subject Invention for States and domestic municipal governments until after the invention has been identified, paragraph (c) (1) of the Patent Rights clauses in § 1-9.107-5 shall be replaced with the following paragraph (c) (1):

(1) Hereby grants to the Government a nonexclusive. nontransferable, paid-up license to make. use, and sell each Subject Invention throughout the world by or on behalf of the Government of the United States (including any Government agency), States and domestic municipal governments, unless the agency head determines after the invention has been identified that it would not be in the public interest to acquire the license for States and domestic municipal governments.

(e) *Right to sublicense foreign governments.*

(1) When the agency head or his duly authorized designee determines at the time of contracting that it would be in the national interest to acquire the right to sublicense foreign governments pursuant to any treaty or agreement a sentence shall be added to the end of paragraph (c) (1) of the Patent Rights clauses in § 1-9.107-5 as follows: This license shall include the right of the Government to sublicense foreign governments pursuant to any treaty or agreement with such foreign governments.

(2) When the agency head wishes to reserve the right to make the determination to sublicense foreign governments pursuant to any treaty or agreement until after the invention has been identified, a sentence shall be added to the end of paragraph (c) (1) of the Patent Rights clauses in § 1-9.107-5 as follows: This license shall include the right of the Government to sublicense

foreign governments pursuant to any treaty or agreement if the agency head determines after the invention has been identified that it would be in the national interest to acquire this right.

(f) *Minimum rights to Contractor (upon request).* When the agency determines that the contractor may reserve a revocable, nonexclusive, royalty-free license in inventions made in the course of or under the contract, only upon a request by the contractor for the retention of such a license, paragraph (d) (1) of the clauses in § 1-9.107-5 shall be replaced with the following paragraph (d) (1) :

(d) *Minimum rights to the Contractor.* (1) The Contractor may reserve upon request a revocable, nonexclusive, royalty-free license in each patent application filed in any country on a Subject Invention and any resulting patent in which the Government acquires title. The license shall extend to the Contractor's domestic subsidiaries and affiliates, if any, within the corporate structure of which the Contractor is a part and shall include the right to grant sublicenses of the same scope to the extent the Contractor was legally obligated to do so at the time the contract was awarded. The license shall be assignable only with approval of the agency except to the successor of that part of the Contractor's business to which the invention pertains.

(g) *Minimum rights to Contractor (irrevocable).* When the agency determines that the contractor may reserve an irrevocable, nonexclusive, royalty-free license in the inventions resulting from the contract, paragraph (d), of the Patent Rights clauses of § 1-9.107-5 shall be replaced with the following paragraph 4(d):

(d) The Contractor reserves an irrevocable, nonexclusive, royalty-free license in each patent application filed in any country on a Subject Invention and any resulting patent in which the Government acquires title. The license shall extend to the Contractor's domestic subsidiaries and affiliates, if any, within the corporate structure of which the Contractor is a part and shall include the right to grant sublicenses of the same scope to the extent the Contractor was legally obligated to do so at the time the contract was awarded. This license shall be transferable only with approval of the agency, except when transferred to the successor of that part of the Contractor's business to which the invention pertains.

(h) *Irrevocable license on Subject Inventions previously constructively reduced to practice.* When an agency decides that the contractor may reserve an irrevocable, nonexclusive and royalty-free license for practice in this country of each invention first actually reduced to practice under a contract which was conceived and constructively reduced to practice by the contractor prior to the effective date of execution of the contract, the following paragraph (d) (4) shall be added to paragraph (d) of the Patents Rights clauses in § 1-9.107-5:

(4) In addition to the provisions of paragraph (d) (1) of this clause, the Contractor reserves an irrevocable, nonexclusive, royalty-free license in each patent application filed in any country and any resulting patent on each Subject Invention constructively reduced to practice by the Contractor prior to the effective date of this contract. The license shall extend to the Contractor's domestic subsidiaries and affiliates, if any, within the corporate structure of which the Contractor is a part and shall include the right to grant sublicenses of the same scope to the extent the Contractor was legally obligated to do so at the time the contract was awarded. The license shall

be assignable only with approval by the agency except to the successor of that part of the Contractor's business to which the invention pertains.

(i) *Publication of invention disclosures.*

(1) When the agency determines that it is in the best interest of the parties to withhold the release or publication of information in an invention disclosure so that the contractor may file foreign patent applications on the invention, the following sentence shall be added to paragraph (e) (4) of the Patent Rights clauses in § 1-9.107-5 and to paragraph (b) (2) of the Patent Rights clauses in § 1-9.107-6:

If the Contractor is to file a foreign patent application on a Subject Invention, the Government agrees, upon written request of the Contractor, to use its best efforts to withhold publication of such invention disclosures until a patent application is filed thereon, but in no event shall the Government or its employees be liable for any publication thereof.

(2) When the agency determines to restrict the Contractor's publication of invention disclosures prior to the filing of patent applications, the following paragraph should be added as a consecutively numbered paragraph to paragraph (e) of the Patent Rights clauses in § 1-9.107-5 and to paragraph (b) (2) of the Patent Rights clauses in § 1-9.107-6:

( ) In order to protect the patent interest of the Government or the Contractor, the Contractor shall obtain the written approval of the Contracting Officer prior to the release or publication of the information in any Subject Invention disclosure by the Contractor or other parties acting on his behalf.

§ 1-9.107-6 Clauses for domestic contracts (short form).

(a) *Patent Rights clause-Acquisition by the Government.* The following clause may be used instead of the clause of § 1-9.107-5(a) in contracts for basic or applied research with nonprofit organizations other than for the operation of a Government-owned research or production facility.

PATENT RIGHTS—ACQUISITION BY THE GOVERNMENT (SHORT FORM)

(a) *Definitions.*

"Subject Invention" means any invention or discovery of the Contractor conceived or first actually reduced to practice in the course of or under this contract, and includes any art, method, process, machine, manufacture, design, or composition of matter, or any new and useful improvement thereof, or any variety of plant which is or may be patentable under the Patent Laws of the United States of America or any foreign country.

(b) *Invention disclosures and reports.* (1) The Contractor shall furnish the Contracting Officer:

(i) A complete technical disclosure for each Subject Invention, within 6 months after conception or first actual reduction to practice, whichever occurs first in the course of or under

the contract, but in any event prior to any on sale, public use, or publication of the invention known to the Contractor. The disclosure shall identify the contract and inventor, and shall be sufficiently complete in technical detail and appropriately illustrated by sketch or diagram to convey to one skilled in the art to which the invention pertains a clear understanding of the nature, purpose, operation, and to the extent known, the physical, chemical, biological, or electrical characteristics of the invention;

(ii) Interim reports[499] at least every 12 months from the date of the contract listing Subject Inventions for the period and certifying that all Subject Inventions have been disclosed or that there are no such inventions; and

(iii) An acceptable final report[500] within 3 months after completion of the contract work, listing all Subject Inventions or certifying that there were no such Inventions.

(2) The Contractor agrees that the Government may duplicate and disclose Subject Invention disclosures and all other reports and papers furnished or required to be furnished pursuant to this clause.

(c) *Allocation of principal rights.* (1) The Contractor agrees to assign to the Government the entire right, title, and interest throughout the world in and to each Subject Invention, except to the extent that rights are retained by the Contractor under paragraphs (a) (2) and (d) of this clause.

(2) The Contractor or the employee-inventor with authorization of the Contractor may retain greater rights than the nonexclusive license provided in paragraph (d) of this clause in accordance with the procedure and criteria of 41 CFR 1-9.109-6. A request for a determination of whether the Contractor or the employee-inventor is entitled to retain such greater rights must be submitted to the Contracting Officer at the time of the first disclosure of the invention pursuant to paragraph (b) (1) of this clause, or not later than 3 months thereafter or such longer period as may be authorized by the Contracting Officer for good cause shown in writing by the Contractor. The information to be submitted for a greater rights determination is specified in 41 CFR 1-9.109-6. Each determination of greater rights under this contract shall be subject to the provisions of paragraph (c) "Minimum rights acquired by the Government" of the clause in 41 CFR 1-9.107-5(a), and to the reservations and conditions deemed appropriate by the agency.

(d) *Minimum rights to the Contractor.* The Contractor reserves a revocable, nonexclusive, royalty-free license in each patent application filed in any country on a Subject Invention and any resulting patent in which the Government acquires title. Revocation shall be in accordance with the procedure of the clause in 41 CFR 1-9.107-5 (d) (2) and (3).

(e) *Employee and Subcontractor agreements.* Unless otherwise authorized in writing by the Contracting Officer, the Contractor shall:

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[499] Agency may specify a form.

[500] Agency may specify a form.

(1) Obtain patent agreements to effectuate the provisions of this clause from all persons who perform any part of the work under this contract except nontechnical personnel, such as clerical employees and manual laborers;

(2) Insert in each subcontract having experimental, developmental, or research work as one of its purposes provisions making this clause applicable to the Subcontractor and his employees; and

(b) *Patent Rights clause-Deferred (short form).* This clause may be used instead of the clause of § 1-9.107-5(c) in contracts for basic or applied research with nonprofit organizations. When the agency determines that a contract falls within § 1-9.107-3(c) and that a short form Patent Rights clause is to be used pursuant to § 1-9.107-4(a) (5), the Patent Rights clause set forth in § 1-9.107-6(a) shall be included in the contract except that the name of the clause shall be changed to "Patent Rights—Deferred (short form)"; and paragraph (c) (1) of that clause shall be replaced by the following paragraph (c)(1):

(1) After a Subject Invention is identified, the Contractor agrees to assign to the Government the entire right, title, and interest therein throughout the world except to the extent that rights are retained by the Contractor under paragraphs (c)(2) and (d) of this clause.

§ 1-9.107-7 Clause for foreign contracts

A Patent Rights clause shall be included in every contract having as one of its purposes the conduct of experimental, developmental, or research work which is to be performed outside the United States, its possessions, or Puerto Rico. The clauses authorized for domestic contracts in §§ 1-9.107-5 and 1-9.107-6 may be used or replaced by any other clause tailored to meet the requirements peculiar to the foreign procurement.

§ 1-9.108 [Reserved]

§ 1-9.109 Administration of Patent Rights clauses.

It is important that the Government and the contractor know and exercise their rights in inventions conceived or first actually reduced to practice in the course of or under Government contracts in order to ensure their expeditious availability to the public, to enable the Government, the contractor, and the public to avoid unnecessary payment of royalties, and to defend against claims and suits for patent infringement. To attain these ends, contracts having Patent Rights clauses should be so administered that:

(1) Inventions are identified, disclosed, and reported as required by the contract clauses;

(2) The rights of the Government in such inventions are established;

(3) When appropriate, patent applications are timey filed and prosecuted by contractors or by the Government;

(4) The filing of patent applications is documented by formal instruments such as licenses or

assignments; and

(5) Expeditious commercial utilization of such inventions is achieved.

§ 1-9.109-2 Follow-up by contractor.

Each contractor shall establish and maintain effective procedures to ensure that inventions made under the contract are identified, disclosed, and when appropriate, patent applications filed, and that the Government's rights therein are established and protected. When it is determined after the award of a contract that the contractor or subcontractor may not have a clear understanding of the rights and obligations of the parties under a Patent Rights clause, a post-award orientation conference or letter should be used by the Government to explain these rights and obligations. When reviewing a contractor's procedures, particular attention shall be given to ascertaining their effectiveness for identifying and disclosing inventions.

§ 1-9.109-3 Follow-up by Government

Each Government agency shall undertake to ensure compliance by the contractor with the obligations of the Patent Rights clause of this contract. This effort should be directed primarily toward contracts and subcontracts about which there is reason to believe the contractors may not be complying with their contractual obligations. Other contracts and subcontracts should be spotchecked when feasible. These follow-up activities may include:

(1) Reviewing technical reports submitted by the contractor;

(2) Checking sources for patents issued to the contractor in fields related to this Government contracts;

(3) Interviewing contractor personnel regarding work under the contract, observing work under the contract, and inspecting laboratory notebooks and other records of the contractor related to work under the contract; and

(4) Interviewing agency technical ments in contracts under their cognizance.

§ 1-9.109-4 Remedies

If the contractor operating under the Patent Rights clauses of § 1-9.107-5 fails to establish, maintain, or follow effective procedures for identifying and disclosing inventions as required by the Patent Rights clause or fails to correct any deficiency after notice thereof, the contracting officer may require the contractor to make available for examination books, records and documents relating to inventions in the same field of technology as the contract to enable an agency determination of whether there are such inventions, and may invoke the withholding of payments provision. Further, the contracting officer may invoke the withholding or payments provision if the contract fails to disclose an invention deemed by the agency to be a Subject Invention.

§ 1-9.109-5 Conveyance of invention rights acquired by the Government.

(a) Where the Government acquires the entire right, title, and interest in an invention pursuant to a contract, assignments are required from the inventor to the contractor and from the contractor to the Government, or from the inventor to the Government with the consent of the contractor, to establish clearly the chain of title from the inventor to the Government. The form of conveyance of title fro the inventor to the contractor must be legally sufficient to convey the rights the contractor is required to convey to the Government. The optional form of assignment set forth hereinafter provides the complete chain of title in a single instrument and may be used to convey title to the Government. Alternatively, if separate assignments are used, both documents shall be forwarded simultaneously to the agency for recording.

ASSIGNMENT

Inventor(s): _____
Contractor: _____
Contracting Government Agency: _____
Contract No.: _____
Application Title: _____
Contractor's Invention Docket No.: _____
Agency Invention Docket No.: _____
Serial No.: _____ Filing Date: _____
Date(s) Inventor(s) Executed Oath: _____

The undersigned Inventor(s), in recognition of his (their) obligation as employee(s) of the Contractor to assign inventions to the Contractor, and pursuant to the obligations of the Contractor to the Government under the above contract hereby assigns (assign) to the United States of America, as represented by the above-identified agency, the entire right, title, and interest in and to each invention disclosed and claimed in the above U.S. patent application and any substitution, division, continuation-in-part, or continuation of such patent application and any application for reissue of any patent resulting from such patent application, subject to the reservation of the following license, if any, to the Contractor.

The license reserved to the Contractor shall extend to the Contractor's domestic subsidiaries and affiliates, if any, within the corporate structure of which the Contractor is a part and shall include the right to grant sublicenses of the same scope to the extent the Contractor was legally obligated to do so at the time the contract was awarded. The license shall be transferred to the successor of that part of the Contractor's business to which such invention pertains.

The Inventor(s) further agrees (agree) to assist the Contractor and the Government upon request by furnishing any available information and documents, performing all acts, and doing all things which may be reasonable necessary to make this assignment effective.

The Contractor joins in and agrees to this assignment and except for the above reservation of a license, if any, relinquishes and assigns the entire right, title, and interest in and to such inventions, and further agrees to furnish to the Government upon request any available information and documents necessary for the prosecution of the above-identified application for patent.

Signed this _____ days of _____, 19__

[Seal] _____
(Inventor)
Attest: _____
Repeat above for each inventor.
Signed this _____ day of _____, 19__.

_____
(Contractor's Official and Title)
Attest: _____
Accepted and agreed to on behalf of the Government

_____
(Agency Official)

_____
(Date)

(b) When the clause of §1-9.107-5(b) is included in a contract or when a party retains title to an identified invention and the right to file a patent application pursuant to a greater rights determination of § 1-9.109-6, the optional form of confirmatory Instrument set forth hereinafter is approved for use by the contractor or by the party retaining title.

CONFIRMATORY INSTRUMENT

(License to the Government)

Application for: _____
(Title of invention)
Inventor(s): _____
Serial No.: _____ Contract No.: _____
Filing Date: _____ Contractor: _____
Filing Date: _____ Contractor: _____

The invention identified above is a "Subject Invention" under Patent Rights clause,

_____
(identify clause)
(_____) included in Contract No _____
(date)
with _____
(specify agency)

This document is confirmatory of the paid-up license granted to the Government in this invention, patent application, and any resulting patent, and all other rights acquired by the Government under the referenced contract.

It is understood and agreed that this document does not preclude the Government from asserting rights under the provisions of said contract or of any other agreement between the Government and the Contractor, or any other rights of the Government with respect to the above-identified invention.

The Government is hereby granted an irrevocable power to inspect and make copies of the

above-identified patent application.
Signed this _____ day of _____,
19_____

[SEAL] _____
Applicant or Assignee (Recorded)
By _____
ATTEST: _____
_____
Business Address

(c) Assignments, licenses, confirmatory instruments, and other papers evidencing any rights of the Government in patents or patent applications shall be recorded in the Statutory Register and/or documented in the Governmental Register maintained by the U.S. Patent and Trademark Office pursuant to Executive Order 9424,- February 18, 1944. Such documents shall be sent to the Commissioner of Patents and Trademarks, Attention: Assignment Branch, Washington, DC 20231, and when the document is to be recorded in the Statutory Register, shall be accompanied by the required fee. When the document is recorded in the Statutory Register, the Patent and Trademark Office places a copy of this recording in the Governmental Register. If the agency does not have the document recorded in the Statutory Register, it shall send two copies of the document to the Commissioner of Patents and Trademarks and request that these documents be filed in a designated section of the Governmental Register. The Governmental Register contains several sections including a secret, departmental, and public section. The secret section is for applications bearing a security classification; the departmental section is for documents which are available to the Government and to the public only upon approval of the Government agency; and the public section permits access to the public.

§ 1-9.109-6 Retention of greater rights.

(a) *Request for the retention of greater domestic rights.* A contractor's request for a determination that he retain greater domestic rights in an identified invention under the Patent Rights clauses of § 1-9.107-5 (a) or (c) or § 1-9.107-6 shall be submitted in writing to the agency.

(1) The request shall contain the following information:

(i) The prime contract number and the subcontract number, if applicable, under which the invention was made and an identification of the agency's contracting office;

(ii) A brief description of the invention or a copy of the invention disclosure;

(iii) The nature and extent of the rights desired;

(iv) A description of the development, risk capital and expense, and time required to bring the invention to the point of practical application;

(v) A statement of the contractor's plans and intentions to bring the invention to the point of

practical application including:

(A) If further development and marketing are to be conducted by the contractor, a description of the facilities, personnel, and marketing outlets available for that purpose, and the extent to which such development is to be undertaken by the contractor or others on his behalf and/or;

(B) If licensing of the invention is intended, a brief description of the contractor's licensing program; and

(vi) A statement, where the invention falls within § 1-9.107-3(a), of the contractor's contribution when the contention is made that the Government's contribution to the invention is small compared to his contribution.

(2) Agencies may request additional information which would facilitate a determination that greater rights should be retained by the contractor. Illustrations of such items of information include the following:

(i) The relationship of the invention to a principal purpose of the contract;

(ii) Any facts or information known to the contractor about whether the invention is intended to be developed by the Government for commercial use or is to be required for such use by governmental regulation;

(iii) The relationship, if any, of the invention to the public health, safety, or welfare; and

(iv) The field of science and technology of the invention and whether the Government has been the principal developer of this field.

(3) The contractor's employee(s) who made an invention in the course of or under a contract may also request, with proper authorization from his employer, a determination that he retain greater rights whenever the contract so provides. A copy of the authorization of the contractor-employer should be submitted with the employee-inventor's request or such a determination. In submitting the information required for a determination for the retention of greater rights as provided in § 1-9.109-6(a) (1), and in applying the other provisions of this paragraph, the term contractor shall be understood to also mean the employee-inventor.

(b) *Reimbursement of costs for filing patent applications.* In order to protect the interest of the Government and the party submitting a request for a determination that greater rights be retained, the filing of a United States patent application prior to the agency's determination is permissible. If an application on a Subject Invention is filed during the pendency of the determination, or within 60 days prior to the receipt of a request by the agency, the agency shall reimburse the party filing the application for the reasonable filing costs and for any patent prosecution as may have occurred as provided by § 1-15.205-26 or § 1-15.309-22. Whenever such costs are not covered by § 1-15.205-26 or § 1-15.309-22, the agency may nevertheless reimburse the party causing the application to be filed for the reasonable costs of such filing and for any patent prosecution that may have occurred, subject to the availability of funds, provided:

(1) The agency determines that the party is not entitled to the retention of greater rights which are coextensive with the party's request; and

(2) Prior to reimbursement the party requesting such determination assigns the application to a Government agency and the agency accepts the assignment of the application.

(c) *Agency consideration.* The agency shall consider each request for a determination for the retention of greater domestic rights which was submitted within the period specified in the Patent Rights clause and shall make the determination in accordance with the criteria set out in paragraphs (d) or (e) of this section, as applicable.

(d) *Criteria for a determination for the retention of greater rights-Acquisition by the Government clause.* When the request for a determination for the retention of greater rights relates to an invention reported under the Patent Rights clause of § 1-9.107-5(a) or § 1-9.107-6(a):

(1) The requesting party may retain greater rights regardless of whether the invention is or is not directly related to a principal purpose of the contract when the agency finds that the invention comes within the criteria of § 1-9.107-3 (a) (1) through (4); and

(i) The retention of greater rights is a necessary incentive to call forth private risk capital and expense to bring the invention to the point of practical application; or

(ii) The Government's contribution to the invention is small compared to that of the contractor.

(2) The requesting party also may retain greater rights when the agency finds that:

(i) The invention is not directly related to a principal purpose of the contract and does not come within the criteria of § 1-9.107-3 (a) (1) through (4); and

(ii) The likelihood is that the invention will be more expeditiously developed to the point of practical application by the intentions and plans of the requesting party than by the activities of the Government.

(e) *Criteria for a determination for the retention of greater rights-Deferred clause.* When the request for a determination for the retention of greater rights relates to an invention reported under the Patent Rights clause of § 1-9.107-5(c) or § 1-9.107-6(b),

(1) The requesting party may retain greater rights where the agency finds:

(i) The invention does not come within the criteria of § 1-9.107-3 (a) (1) through (4); and

(ii) The likelihood is that the invention will be more expeditiously developed to the point of practical application by the intentions and plans of the requesting party than by the activities of

the Government.

(2) The requesting party may retain greater rights when an agency finds that the invention comes within the criteria of § 1 -9.107-3(a) (1) through (4); and

(i) The retention of greater rights is a necessary incentive to call forth risk capital and expense to bring the invention to the point of practical application; or

(ii) The Government's contribution to the invention is small compared to that of the contractor.

(f) Agency determination-Domestic rights. (1) The agency shall notify the party requesting a determination for the retention of greater rights of its decision. If the agency's determination is not coextensive with the party's request, the agency shall inform the party of the reasons on which the final action is based.

(2) Where the determination provides for the requesting party to retain title, the determination shall require that a domestic patent application be filed on the invention by the requesting party, and the following provisions shall apply:

(i) The application shall be filed within 6 months from the date of the determination, or such longer period as may be authorized in writing by the agency for good cause shown in writing by the requesting party;

(ii) For each patent application filed, the party shall:

(A) Within 2 months after such filing or within 2 months after the date of a determination if such patent application previously has been filed, deliver to the agency a copy of the application as filed, including the filing date and serial number;

(B) Include the following statement in the second paragraph of the specification of the application and any resulting patent: "The Government has rights in this invention pursuant to Contract No._____ (or Grant No . _____ **)** awarded by (identify the agency).";

(C) Within 6 months after such filing, or within 6 months after submission of the invention disclosure if the patent application has been previously filed, deliver to the agency's duly executed and approved instrument prepared by the Government fully confirmatory of all the rights to which the Government is entitled, and provide the agency an irrevocable power to inspect and make copies of the patent application filed;

(D) Provide the agency with a copy of the patent within 2 months after a patent is issued on the application; and

(E) Not less than 30 days before the expiration of the response period for any action required by the Patent and Trademark Office, notify the agency of any decision not to continue prosecution of the application and deliver to the agency executed instruments granting the

Government a power of attorney to prosecute the application; and

(iii) If the requesting party fails to file an application within the prescribed time periods, decides not to continue prosecution of the application, or no longer desires to retain title, he shall convey to the Government, upon request, his entire right, title, and interest in the invention, and to any corresponding patent application or patent. The conveyance shall be made by delivering to the agency duly executed instruments (prepared by the Government) and, if applicable, such other papers as are deemed necessary to vest in the Government the entire right, title, and interest in the invention and any corresponding patent application, and to enable the Government to prosecute the application.

(3) Where the determination provides for the requesting party to retain title, the determination shall be subject to a license to the Government, and the licensing and the commercial use reporting requirements of paragraph (c) "Minimum rights acquired by the Government," of the Patent Rights clauses of § 1-9.107-5. The determination normally shall also be subject to any other reservation or condition deemed to be appropriate by the agency.

(g) *Agency determination-Foreign rights* . (1) A contractor's request for a determination that he retain greater foreign rights in an invention under the Patent Rights clauses of either § 1-9.107-5 (a) or (c) or § 1-9.107-6 (a) or (b) may accompany a request for a determination that he retain greater domestic rights under § 1-9.109-6(a), or may be submitted independently thereof. The request shall contain the following information:

(i) The prime contract number and the subcontract number, if applicable, under which the invention was made and an identification of the agency's contracting office;

(ii) A brief description of the invention or a copy of the invention disclosure;

(iii) The countries in which the requesting party intends to file a patent application; and

(iv) Other information required by the agency.

(2) If the Government determines not to file a patent application on a Subject Invention of the contractor in any foreign country, the agency may authorize the requesting party to file a patent application on the invention in such foreign country and to retain the entire right, title, and interest therein if it determines such authorization to be in the public interest, subject to the license to the Government provided in paragraph (c) of the Patent Rights clause in § 1-9.107-5(a) or § 1-9.107-6(a).

(3) Where the determination includes a requirement that the requesting party file and prosecute a foreign patent application on the invention, the following provisions shall apply:

(i) The requesting party shall file and prosecute a patent application on the invention in (identify the foreign countries) in accordance with applicable statutes and regulations and within one of the following periods:

(A) Eight months from the date the corresponding United States patent application is filed by or on behalf of the requesting party; or if such an application is not filed, 6 months from the date of this agreement;

(B) Six months from the date a license is granted by the Commissioner of Patents and Trademarks to file foreign applications where such filing has been prohibited by security reasons; or

(C) Such longer period as may be approved by the agency;

(ii) The requesting party shall notify the agency promptly of each foreign application filed and upon written request of the agency shall furnish an English version of the foreign application without additional compensation; and

(iii) If the requesting party files or causes to be filed a patent application on a Subject Invention in any foreign country, or if a patent is obtained on such application, the party shall notify the agency, not less than 60 days before the expiration period for any action required by the foreign patent office, of any decision not to continue prosecution of the application or not to pay any maintenance fee covering the invention, and within such period shall deliver to the agency:

(A) Executed instruments granting to the Government power of attorney in the application;

(B) An English version of the application, if not previously provided, to the agency; and

(C) Upon request, a conveyance of the party's entire right, title, and interest in the invention in the foreign country, and to any corresponding patent application.

(Sec. 205(c), 63 Stat. 390; 40 U.S.C. 486(c))

APPENDIX E: BAYH-DOLE ACT OF 1980 AS ENACTED

Public Law 96-517
96th Congress

An Act

To amend the patent and trademark laws.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That title 35 of the United States Code, entitled "Patents", is amended by adding after chapter 29 the following new chapter 30:

"CHAPTER 30—PRIOR ART CITATIONS TO OFFICE AND REEXAMINATION OF PATENTS

. . .

SEC. 2. Section 41 of title 35, United States Code, is amended to read as follows

. . .

SEC. 3. Section 42 of title 35, United States Code, is amended to read as follows:

. . .

SEC. 4. Section 154 of title 35, United States Code, is amended by deleting the word "issue".

SEC. 5. Section 31 of the Trademark Act of 1946, as amended (15 U.S.C. 1113), is amended to read as follows:

. . .

SEC. 6. (a) Title 35 of the United States Code, entitled "Patents", is amended by adding after chapter 37 the following new chapter 38:

"CHAPTER 38—PATENT RIGHTS IN INVENTIONS MADE WITH FEDERAL ASSISTANCE

"Sec.
"200. Policy and objective.
"201. Definitions.
"202. Disposition of rights.
"203. March-in Rights.
"204. Preference for United States industry.
"205. Confidentiality
"206. Uniform clauses and regulations.
"207. Domestic and foreign protection of federally owned inventions.
"208. Regulations governing Federal licensing.
"209. Restrictions on licensing of federally owned inventions.
"210. Precedence of chapter.
"211. Relationship to antitrust laws.

"§ 200. Policy and objective

"It is the policy and objective of the Congress to use the patent system to promote the

utilization of inventions arising from federally supported research or development; to encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations, including universities; to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise; to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions; and to minimize the costs of administering policies in this area.

"§ 201. Definitions

"As used in this chapter—

"(a) The term "Federal agency" means any executive agency as defined in section 105 of title 5, United States Code, and the military departments as defined by section 102 of title 5 United States Code.

"(b) The term 'funding agreement' means any contract, grant, or cooperative agreement entered into between any Federal agency, other than the Tennessee Valley Authority, and any contractor for the performance of experimental, developmental, or research work funded in whole or in part by the Federal Government. Such term includes any assignment, substitution of parties, or subcontract of any type entered into for the performance of experimental, developmental, or research work under a funding agreement as herein defined.

"(c) The term 'contractor' means any person, small business firm, or nonprofit organization that is a party to a funding agreement.

"(d) The term 'invention' means any invention or discovery which is or may be patentable or otherwise protectable under this title.

"(e) The term 'subject invention' means any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement.

"(f) The term 'practical application' means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms.

"(g) The term 'made' when used in relation to any invention means the conception or first actual reduction to practice of such invention.

"(h) The term 'small business firm' means a small business concern as defined at

section 2 of Public Law 85–536 (15 U.S.C. 632) and implementing regulations of the Administrator of the Small Business Administration.

"(i) The term 'nonprofit organization" means universities and other institutions of higher education or an organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1954 (26 U.S.C. 501(c)) and exempt from taxation under section 501(a) of the Internal Revenue Code (26 U.S.C. 501 (a)) or any nonprofit scientific or educational organization qualified under a State nonprofit organization statute.

"§ 202. Disposition of rights

"(a) Each nonprofit organization or small business firm may, within a reasonable time after disclosure as required by paragraph (c)(1) of this section, elect to retain title to any subject invention: *Provided*, *however*, That a funding agreement may provide otherwise (i) when the funding agreement is for the operation of a Government-owned research or production facility, (ii) in exceptional circumstances when it is determined by the agency that restriction or elimination of the right to retain title to any subject invention will better promote the policy and objectives of this chapter or (iii) when it is determined by a Government authority which is authorized by statute or Executive order to conduct foreign intelligence or counter-intelligence activities that the restriction or elimination of the right to retain title to any subject invention is necessary to protect the security of such activities or. The rights of the nonprofit organization or small business firm shall be subject to the provisions of paragraph (c) of this section and the other provisions of this chapter.

"(b)(1) Any determination under (ii) of paragraph (a) of this section shall be in writing and accompanied by a written statement of facts justifying the determination. A copy of each such determination and justification shall be sent to the Comptroller General of the United States within thirty days after the award of the applicable funding agreement. In the case of determinations applicable to funding agreements with small business firms copies shall also be sent to the Chief Counsel for Advocacy of the Small Business Administration.

"(2) If the Comptroller General believes that any pattern of determinations by a Federal agency is contrary to the policy and objectives of this chapter or that an agency's policies or practices are otherwise not in conformance with this chapter, the Comptroller General shall so advise the head of the agency. The head of the agency shall advise the Comptroller General in writing within one hundred and twenty days of what action, if any, the agency has taken or plans to take with respect to the matters raised by the Comptroller General.

"(3) At least once each year, the Comptroller General shall transmit a report to the Committees on the Judiciary of the Senate and House of Representatives on the manner in which this chapter is being implemented by the agencies and on such other aspects of Government patent policies and practices with respect to federally funded inventions as the Comptroller General believes appropriate.

"(c) Each funding agreement with a small business firm or nonprofit organization shall

contain appropriate provisions to effectuate the following:

"(1) A requirement that the contractor disclose each subject invention to the Federal agency within a reasonable time after it is made and that the Federal Government may receive title to any subject invention not reported to it within such time.

"(2) A requirement that the contractor make an election to retain title to any subject invention within a reasonable time after disclosure and that the Federal Government may receive title to any subject invention in which the contractor does not elect to retain rights or fails to elect rights within such times.

"(3) A requirement that a contractor electing rights file patent applications within reasonable times and that the Federal Government may receive title to any subject inventions in the United States or other countries in which the contractor has not filed patent applications on the subject invention within such times.

"(4) With respect to any invention in which the contractor elects rights, the Federal agency shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world, and may, if provided in the funding agreement, have additional rights to sublicense any foreign government or international organization pursuant to any existing or future treaty or agreement.

"(5) The right of the Federal agency to require periodic reporting on the utilization or efforts at obtaining utilization that are being made by the contractor or his licensees or assignees: *Provided*, That any such information may be treated by the Federal agency as commercial and financial information obtained from a person and privileged and confidential and not subject to disclosure under section 552 of title 5 of the United States Code.

"(6) An obligation on the part of the contractor, in the event a United States patent application is filed by or on its behalf or by any assignee of the contractor, to include within the specification of such application and any patent issuing thereon, a statement specifying that the invention was made with Government support and that the Government has certain rights in the invention.

"(7) In the case of a nonprofit organization, (A) a prohibition upon the assignment of rights to a subject invention in the United States without the approval of the Federal agency, except where such assignment is made to an organization which has as one of its primary functions the management of inventions and which is not, itself, engaged in or does not hold a substantial interest in other organizations engaged in the manufacture or sale of products that might utilize the invention or be in competition with embodiments of the invention (provided that such assignee shall be subject to the same provisions as the contractor); (B) a prohibition against the granting of exclusive licenses under United States Patents or Patent Applications in a subject invention by the contractor to persons other than small business firms for a period in excess of the earlier of five years from first

commercial sale or use of the invention or eight years from the date of the exclusive license excepting that time before regulatory agencies necessary to obtain premarket clearance unless, on a case-by-case basis, the Federal agency approves a longer exclusive license. If exclusive field of use licenses are granted, commercial sale or use in one field of use shall not be deemed commercial sale or use as to other fields of use, and a first commercial sale or use with respect to a product of the invention shall not be deemed to end the exclusive period to different subsequent products covered by the invention; (C) a requirement that the contractor share royalties with the inventor; and (D) a requirement that the balance of any royalties or income earned by the contractor with respect to subject inventions, after payment of expenses (including payments to inventors) incidental to the administration of subject inventions, be utilized for the support of scientific research or education.

"(8) The requirements of sections 203 and 204 of this chapter.

"(d) If a contractor does not elect to retain title to a subject invention in cases subject to this section, the Federal agency may consider and after consultation with the contractor grant requests for retention of rights by the inventor subject to the provisions of this Act and regulations promulgated hereunder.

"(e) In any case when a Federal employee is a coinventor of any invention made under a funding agreement with a nonprofit organization or small business firm, the Federal agency employing such coinventor is authorized to transfer or assign whatever rights it may acquire in the subject invention from its employees to the contractor subject to the conditions set forth in this chapter.

"(f)(1) No funding agreement with a small business firm or nonprofit organization shall contain a provision allowing a Federal agency to require the licensing to third parties of inventions owned by the contractor that are not subject inventions unless such provision has been approved by the head of the agency and a written justification has been signed by the head of the agency and a written justification has been signed by the head of the agency.. Any such provision shall clearly state whether the licensing may be required in connection with the practice of a subject invention, a specifically identified work object, or both. The head of the agency may not delegate the authority to approve provisions or sign justifications required by this paragraph.

"(2) A Federal agency shall not require the licensing of third parties under any such provision unless the head of the agency determines that the use of the invention by others is necessary for the practice of a subject invention or for the use of a work object of the funding agreement and that such action is necessary to achieve the practical application of the subject invention or work object. Any such determination shall be on the record after an opportunity for an agency hearing. Any action commenced for judicial review of such determination shall be brought within sixty days after notification of such determination.

"§ 203. March-in rights

"With respect to any subject invention in which a small business firm or nonprofit

organization has acquired title under this chapter, the Federal agency under whose funding agreement the subject invention was made shall have the right, in accordance with such procedures as are provided in regulations promulgated hereunder to require the contractor, an assignee or exclusive licensee of a subject invention to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if the contractor, assignee, or exclusive licensee refuses such request, to grant such a license itself, if the Federal agency determines that such—

> "(a) action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use;
>
> "(b) action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees;
>
> "(c) action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees; or
>
> "(d) action is necessary because the agreement required by section 204 has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of its agreement obtained pursuant to section 204.

"§ 204. Preference for United States industry

"Notwithstanding any other provision of this chapter, no small business firm or nonprofit organization which receives title to any subject invention and no assignee of any such small business firm or nonprofit organization shall grant to any person the exclusive right to use or sell any subject invention in the United States unless such person agrees that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States. However, in individual cases, the requirement for such an agreement may be waived by the Federal agency under whose funding agreement the invention was made upon a showing by the small business firm, nonprofit organization, or assignee that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible.

"§ 205. Confidentiality

"Federal agencies are authorized to withhold from disclosure to the public information disclosing any invention in which the Federal Government owns or may own a right, title, or interest (including a nonexclusive license) for a reasonable time in order for a patent application to be filed. Furthermore, Federal agencies shall not be required to release copies of any document which is part of an application for patent filed with the United States Patent and Trademark Office or with any foreign patent office.

"§ 206. Uniform clauses and regulations

"The Office of Federal Procurement Policy, after receiving recommendations of the Office of Science and Technology Policy, may issue regulations which may be made applicable to Federal agencies implementing the provisions of sections 202 through 204 of this chapter and the Office of Federal Procurement Policy shall establish standard funding agreement provisions required under this chapter.

"§ 207. Domestic and foreign protection of federally owned inventions

"Each Federal agency is authorized to—

"(1) apply for, obtain, and maintain patents or other forms of protection in the United States and in foreign countries on inventions in which the Federal Government owns a right, title, or interest;

"(2) grant nonexclusive, exclusive, or partially exclusive licenses under federally owned patent applications, patents, or other forms of protection obtained, royalty-free or for royalties or other consideration, and on such terms and conditions, including the grant to the licensee of the right of enforcement pursuant to the provisions of chapter 29 of this title as determined appropriate in the public interest;

"(3) undertake all other suitable and necessary steps to protect and administer rights to federally owned inventions on behalf of the Federal Government either directly or through contract; and

"(4) transfer custody and administration, in whole or in part, to another Federal agency, of the right, title, or interest in any federally owned invention.

"§ 208. Regulations governing Federal licensing

"The Administrator of General Services is authorized to promulgate regulations specifying the terms and conditions upon which any federally owned invention, other than inventions owned by the Tennessee Valley Authority, may be licensed on a nonexclusive, partially exclusive, or exclusive basis.

"§ 209. Restrictions on licensing of federally owned inventions

"(a) No Federal agency shall grant any license under a patent or patent application on a federally owned invention unless the person requesting the license has supplied the agency with a plan for development and/or marketing of the invention, except that any such plan may be treated by the Federal agency as commercial and financial information obtained from a person and privileged and confidential and not subject to disclosure under section 552 of title 5 of the United States Code.

"(b) A Federal agency shall normally grant the right to use or sell any federally owned invention in the United States only to a licensee that agrees that any products embodying the invention or produced through the use of the invention will be manufactured substantially in the United States.

"(c)(1) Each Federal agency may grant exclusive or partially exclusive licenses in any invention covered by a federally owned domestic patent or patent application only if, after public notice and opportunity for filing written objections, it is determined that—

> "(A) the interests of the Federal Government and the public will best be served by the proposed license, in view of the applicant's intentions, plans, and ability to bring the invention to practical application or otherwise promote the invention's utilization by the public;
>
> "(B) the desired practical application has not been achieved, or is not likely expeditiously to be achieved, under any nonexclusive license which has been granted, or which may be granted, on the invention;
>
> "(C) exclusive or partially exclusive licensing is a reasonable and necessary incentive to call forth the investment of risk capital and expenditures to bring the invention to practical application or otherwise promote the invention's utilization by the public; and
>
> "(D) the proposed terms and scope of exclusivity are not greater than reasonably necessary to provide the incentive for bringing the invention to practical application or otherwise promote the invention's utilization by the public.

"(2) A Federal agency shall not grant such exclusive or partially exclusive license under paragraph (1) of this subsection if it determines that the grant of such license will tend substantially to lessen competition or result in undue concentration in any section of the country in any line of commerce to which the technology to be licensed relates, or to create or maintain other situations inconsistent with the antitrust laws.

"(3) First preference in the exclusive or partially exclusive licensing of federally owned inventions shall go to small business firms submitting plans that are determined by the agency to be within the capabilities of the firms and equally likely, if executed, to bring the invention to practical application as any plans submitted by applicants that are not small business firms.

"(d) After consideration of whether the interests of the Federal Government or United States industry in foreign commerce will be enhanced, any Federal agency may grant exclusive or partially exclusive licenses in any invention covered by a foreign patent application or patent, after public notice and opportunity for filing written objections, except that a Federal agency shall not grant such exclusive or partially exclusive license if it determines that the grant of such license will tend substantially to lessen competition or result in undue concentration in any section of the United States in any line of commerce to which the technology to be licensed relates, or to create or maintain other situations inconsistent with antitrust laws.

"(e) The Federal agency shall maintain a record of determinations to grant exclusive or partially exclusive licenses.

"(f) Any grant of a license shall contain such terms and conditions as the Federal agency determines appropriate for the protection of the interests of the Federal Government and the public, including provisions for the following:

"(1) periodic reporting on the utilization or efforts at obtaining utilization that are being made by the licensee with particular reference to the plan submitted: *Provided*, That any such information may be treated by the Federal agency as commercial and financial information obtained from a person and privileged and confidential and not subject to disclosure under section 552 of title 5 of the United States Code;

"(2) the right of the Federal agency to terminate such license in whole or in part of it determines that the licensee is not executing the plan submitted with its request for a license and the licensee cannot otherwise demonstrate to the satisfaction of the Federal agency that it has taken or can be expected to take within a reasonable time, effective steps to achieve practical application of the invention;

"(3) the right of the Federal agency to terminate such license in whole or in part if the licensee is in breach of an agreement obtained pursuant to paragraph (b) of this section; and

"(4) the right of the Federal agency to terminate the license in whole or in part if the agency determines that such action is necessary to meet requirements for public use specified by Federal regulations issued after the date of the license and such requirements are not reasonably satisfied by the licensee.

"§ 210. Precedence of chapter

"(a) This chapter shall take precedence over any other Act which would require a disposition of rights in subject inventions of small business firms or nonprofit organizations contractors in a manner that is inconsistent with this chapter, including but not necessarily limited to the following:

"(1) section 10(a) of the Act of June 29, 1935, as added by title I of the Act of August 14, 1946 (7 U.S.C. 427i (a); 60 Stat. 1085);

"(2) section 205(a) of the Act of August 14, 1946 (7 U.S.C. 1624 (a); 60 Stat. 1090);

"(3) section 501(c) of the Federal Mine Safety and Health Act of 1977 (30 U.S.C. 951 (c); 83 Stat. 742);

"(4) section 106(c) of the National Traffic and Motor Vehicle Safety Act of 1966 (15 U.S.C. 1395(c); 80 Stat. 721);

"(5) section 12 of the National Science Foundation Act of 1950 (42 U.S.C. 1871 (a); 82 Stat. 360);

"(6) section 152 of the Atomic Energy Act of 1954 (42 U.S.C. 2182; 68 Stat. 943);

"(7) section 305 of the National Aeronautics and Space Act of 1958 (42 U.S.C. 2457);

"(8) section 6 of the Coal Research and Development Act of 1960 (30 U.S.C. 666; 74 Stat. 337);

"(9) section 4 of the Helium Act Amendments of 1960 (50 U.S.C. 167b; 74 Stat. 920);

"(10) section 32 of the Arms Control and Disarmament Act of 1961 (22 U.S.C. 2572; 75 Stat. 634);

"(11) subsection (e) of section 302 of the Appalachian Regional Development Act of 1965 (40 U.S.C. App. 302(e); 79 Stat. 5);

"(12) section 9 of the Federal Nonnuclear Energy Research and Development Act of 1974 (42 U.S.C. 5908; 88 Stat. 1878);

"(13) section 5(d) of the Consumer Product Safety Act (15 U.S.C. 2054 (d); 86 Stat. 1211);

"(14) section 3 of the Act of April 5, 1944 (30 U.S.C. 323; 58 Stat. 191);

"(15) section 8001(c)(3) of the Solid Waste Disposal Act (42 U.S.C. 6981 (c); 90 Stat. 2829);

"(16) section 219 of the Foreign Assistance Act of 1961 (22 U.S.C. 2179; 83 Stat. 806);

"(17) section 427(b) of the Federal Mine Health and Safety Act of 1977 (30 U.S.C. 937 (b); 86 Stat. 155);

"(18) section 306(d) of the Surface Mining and Reclamation Act of 1977 (30 U.S.C. 1226 (d); 91 Stat. 455);

"(19) section 21(d) of the Federal Fire Prevention and Control Act of 1974 (15 U.S.C. 2218 (d); 88 Stat. 1548);

"(20) section 6(b) of the Solar Photovoltaic Energy Research Development and Demonstration Act of 1978 (42 U.S.C. 5585 (b); 92 Stat. 2516);

"(21) section 12 of the Native Latex Commercialization and Economic Development Act of 1978 (7 U.S.C. 178j; 92 Stat. 2533); and

"(22) section 408 of the Water Resources and Development Act of 1978 (42 U.S.C. 7879; 92 Stat. 1360).

The Act creating this chapter shall be construed to take precedence over any future Act unless that Act specifically cites this Act and provides that it shall take precedence over this Act.

"(b) Nothing in this chapter is intended to alter the effect of the laws cited in paragraph (a) of this section or any other laws with respect to the disposition of rights in inventions made in the performance of funding agreements with persons other than nonprofit organizations or small business firms.

"(c) Nothing in this chapter is intended to limit the authority of agencies to agree to the disposition of rights in inventions made in the performance of work under funding agreements with persons other than nonprofit organizations or small business firms in accordance with the Statement of Government Patent Policy issued on August 23, 1971 (36 Fed. Reg. 16887), agency regulations, or other applicable regulations or to otherwise limit the authority of agencies to allow such persons to retain ownership of inventions. Any disposition of rights in inventions made in accordance with the Statement or implementing regulations, including any disposition occurring before enactment of this section, are hereby authorized.

"(d) Nothing in this chapter shall be construed to require the disclosure of intelligence sources or methods or to otherwise affect the authority granted to the Director of Central Intelligence by statute or Executive order for the protection of intelligence sources or methods.

"§ 211. Relationship to antitrust laws

"Nothing in this chapter shall be deemed to convey to any person immunity from civil or criminal liability, or to create any defenses to actions, under any antitrust law.

(b) The table of chapters for Title 35, United States Code, is amended by adding immediately after the item relating to chapter 37 the following:

"38. Patent rights in inventions made with Federal assistance.".

SEC. 7. AMENDMENTS TO OTHER ACTS . . .
. . .
SEC. 8. [providing effective dates for various provisions of Act]
. . .
SEC. 9. [requiring the Commissioner of Patents and Trademarks to report a plan to develop computerized data and retrieval systems for the USPTO]
SEC. 10. [adding a new section to the Copyright Act regarding infringement of copyright in computer programs for a copy to be made for each of the use of the program by a computer and a single archival copy]

APPENDIX F: MEMORANDUM ON GOVERNMENT PATENT POLICY ISSUED BY PRESIDENT RONALD REAGAN ON FEBRUARY 18, 1983

MEMORANDUM TO THE HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES

SUBJECT: GOVERNMENT PATENT POLICY

To the extent permitted by law, agency policy with respect to the disposition of any invention made in the performance of a federally-funded research and development contract, grant or cooperative agreement award shall be the same or substantially the same as applied to small business firms and nonprofit organizations under Chapter 38 of Title 35 of the United States Code.

In awards not subject to Chapter 38 of Title 35 of the United States Code, any of the rights of the Government or obligations of the performer described in 35 U.S.C. 202-204 may be waived or omitted if the agency determines (1) that the interests of the United States and the general public will be better served thereby as, for example, where this is necessary to obtain a uniquely or highly qualified performer; or (2) that the award involves co-sponsored, cost sharing, or joint venture research and development, and the performer, cosponsor or joint venturer is making substantial contribution of funds, facilities or equipment to the work performed under the award.

In addition, agencies should protect the confidentiality of invention disclosure, patent applications and utilization reports required in performance or in consequence of awards to the extent permitted by 35 U.S.C. 205 or other applicable laws.

RONALD REAGAN

APPENDIX G: CURRENT VERSION OF BAYH-DOLE ACT OF 1980
AS AMENDED THROUGH 2000 AND CODIFIED AT
35 USC §§200-212

of any other department or agency of the Government designated by the President as a defense agency of the United States, and the Secretary of Commerce, may separately issue rules and regulations to enable the respective department or agency to carry out the provisions of this chapter, and may delegate any power conferred by this chapter.

(July 19, 1952, ch. 950, 66 Stat. 808.)

HISTORICAL AND REVISION NOTES

Based on Title 35, U.S.C., 1946 ed., § 158 (Feb. 1, 1952, ch. 4, § 8, 66 Stat. 6).

Language is changed.

TRANSFER OF FUNCTIONS

Atomic Energy Commission abolished and functions transferred by sections 5814 and 5841 of Title 42, The Public Health and Welfare. See, also, Transfer of Functions notes set out under those sections.

DEFENSE AGENCIES

Department of Justice designated as a defense agency of United States for purposes of this chapter by Executive Order No. 10457, May 27, 1953, 18 F.R. 3083.

CHAPTER 18—PATENT RIGHTS IN INVENTIONS MADE WITH FEDERAL ASSISTANCE

AMENDMENTS

2000—Pub. L. 106–404, § 4(b), Nov. 1, 2000, 114 Stat. 1744, substituted ''Licensing federally owned inventions'' for ''Restrictions on licensing of federally owned inventions'' in item 209.

1984—Pub. L. 98–620, title V, § 501(15), Nov. 8, 1984, 98 Stat. 3368, added item 212.

1982—Pub. L. 97–256, title I, § 101(5), Sept. 8, 1982, 96 Stat. 816, redesignated chapter 38, as added by Pub. L. 96–517, § 6(a), Dec. 12, 1980, 94 Stat. 3018, comprising sections 200 to 211, as chapter 18, and transferred chapter 18, as so redesignated, to end of this part from end of part IV.

§ 200. Policy and objective

It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development; to encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations, including universities; to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery; to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions; and to minimize the costs of administering policies in this area.

(Added Pub. L. 96–517, § 6(a), Dec. 12, 1980, 94 Stat. 3018; amended Pub. L. 106–404, § 5, Nov. 1, 2000, 114 Stat. 1745.)

AMENDMENTS

2000—Pub. L. 106–404 substituted ''enterprise without unduly encumbering future research and discovery;'' for ''enterprise;''.

EFFECTIVE DATE

Chapter effective July 1, 1981, but implementing regulations authorized to be issued earlier, see section 8(f) of Pub. L. 96–517, set out as an Effective Date of 1980 Amendment note under section 41 of this title.

§ 201. Definitions

As used in this chapter—

(a) The term ''Federal agency'' means any executive agency as defined in section 105 of title 5, and the military departments as defined by section 102 of title 5.

(b) The term ''funding agreement'' means any contract, grant, or cooperative agreement entered into between any Federal agency, other than the Tennessee Valley Authority, and any contractor for the performance of experimental, developmental, or research work funded in whole or in part by the Federal Government. Such term includes any assignment, substitution of parties, or subcontract of any type entered into for the performance of experimental, developmental, or research work under a funding agreement as herein defined.

(c) The term ''contractor'' means any person, small business firm, or nonprofit organization that is a party to a funding agreement.

(d) The term ''invention'' means any invention or discovery which is or may be patentable or otherwise protectable under this title or any novel variety of plant which is or may be protectable under the Plant Variety Protection Act (7 U.S.C. 2321 et seq.).

(e) The term ''subject invention'' means any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement: *Provided*, That in the case of a variety of plant, the date of determination (as defined in section 41(d)[1] of the Plant Variety Protection Act (7 U.S.C. 2401(d))) must also occur during the period of contract performance.

(f) The term ''practical application'' means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms.

[1] See References in Text note below.

(g) The term ''made'' when used in relation to any invention means the conception or first actual reduction to practice of such invention.

(h) The term ''small business firm'' means a small business concern as defined at section 2 of Public Law 85–536 (15 U.S.C. 632) and implementing regulations of the Administrator of the Small Business Administration.

(i) The term ''nonprofit organization'' means universities and other institutions of higher education or an organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1986 (26 U.S.C. 501(c)) and exempt from taxation under section 501(a) of the Internal Revenue Code (26 U.S.C. 501(a)) or any nonprofit scientific or educational organization qualified under a State nonprofit organization statute.

(Added Pub. L. 96–517, § 6(a), Dec. 12, 1980, 94 Stat. 3019; amended Pub. L. 98–620, title V, § 501(1), (2), Nov. 8, 1984, 98 Stat. 3364; Pub. L. 99–514, § 2, Oct. 22, 1986, 100 Stat. 2095; Pub. L. 107–273, div. C, title III, § 13206(a)(12), Nov. 2, 2002, 116 Stat. 1904.)

REFERENCES IN TEXT

The Plant Variety Protection Act, referred to in subsec. (d), is Pub. L. 91–577, Dec. 24, 1970, 84 Stat. 1542, as amended, which is classified principally to chapter 57 (§ 2321 et seq.) of Title 7, Agriculture. For complete classification of this Act to the Code, see Short Title note set out under section 2321 of Title 7 and Tables.

Section 41 of the Plant Variety Protection Act (7 U.S.C. 2401(d)), referred to in subsec. (e), was subsequently amended, and no longer defines the term ''date of determination''.

AMENDMENTS

2002—Subsec. (a). Pub. L. 107–273 struck out ''United States Code,'' after ''section 105 of title 5,'' and '', United States Code'' after ''section 102 of title 5''.

1986—Subsec. (i). Pub. L. 99–514 substituted ''Internal Revenue Code of 1986'' for ''Internal Revenue Code of 1954''.

1984—Subsec. (d). Pub. L. 98–620, § 501(1), inserted ''or any novel variety of plant which is or may be protectable under the Plant Variety Protection Act (7 U.S.C. 2321 et seq.)'' after ''title''.

Subsec. (e). Pub. L. 98–620, § 501(2), inserted '': *Provided*, That in the case of a variety of plant, the date of determination (as defined in section 41(d) of the Plant Variety Protection Act (7 U.S.C. 2401(d))) must also occur during the period of contract performance'' after ''agreement''.

§ 202. Disposition of rights

(a) Each nonprofit organization or small business firm may, within a reasonable time after disclosure as required by paragraph (c)(1) of this section, elect to retain title to any subject invention: *Provided*, *however*, That a funding agreement may provide otherwise (i) when the contractor is not located in the United States or does not have a place of business located in the United States or is subject to the control of a foreign government, (ii) in exceptional circumstances when it is determined by the agency that restriction or elimination of the right to retain title to any subject invention will better promote the policy and objectives of this chapter (iii) when it is determined by a Government authority which is authorized by statute or Executive order to conduct foreign intelligence or counter-intelligence activities that the restriction or elimination of the right to retain title to any subject invention is necessary to protect the security of such activities or, (iv) when the funding agreement includes the operation of a Government-owned, contractor-operated facility of the Department of Energy primarily dedicated to that Department's naval nuclear propulsion or weapons related programs and all funding agreement limitations under this subparagraph on the contractor's right to elect title to a subject invention are limited to inventions occurring under the above two programs of the Department of Energy. The rights of the nonprofit organization or small business firm shall be subject to the provisions of paragraph (c) of this section and the other provisions of this chapter.

(b)(1) The rights of the Government under subsection (a) shall not be exercised by a Federal agency unless it first determines that at least one of the conditions identified in clauses (i) through (iv) of subsection (a) exists. Except in the case of subsection (a)(iii), the agency shall file with the Secretary of Commerce, within thirty days after the award of the applicable funding agreement, a copy of such determination. In the case of a determination under subsection (a)(ii), the statement shall include an analysis justifying the determination. In the case of determinations applicable to funding agreements with small business firms, copies shall also be sent to the Chief Counsel for Advocacy of the Small Business Administration. If the Secretary of Commerce believes that any individual determination or pattern of determinations is contrary to the policies and objectives of this chapter or otherwise not in conformance with this chapter, the Secretary shall so advise the head of the agency concerned and the Administrator of the Office of Federal Procurement Policy, and recommend corrective actions.

(2) Whenever the Administrator of the Office of Federal Procurement Policy has determined that one or more Federal agencies are utilizing the authority of clause (i) or (ii) of subsection (a) of this section in a manner that is contrary to the policies and objectives of this chapter, the Administrator is authorized to issue regulations describing classes of situations in which agencies may not exercise the authorities of those clauses.

(3) At least once every 5 years, the Comptroller General shall transmit a report to the Committees on the Judiciary of the Senate and House of Representatives on the manner in which this chapter is being implemented by the agencies and on such other aspects of Government patent policies and practices with respect to federally funded inventions as the Comptroller General believes appropriate.

(4) If the contractor believes that a determination is contrary to the policies and objectives of this chapter or constitutes an abuse of discretion by the agency, the determination shall be subject to the[1] section 203(b).

(c) Each funding agreement with a small business firm or nonprofit organization shall contain appropriate provisions to effectuate the following:

[1] So in original. The word ''the'' probably should not appear.

(1) That the contractor disclose each subject invention to the Federal agency within a reasonable time after it becomes known to contractor personnel responsible for the administration of patent matters, and that the Federal Government may receive title to any subject invention not disclosed to it within such time.

(2) That the contractor make a written election within two years after disclosure to the Federal agency (or such additional time as may be approved by the Federal agency) whether the contractor will retain title to a subject invention: *Provided*, That in any case where publication, on sale, or public use, has initiated the one year statutory period in which valid patent protection can still be obtained in the United States, the period for election may be shortened by the Federal agency to a date that is not more than sixty days prior to the end of the statutory period: *And provided further*, That the Federal Government may receive title to any subject invention in which the contractor does not elect to retain rights or fails to elect rights within such times.

(3) That a contractor electing rights in a subject invention agrees to file a patent application prior to any statutory bar date that may occur under this title due to publication, on sale, or public use, and shall thereafter file corresponding patent applications in other countries in which it wishes to retain title within reasonable times, and that the Federal Government may receive title to any subject inventions in the United States or other countries in which the contractor has not filed patent applications on the subject invention within such times.

(4) With respect to any invention in which the contractor elects rights, the Federal agency shall have a nonexclusive, nontransferrable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world: *Provided*, That the funding agreement may provide for such additional rights, including the right to assign or have assigned foreign patent rights in the subject invention, as are determined by the agency as necessary for meeting the obligations of the United States under any treaty, international agreement, arrangement of cooperation, memorandum of understanding, or similar arrangement, including military agreement relating to weapons development and production.

(5) The right of the Federal agency to require periodic reporting on the utilization or efforts at obtaining utilization that are being made by the contractor or his licensees or assignees: *Provided*, That any such information as well as any information on utilization or efforts at obtaining utilization obtained as part of a proceeding under section 203 of this chapter shall be treated by the Federal agency as commercial and financial information obtained from a person and privileged and confidential and not subject to disclosure under section 552 of title 5.

(6) An obligation on the part of the contractor, in the event a United States patent application is filed by or on its behalf or by any assignee of the contractor, to include within the specification of such application and any patent issuing thereon, a statement specifying that the invention was made with Government support and that the Government has certain rights in the invention.

(7) In the case of a nonprofit organization, (A) a prohibition upon the assignment of rights to a subject invention in the United States without the approval of the Federal agency, except where such assignment is made to an organization which has as one of its primary functions the management of inventions (provided that such assignee shall be subject to the same provisions as the contractor); (B) a requirement that the contractor share royalties with the inventor; (C) except with respect to a funding agreement for the operation of a Government-owned-contractor-operated facility, a requirement that the balance of any royalties or income earned by the contractor with respect to subject inventions, after payment of expenses (including payments to inventors) incidental to the administration of subject inventions, be utilized for the support of scientific research or education; (D) a requirement that, except where it proves infeasible after a reasonable inquiry, in the licensing of subject inventions shall be given to small business firms; and (E) with respect to a funding agreement for the operation of a Government-owned-contractor-operated facility, requirements (i) that after payment of patenting costs, licensing costs, payments to inventors, and other expenses incidental to the administration of subject inventions, 100 percent of the balance of any royalties or income earned and retained by the contractor during any fiscal year up to an amount equal to 5 percent of the annual budget of the facility, shall be used by the contractor for scientific research, development, and education consistent with the research and development mission and objectives of the facility, including activities that increase the licensing potential of other inventions of the facility; provided that if said balance exceeds 5 percent of the annual budget of the facility, that 75 percent of such excess shall be paid to the Treasury of the United States and the remaining 25 percent shall be used for the same purposes as described above in this clause (D); and (ii) that, to the extent it provides the most effective technology transfer, the licensing of subject inventions shall be administered by contractor employees on location at the facility.

(8) The requirements of sections 203 and 204 of this chapter.

(d) If a contractor does not elect to retain title to a subject invention in cases subject to this section, the Federal agency may consider and after consultation with the contractor grant requests for retention of rights by the inventor subject to the provisions of this Act and regulations promulgated hereunder.

(e) In any case when a Federal employee is a coinventor of any invention made with a nonprofit organization, a small business firm, or a non-Federal inventor, the Federal agency employing such coinventor may, for the purpose of

consolidating rights in the invention and if it finds that it would expedite the development of the invention—

(1) license or assign whatever rights it may acquire in the subject invention to the nonprofit organization, small business firm, or non-Federal inventor in accordance with the provisions of this chapter; or

(2) acquire any rights in the subject invention from the nonprofit organization, small business firm, or non-Federal inventor, but only to the extent the party from whom the rights are acquired voluntarily enters into the transaction and no other transaction under this chapter is conditioned on such acquisition.

(f)(1) No funding agreement with a small business firm or nonprofit organization shall contain a provision allowing a Federal agency to require the licensing to third parties of inventions owned by the contractor that are not subject inventions unless such provision has been approved by the head of the agency and a written justification has been signed by the head of the agency. Any such provision shall clearly state whether the licensing may be required in connection with the practice of a subject invention, a specifically identified work object, or both. The head of the agency may not delegate the authority to approve provisions or sign justifications required by this paragraph.

(2) A Federal agency shall not require the licensing of third parties under any such provision unless the head of the agency determines that the use of the invention by others is necessary for the practice of a subject invention or for the use of a work object of the funding agreement and that such action is necessary to achieve the practical application of the subject invention or work object. Any such determination shall be on the record after an opportunity for an agency hearing. Any action commenced for judicial review of such determination shall be brought within sixty days after notification of such determination.

(Added Pub. L. 96–517, § 6(a), Dec. 12, 1980, 94 Stat. 3020; amended Pub. L. 98–620, title V, § 501(3)–(8), Nov. 8, 1984, 98 Stat. 3364–3366; Pub. L. 102–204, § 10, Dec. 10, 1991, 105 Stat. 1641; Pub. L. 106–113, div. B, § 1000(a)(9) [title IV, § 4732(a)(12)], Nov. 29, 1999, 113 Stat. 1536, 1501A–583; Pub. L. 106–404, § 6(1), Nov. 1, 2000, 114 Stat. 1745; Pub. L. 107–273, div. C, title III, § 13206(a)(13), Nov. 2, 2002, 116 Stat. 1905.)

REFERENCES IN TEXT

This Act, referred to in subsec. (d), probably means Pub. L. 96–517, Dec. 12, 1980, 94 Stat. 3015, which enacted sections 200 to 211 and 301 to 307 of this title, amended sections 41, 42, and 154 of this title, section 1113 of Title 15, Commerce and Trade, sections 101 and 117 of Title 17, Copyrights, and sections 2186, 2457, and 5908 of Title 42, The Public Health and Welfare, and enacted provisions set out as notes under sections 13 and 41 of this title. For complete classification of this Act to the Code, see Tables.

AMENDMENTS

2002—Subsec. (b)(4). Pub. L. 107–273, § 13206(a)(13)(A), substituted ''section 203(b)'' for ''last paragraph of section 203(2)''.

Subsec. (c)(4). Pub. L. 107–273, § 13206(a)(13)(B)(i), substituted ''additional rights,'' for ''additional rights;''.

Subsec. (c)(5). Pub. L. 107–273, § 13206(a)(13)(B)(ii), struck out ''of the United States Code'' after ''section 552 of title 5''.

2000—Subsec. (e). Pub. L. 106–404 amended subsec. (e) generally. Prior to amendment, subsec. (e) read as follows: ''In any case when a Federal employee is a coinventor of any invention made under a funding agreement with a nonprofit organization or small business firm, the Federal agency employing such coinventor is authorized to transfer or assign whatever rights it may acquire in the subject invention from its employee to the contractor subject to the conditions set forth in this chapter.''

1999—Subsec. (a). Pub. L. 106–113, in first sentence, substituted ''(iv)'' for ''iv)'' and struck out a second period at end.

1991—Subsec. (b)(3). Pub. L. 102–204 substituted ''every 5 years'' for ''each year''.

1984—Subsec. (a). Pub. L. 98–620, § 501(3), substituted ''when the contractor is not located in the United States or does not have a place of business located in the United States or is subject to the control of a foreign government'' for ''when the funding agreement is for the operation of a Government-owned research or production facility'', struck out ''or'' before ''(ii)'', which was executed by striking out ''or'' before ''(iii)'' as the probable intent of Congress, and added cl. (iv).

Subsec. (b)(1). Pub. L. 98–620, § 501(4), gave to the Department of Commerce oversight of agency use of the exceptions to small business or nonprofit organization invention ownership.

Subsec. (b)(2). Pub. L. 98–620, § 501(4), substituted provisions authorizing the Administrator of the Office of Federal Procurement Policy to issue regulations describing situations in which agencies may not exercise the authorities of clauses (i) or (ii) of subsec. (a), whenever the Administrator has determined that one or more agencies are utilizing such authority in violation of this chapter for provisions which gave to the Comptroller General oversight of agency actions under this chapter.

Subsec. (b)(4). Pub. L. 98–620, § 501(4A), added par. (4).

Subsec. (c)(1). Pub. L. 98–620, § 501(5), substituted provisions requiring disclosure of each invention within a reasonable time after it becomes known to contractor personnel responsible for the administration of patent matters for provision requiring disclosure of each invention within a reasonable time after it is made.

Subsec. (c)(2). Pub. L. 98–620, § 501(5), substituted provisions requiring the contractor to make a written election within two years after disclosure to the Federal agency (or such additional time as may be approved by the Federal agency) whether the contractor will retain title to a subject invention for provision requiring election to retain title within a reasonable time after disclosure, and inserted provision authorizing the Federal agency to shorten the period for election under certain circumstances.

Subsec. (c)(3). Pub. L. 98–620, § 501(5), substituted provisions requiring a contractor electing rights in a subject invention to file a patent application prior to any statutory bar date that may occur under this title due to publication, on sale, or public use, and thereafter to file corresponding patent applications in other countries in which it wishes to retain title within reasonable times for provisions requiring the contractor to file patent applications within a reasonable time.

Subsec. (c)(4). Pub. L. 98–620, § 501(5), substituted provision that the funding agreement may provide for such additional rights, including the right to assign or have assigned foreign patent rights in the subject invention, as are determined by the agency as necessary for meeting the obligations of the United States under any treaty, international agreement, arrangement of cooperation, memorandum of understanding, or similar arrangement, including any military agreement relating to weapons development and production for provision that the agency could, if provided in the funding agreement, have additional rights to sublicense any foreign government or international organization pursuant to any existing or future treaty or agreement.

Subsec. (c)(5). Pub. L. 98–620, § 501(6), substituted ''as well as any information on utilization or efforts at obtaining utilization obtained as part of a proceeding under section 203 of this chapter shall be treated'' for ''may be treated''.

Subsec. (c)(7)(A). Pub. L. 98–620, § 501(7), struck out provision which made an exception for organizations which were not themselves engaged in or did not hold a substantial interest in other organizations engaged in the manufacture or sales of products or the use of processes that might utilize the invention or be in competition with embodiments of the invention.

Subsec. (c)(7)(B). Pub. L. 98–620, § 501(8), redesignated cl. (C) as (B). Former cl. (B), relating to a prohibition against the granting of exclusive licenses under United States Patents or Patent Applications in a subject invention by the contractor to persons other than small business firms for periods in excess of certain specified periods and relating to commercial sales, was struck out.

Subsec. (c)(7)(C). Pub. L. 98–620, § 501(8), added cl. (C). Former cl. (C) redesignated (B).

Subsec. (c)(7)(D). Pub. L. 98–620, § 501(8), added cl. (D). Former cl. (D) redesignated (E).

Subsec. (c)(7)(E). Pub. L. 98–620, § 501(8), redesignated former cl. (D) as (E) and inserted provisions placing a limit on the amount of royalties that the contract operators of Government-owned laboratories are entitled to retain after paying patent administrative expenses and a share of the royalties to inventors, requiring payment of amounts in excess of such limits to the United States Treasury, and requiring that, to the extent it provides the most effective technology transfer, the licensing of subject inventions shall be administered by contractor employees on location at the facility.

EFFECTIVE DATE OF 1999 AMENDMENT

Amendment by Pub. L. 106–113 effective 4 months after Nov. 29, 1999, see section 1000(a)(9) [title IV, § 4731] of Pub. L. 106–113, set out as a note under section 1 of this title.

§ 203. March-in rights

(a) With respect to any subject invention in which a small business firm or nonprofit organization has acquired title under this chapter, the Federal agency under whose funding agreement the subject invention was made shall have the right, in accordance with such procedures as are provided in regulations promulgated hereunder to require the contractor, an assignee or exclusive licensee of a subject invention to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if the contractor, assignee, or exclusive licensee refuses such request, to grant such a license itself, if the Federal agency determines that such—

(1) action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use;

(2) action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees;

(3) action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees; or

(4) action is necessary because the agreement required by section 204 has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of its agreement obtained pursuant to section 204.

(b) A determination pursuant to this section or section 202(b)(4) shall not be subject to the Contract Disputes Act (41 U.S.C. § 601 et seq.). An administrative appeals procedure shall be established by regulations promulgated in accordance with section 206. Additionally, any contractor, inventor, assignee, or exclusive licensee adversely affected by a determination under this section may, at any time within sixty days after the determination is issued, file a petition in the United States Court of Federal Claims, which shall have jurisdiction to determine the appeal on the record and to affirm, reverse, remand or modify, as appropriate, the determination of the Federal agency. In cases described in paragraphs (1) and (3) of subsection (a), the agency's determination shall be held in abeyance pending the exhaustion of appeals or petitions filed under the preceding sentence.

(Added Pub. L. 96–517, § 6(a), Dec. 12, 1980, 94 Stat. 3022; amended Pub. L. 98–620, title V, § 501(9), Nov. 8, 1984, 98 Stat. 3367; Pub. L. 102–572, title IX, § 902(b)(1), Oct. 29, 1992, 106 Stat. 4516; Pub. L. 107–273, div. C, title III, § 13206(a)(14), Nov. 2, 2002, 116 Stat. 1905.)

REFERENCES IN TEXT

The Contract Disputes Act of 1978, referred to in subsec. (b), is Pub. L. 95–563, Nov. 1, 1978, 92 Stat. 2383, as amended, which is classified principally to chapter 9 (§ 601 et seq.) of Title 41, Public Contracts. For complete classification of this Act to the Code see Short Title note set out under section 601 of Title 41 and Tables.

AMENDMENTS

2002—Pub. L. 107–273 redesignated par. (1) as subsec. (a) and former subpars. (a) to (d) as pars. (1) to (4), respectively, redesignated former par. (2) as subsec. (b), struck out quotation marks and comma before ''as appropriate'', and substituted ''paragraphs (1) and (3) of subsection (a)'' for ''paragraphs (a) and (c)''.

1992—Par. (2). Pub. L. 102–572 substituted ''United States Court of Federal Claims'' for ''United States Claims Court''.

1984—Pub. L. 98–620 designated existing provisions as par. (1) and added par. (2).

EFFECTIVE DATE OF 1992 AMENDMENT

Amendment by Pub. L. 102–572 effective Oct. 29, 1992, see section 911 of Pub. L. 102–572, set out as a note under section 171 of Title 28, Judiciary and Judicial Procedure.

§ 204. Preference for United States industry

Notwithstanding any other provision of this chapter, no small business firm or nonprofit organization which receives title to any subject invention and no assignee of any such small business firm or nonprofit organization shall grant to any person the exclusive right to use or sell any subject invention in the United States unless such person agrees that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States. However, in individual cases, the requirement for such an agreement may be waived by the Federal agency under whose funding

agreement the invention was made upon a showing by the small business firm, nonprofit organization, or assignee that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible.

(Added Pub. L. 96–517, § 6(a), Dec. 12, 1980, 94 Stat. 3023.)

§ 205. Confidentiality

Federal agencies are authorized to withhold from disclosure to the public information disclosing any invention in which the Federal Government owns or may own a right, title, or interest (including a nonexclusive license) for a reasonable time in order for a patent application to be filed. Furthermore, Federal agencies shall not be required to release copies of any document which is part of an application for patent filed with the United States Patent and Trademark Office or with any foreign patent office.

(Added Pub. L. 96–517, § 6(a), Dec. 12, 1980, 94 Stat. 3023.)

§ 206. Uniform clauses and regulations

The Secretary of Commerce may issue regulations which may be made applicable to Federal agencies implementing the provisions of sections 202 through 204 of this chapter and shall establish standard funding agreement provisions required under this chapter. The regulations and the standard funding agreement shall be subject to public comment before their issuance.

(Added Pub. L. 96–517, § 6(a), Dec. 12, 1980, 94 Stat. 3023; amended Pub. L. 98–620, title V, § 501(10), Nov. 8, 1984, 98 Stat. 3367.)

AMENDMENTS

1984—Pub. L. 98–620 amended section generally. Prior to amendment, section read as follows: ''The Office of Federal Procurement Policy, after receiving recommendations of the Office of Science and Technology Policy, may issue regulations which may be made applicable to Federal agencies implementing the provisions of sections 202 through 204 of this chapter and the Office of Federal Procurement Policy shall establish standard funding agreement provisions required under this chapter.''

§ 207. Domestic and foreign protection of federally owned inventions

(a) Each Federal agency is authorized to—

(1) apply for, obtain, and maintain patents or other forms of protection in the United States and in foreign countries on inventions in which the Federal Government owns a right, title, or interest;

(2) grant nonexclusive, exclusive, or partially exclusive licenses under federally owned inventions, royalty-free or for royalties or other consideration, and on such terms and conditions, including the grant to the licensee of the right of enforcement pursuant to the provisions of chapter 29 of this title as determined appropriate in the public interest;

(3) undertake all other suitable and necessary steps to protect and administer rights to federally owned inventions on behalf of the Federal Government either directly or through contract, including acquiring rights for and administering royalties to the Federal Government in any invention, but only to the extent the party from whom the rights are acquired voluntarily enters into the transaction, to facilitate the licensing of a federally owned invention; and

(4) transfer custody and administration, in whole or in part, to another Federal agency, of the right, title, or interest in any federally owned invention.

(b) For the purpose of assuring the effective management of Government-owned inventions, the Secretary of Commerce is authorized to—

(1) assist Federal agency efforts to promote the licensing and utilization of Government-owned inventions;

(2) assist Federal agencies in seeking protection and maintaining inventions in foreign countries, including the payment of fees and costs connected therewith; and

(3) consult with and advise Federal agencies as to areas of science and technology research and development with potential for commercial utilization.

(Added Pub. L. 96–517, § 6(a), Dec. 12, 1980, 94 Stat. 3023; amended Pub. L. 98–620, title V, § 501(11), Nov. 8, 1984, 98 Stat. 3367; Pub. L. 106–404, § 6(2), Nov. 1, 2000, 114 Stat. 1745.)

AMENDMENTS

2000—Subsec. (a)(2). Pub. L. 106–404, § 6(2)(A), substituted ''inventions'' for ''patent applications, patents, or other forms of protection obtained''.

Subsec. (a)(3). Pub. L. 106–404, § 6(2)(B), inserted '', including acquiring rights for and administering royalties to the Federal Government in any invention, but only to the extent the party from whom the rights are acquired voluntarily enters into the transaction, to facilitate the licensing of a federally owned invention'' after ''or through contract''.

1984—Pub. L. 98–620 designated existing provisions as subsec. (a) and added subsec. (b).

EX. ORD. NO. 9424. ESTABLISHMENT OF A REGISTER OF GOVERNMENT INTERESTS IN PATENTS

Ex. Ord. No. 9424, Feb. 18, 1944, 9 F.R. 1959, provided:

1. The Secretary of Commerce shall cause to be established in the United States Patent Office [now Patent and Trademark Office] a separate register for the recording of all rights and interests of the Government in or under patents and applications for patents.

2. The several departments and other executive agencies of the Government, including Government-owned or Government-controlled corporations, shall forward promptly to the Commissioner of Patents [now Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office] for recording in the separate register provided for in paragraph 1 hereof all licenses, assignments, or other interests of the Government in or under patents or applications for patents, in accordance with such rules and regulations as may be prescribed pursuant to paragraph 4 hereof; but the lack of recordation in such register of any right or interest of the Government in or under any patent or application therefor shall not prejudice in any way the assertion of such right or interest by the Government.

3. The register shall be open to inspection except as to such entries or documents which, in the opinion of the department or agency submitting them for recording, should be maintained in secrecy: *Provided*, *however*,

That the right of inspection may be restricted to authorized representatives of the Government pending the final report to the President by the National Patent Planning Commission under Executive Order No. 8977 of December 12, 1941, and action thereon by the President.

4. The Commissioner of Patents [now Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office], with the approval of the Secretary of Commerce, shall prescribe such rules and regulations as he may deem necessary to effectuate the purposes of this order.

EX. ORD. NO. 9865. PATENT PROTECTION ABROAD OF INVENTIONS RESULTING FROM RESEARCH FINANCED BY THE GOVERNMENT

Ex. Ord. No. 9865, June 14, 1947, 12 F.R. 3907, as amended by Ex. Ord. No. 10096, Jan. 23, 1950, 15 F.R. 389, provided:

1. All Government departments and agencies shall, whenever practicable, acquire the right to file foreign patent applications on inventions resulting from research conducted or financed by the Government.

2. All Government departments and agencies which have or may hereafter acquire title to inventions or the right to file patent applications abroad thereon, shall fully and continuously inform the Chairman of Government Patents Board [now Secretary of Commerce. See Ex. Ord. No. 10930 set out as a note below] concerning such inventions, except as provided in section 6 hereof, and shall make recommendations to the Chairman of Government Patents Board as to which of such inventions should receive patent protection by the United States abroad and the foreign jurisdictions in which such patent protection should be sought. The recommendations of such departments and agencies shall indicate the immediate or future industrial, commercial or other value of the invention concerned, including its value to public health.

3. The Chairman of Government Patents Board shall determine whether, and in what foreign jurisdictions, the United States should seek patents for such inventions, and, to the extent of appropriations available therefor, shall procure patent protection for such inventions, taking all action, consistent with existing law, necessary to acquire and maintain patent rights abroad. Such determinations of the said Department shall be made after full consultation with United States industry and commerce, with the Department of State, and with other Government agencies familiar with the technical, scientific, industrial, commercial or other economic or social factors affecting the invention involved, and after consideration of the availability of valid patent protection in the countries determined to be immediate or potential markets for, or producers of, products, processes, or services covered by or relating to the invention.

4. The Chairman of Government Patents Board shall administer foreign patents acquired by the United States under the terms of this order and shall issue licenses thereunder in accordance with law under such rules and regulations as he shall prescribe. Nationals of the United States shall be granted licenses on a nonexclusive royalty free basis except in such cases as he shall determine and proclaim it to be inconsistent with the public interest to issue such licenses on a nonexclusive royalty free basis.

5. The Department of State, in consultation with the Chairman of Government Patents Board, shall negotiate arrangements among governments under which each government and its nationals shall have access to the foreign patents of the other participating governments. Patents relating to matters of public health may be licensed by the Chairman of Government Patents Board, with the approval of the Secretary of State, to any country or its nationals upon such terms and conditions as are in accordance with law and as the Chairman of Government Patents Board determines to be appropriate, regardless of whether such country is a party to the arrangements provided for in this section.

6. There shall be exempted from the provisions of this order (a) all inventions within the jurisdiction of the Atomic Energy Commission except in such cases as the said Commission specifically authorizes the inclusion of an invention under the terms of this order; and (b) all other inventions officially classified as secret or confidential for reasons of the national security. Nothing in this order shall supersede the declassification policies and procedures established by Executive Orders Nos. 9568 of June 8, 1945, 9604 of August 25, 1945, and 9809 of December 12, 1946.

[Atomic Energy Commission abolished and all functions transferred to Administrator of Energy Research and Development Administration (unless otherwise specifically provided) by section 5814 of Title 42, The Public Health and Welfare. Energy Research and Development Administration terminated and functions vested by law in Administrator thereof transferred to Secretary of Energy (unless otherwise specifically provided) by sections 7151(a) and 7293 of Title 42.]

EX. ORD. NO. 10096. UNIFORM GOVERNMENT PATENT POLICY FOR INVENTIONS BY GOVERNMENT EMPLOYEES

Ex. Ord. No. 10096, Jan. 23, 1950, 15 F.R. 389, as amended by Ex. Ord. No. 10695, Jan. 16, 1957, 22 F.R. 365; Ex. Ord. No. 10930, Mar. 24, 1961, 26 F.R. 2583, provided:

NOW, THEREFORE, by virtue of the authority vested in me by the Constitution and statutes, and as President of the United States and Commander in Chief of the armed forces of the United States, in the interest of the establishment and operation of a uniform patent policy for the Government with respect to inventions made by Government employees, it is hereby ordered as follows:

1. The following basic policy is established for all Government agencies with respect to inventions hereafter made by any Government employee:

(a) The Government shall obtain the entire right, title, and interest in and to all inventions made by any Government employee (1) during working hours, or (2) with a contribution by the Government of facilities, equipment, materials, funds, or information, or of time or services of other Government employees on official duty, or (3) which bear a direct relation to or are made in consequence of the official duties of the inventor.

(b) In any case where the contribution of the Government, as measured by any one or more of the criteria set forth in paragraph (a) last above, to the invention, is insufficient equitably to justify a requirement of assignment to the Government of the entire right, title and interest to such invention, or in any case where the Government has insufficient interest in an invention to obtain entire right, title and interest therein (although the Government could obtain some under paragraph (a), above), the Government agency concerned, subject to the approval of the Chairman of the Government Patents Board [now Secretary of Commerce. See Ex. Ord. No. 10930 set out as a note below] (provided for in paragraph 3 of this order and hereinafter referred to as the Chairman), shall leave title to such invention in the employee, subject, however, to the reservation to the Government of a non-exclusive, irrevocable, royalty-free license in the invention with power to grant licenses for all governmental purposes, such reservation, in the terms thereof, to appear, where practicable, in any patent, domestic or foreign, which may issue on such invention.

(c) In applying the provisions of paragraphs (a) and (b), above, to the facts and circumstances relating to the making of any particular invention, it shall be presumed that an invention made by an employee who is employed or assigned (i) to invent or improve or perfect any art, machine, manufacture, or composition of matter, (ii) to conduct or perform research, development work, or both, (iii) to supervise, direct, coordinate, or review Government financed or conducted research, development work, or both, or (iv) to act in a liaison capacity among governmental or nongovernmental agencies or individuals engaged in such work, or made by an employee included within any other category of em-

ployees specified by regulations issued pursuant to section 4(b) hereof, falls within the provisions of paragraph (a), above, and it shall be presumed that any invention made by any other employee falls within the provisions of paragraph (b), above. Either presumption may be rebutted by the facts or circumstances attendant upon the conditions under which any particular invention is made and, notwithstanding the foregoing, shall not preclude a determination that the invention falls within the provisions of paragraph (d) next below.

(d) In any case wherein the Government neither (1) pursuant to the provisions of paragraph (a) above, obtains entire right, title and interest in and to an invention nor (2) pursuant to the provisions of paragraph (b) above, reserves a non-exclusive, irrevocable, royalty-free license in the invention with power to grant licenses for all governmental purposes, the Government shall leave the entire right, title and interest in and to the invention in the Government employee, subject to law.

(e) Actions taken, and rights acquired, under the foregoing provisions of this section, shall be reported to the Chairman in accordance with procedures established by him.

2. Subject to considerations of national security, or public health, safety, or welfare, the following basic policy is established for the collection, and dissemination to the public, of information concerning inventions resulting from Government research and development activities:

(a) When an invention is made under circumstances defined in paragraph 1(a) of this order giving the United States the right to title thereto, the Government agency concerned shall either prepare and file an application for patent therefor in the United States Patent Office [now Patent and Trademark Office] or make a full disclosure of the invention promptly to the Chairman, who may, if he determines the Government interest so requires, cause application for patent to be filed or cause the invention to be fully disclosed by publication thereof: *Provided, however*, That, consistent with present practice of the Department of Agriculture, no application for patent shall, without the approval of the Secretary of Agriculture, be filed in respect of any variety of plant invented by any employee of that Department.

(b) [Revoked. Ex. Ord. No. 10695, Jan. 16, 1957, 22 F.R. 365]

3. (a) [Revoked. Ex. Ord. No. 10930, Mar. 24, 1961, 26 F.R. 2583]

(b) The Government Patents Board shall advise and confer with the Chairman concerning the operation of those aspects of the Government's patent policy which are affected by the provisions of this order or of Executive Order No. 9865 [set out above], and suggest modifications or improvements where necessary.

(c) [Revoked. Ex. Ord. No. 10930, Mar. 24, 1961, 26 F.R. 2583]

(d) The Chairman shall establish such committees and other working groups as may be required to advise or assist him in the performance of any of his functions.

(e) The Chairman of the Government Patents Board and the Chairman of the Interdepartmental Committee on Scientific Research and Development (provided for by Executive Order No. 9912 of December 24, 1947), shall establish and maintain such mutual consultation as will effect the proper coordination of affairs of common concern.

4. With a view to obtaining uniform application of the policies set out in this order and uniform operations thereunder, the Chairman is authorized and directed:

(a) To consult and advise with Government agencies concerning the application and operation of the policies outlined herein;

(b) After consultation with the Government Patents Board, to formulate and submit to the President for approval such proposed rules and regulations as may be necessary or desirable to implement and effectuate the aforesaid policies, together with the recommendations of the Government Patents Board thereon;

(c) To submit annually a report to the President concerning the operation of such policies, and from time to time such recommendations for modification thereof as may be deemed desirable;

(d) To determine with finality any controversies or disputes between any Government agency and its employees, to the extent submitted by any party to the dispute, concerning the ownership of inventions made by such employees or rights therein; and

(e) To perform such other or further functions or duties as may from time to time be prescribed by the President or by statute.

5. The functions and duties of the Secretary of Commerce and the Department of Commerce under the provisions of Executive Order No. 9865 of June 14, 1947 [set out above] are hereby transferred to the Chairman and the whole or any part of such functions and duties may be delegated by him to any Government agency or officer: *Provided*, That said Executive Order No. 9865 shall not be deemed to be amended or affected by any provision of this Executive order other than this paragraph 5.

6. Each Government agency shall take all steps appropriate to effectuate this order, including the promulgation of necessary regulations which shall not be inconsistent with this order or with regulations issued pursuant to paragraph 4(b) hereof.

7. As used in this Executive order, the next stated terms, in singular and plural, are defined as follows for the purposes hereof:

(a) ''Government agency'' includes any executive department and any independent commission, board, office, agency, authority, or other establishment of the Executive Branch of the Government of the United States (including any such independent regulatory commission or board, any such wholly-owned corporation, and the Smithsonian Institution), but excludes the Atomic Energy Commission.

(b) ''Government employee'' includes any officer or employee, civilian or military, of any Government agency, except such part-time consultants or employees as may be excluded by regulations promulgated pursuant to paragraph 4(b) hereof.

(c) ''Invention'' includes any art, machine, manufacture, design, or composition of matter, or any new and useful improvement thereof, or any variety of plant, which is or may be patentable under the patent laws of the United States.

EX. ORD. NO. 10695. TRANSFER OF RECORDS TO DEPARTMENT OF COMMERCE

Section 2 of Ex. Ord. 10695, Jan. 16, 1957, 22 F.R. 365, provided that: ''The Chairman of the Government Patents Board is hereby authorized to transfer to the Department of Commerce any or all of the records heretofore prepared by the Board pursuant to paragraph 2(b) of Executive Order No. 10096 [set out above].''

EX. ORD. NO. 10930. ABOLITION OF GOVERNMENT PATENTS BOARD

Ex. Ord. No. 10930, Mar. 24, 1961, 26 F.R. 2583, provided:

By virtue of the authority vested in me as President of the United States, it is ordered as follows:

SECTION 1. The Government Patents Board, established by section 3(a) of Executive Order No. 10096 of January 23, 1950 [set out above], and all positions established thereunder or pursuant thereto are hereby abolished.

SEC. 2. All functions of the Government Patents Board and of the Chairman thereof under the said Executive Order No. 10096, except the functions of conference and consultation between the Board and the Chairman, are hereby transferred to the Secretary of Commerce, who may provide for the performance of such transferred functions by such officer, employee, or agency of the Department of Commerce as he may designate.

SEC. 3. The Secretary of Commerce shall make such provision as may be necessary and consonant with law

for the disposition or transfer of property, personnel, records, and funds of the Government Patents Board.

SEC. 4. Except to the extent that they may be inconsistent with this order, all determinations, regulations, rules, rulings, orders, and other actions made or issued by the Government Patents Board, or by any Government agency with respect to any function transferred by this order, shall continue in full force and effect until amended, modified, or revoked by appropriate authority.

SEC. 5. Subsections (a) and (c) of section 3 of Executive Order No. 10096 are hereby revoked, and all other provisions of that order are hereby amended to the extent that they are inconsistent with the provisions of this order.

JOHN F. KENNEDY.

§ 208. Regulations governing Federal licensing

The Secretary of Commerce is authorized to promulgate regulations specifying the terms and conditions upon which any federally owned invention, other than inventions owned by the Tennessee Valley Authority, may be licensed on a nonexclusive, partially exclusive, or exclusive basis.

(Added Pub. L. 96–517, § 6(a), Dec. 12, 1980, 94 Stat. 3024; amended Pub. L. 98–620, title V, § 501(12), Nov. 8, 1984, 98 Stat. 3367.)

AMENDMENTS

1984—Pub. L. 98–620 substituted ''Secretary of Commerce'' for ''Administrator of General Services''.

§ 209. Licensing federally owned inventions

(a) AUTHORITY.—A Federal agency may grant an exclusive or partially exclusive license on a federally owned invention under section 207(a)(2) only if—

(1) granting the license is a reasonable and necessary incentive to—

(A) call forth the investment capital and expenditures needed to bring the invention to practical application; or

(B) otherwise promote the invention's utilization by the public;

(2) the Federal agency finds that the public will be served by the granting of the license, as indicated by the applicant's intentions, plans, and ability to bring the invention to practical application or otherwise promote the invention's utilization by the public, and that the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application, as proposed by the applicant, or otherwise to promote the invention's utilization by the public;

(3) the applicant makes a commitment to achieve practical application of the invention within a reasonable time, which time may be extended by the agency upon the applicant's request and the applicant's demonstration that the refusal of such extension would be unreasonable;

(4) granting the license will not tend to substantially lessen competition or create or maintain a violation of the Federal antitrust laws; and

(5) in the case of an invention covered by a foreign patent application or patent, the interests of the Federal Government or United States industry in foreign commerce will be enhanced.

(b) MANUFACTURE IN UNITED STATES.—A Federal agency shall normally grant a license under section 207(a)(2) to use or sell any federally owned invention in the United States only to a licensee who agrees that any products embodying the invention or produced through the use of the invention will be manufactured substantially in the United States.

(c) SMALL BUSINESS.—First preference for the granting of any exclusive or partially exclusive licenses under section 207(a)(2) shall be given to small business firms having equal or greater likelihood as other applicants to bring the invention to practical application within a reasonable time.

(d) TERMS AND CONDITIONS.—Any licenses granted under section 207(a)(2) shall contain such terms and conditions as the granting agency considers appropriate, and shall include provisions—

(1) retaining a nontransferrable, irrevocable, paid-up license for any Federal agency to practice the invention or have the invention practiced throughout the world by or on behalf of the Government of the United States;

(2) requiring periodic reporting on utilization of the invention, and utilization efforts, by the licensee, but only to the extent necessary to enable the Federal agency to determine whether the terms of the license are being complied with, except that any such report shall be treated by the Federal agency as commercial and financial information obtained from a person and privileged and confidential and not subject to disclosure under section 552 of title 5; and

(3) empowering the Federal agency to terminate the license in whole or in part if the agency determines that—

(A) the licensee is not executing its commitment to achieve practical application of the invention, including commitments contained in any plan submitted in support of its request for a license, and the licensee cannot otherwise demonstrate to the satisfaction of the Federal agency that it has taken, or can be expected to take within a reasonable time, effective steps to achieve practical application of the invention;

(B) the licensee is in breach of an agreement described in subsection (b);

(C) termination is necessary to meet requirements for public use specified by Federal regulations issued after the date of the license, and such requirements are not reasonably satisfied by the licensee; or

(D) the licensee has been found by a court of competent jurisdiction to have violated the Federal antitrust laws in connection with its performance under the license agreement.

(e) PUBLIC NOTICE.—No exclusive or partially exclusive license may be granted under section 207(a)(2) unless public notice of the intention to grant an exclusive or partially exclusive license on a federally owned invention has been provided in an appropriate manner at least 15 days before the license is granted, and the Federal

agency has considered all comments received before the end of the comment period in response to that public notice. This subsection shall not apply to the licensing of inventions made under a cooperative research and development agreement entered into under section 12 of the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3710a).

(f) PLAN.—No Federal agency shall grant any license under a patent or patent application on a federally owned invention unless the person requesting the license has supplied the agency with a plan for development or marketing of the invention, except that any such plan shall be treated by the Federal agency as commercial and financial information obtained from a person and privileged and confidential and not subject to disclosure under section 552 of title 5.

(Added Pub. L. 96–517, § 6(a), Dec. 12, 1980, 94 Stat. 3024; amended Pub. L. 106–404, § 4(a), Nov. 1, 2000, 114 Stat. 1743; Pub. L. 107–273, div. C, title III, § 13206(a)(15), Nov. 2, 2002, 116 Stat. 1905.)

AMENDMENTS

2002—Subsecs. (d)(2), (f). Pub. L. 107–273 struck out ''of the United States Code'' after ''title 5''.

2000—Pub. L. 106–404 amended section catchline and text generally, restructuring and revising provisions setting forth criteria, terms, and conditions relating to granting of licenses on federally owned inventions.

§ 210. Precedence of chapter

(a) This chapter shall take precedence over any other Act which would require a disposition of rights in subject inventions of small business firms or nonprofit organizations contractors in a manner that is inconsistent with this chapter, including but not necessarily limited to the following:

(1) section 10(a) of the Act of June 29, 1935, as added by title I of the Act of August 14, 1946 (7 U.S.C. 427i(a); 60 Stat. 1085);

(2) section 205(a) of the Act of August 14, 1946 (7 U.S.C. 1624(a); 60 Stat. 1090);

(3) section 501(c) of the Federal Mine Safety and Health Act of 1977 (30 U.S.C. 951(c); 83 Stat. 742);

(4) section 30168(e) of title 49;

(5) section 12 of the National Science Foundation Act of 1950 (42 U.S.C. 1871(a); [1] 82 Stat. 360);

(6) section 152 of the Atomic Energy Act of 1954 (42 U.S.C. 2182; 68 Stat. 943);

(7) section 305 of the National Aeronautics and Space Act of 1958 (42 U.S.C. 2457);

(8) section 6 of the Coal Research and Development Act of 1960 (30 U.S.C. 666; 74 Stat. 337);

(9) section 4 of the Helium Act Amendments of 1960 (50 U.S.C. 167b; 74 Stat. 920);

(10) section 32 of the Arms Control and Disarmament Act of 1961 (22 U.S.C. 2572; 75 Stat. 634);

(11) section 9 of the Federal Nonnuclear Energy Research and Development Act of 1974 (42 U.S.C. 5908; 88 Stat. 1878);

(12) section 5(d) of the Consumer Product Safety Act (15 U.S.C. 2054(d); 86 Stat. 1211);

(13) section 3 of the Act of April 5, 1944 (30 U.S.C. 323; 58 Stat. 191); [1]

(14) section 8001(c)(3) of the Solid Waste Disposal Act (42 U.S.C. 6981(c); 90 Stat. 2829);

(15) section 219 of the Foreign Assistance Act of 1961 (22 U.S.C. 2179; 83 Stat. 806);

(16) section 427(b) of the Federal Mine Health and Safety Act of 1977 (30 U.S.C. 937(b); 86 Stat. 155);

(17) section 306(d) of the Surface Mining and Reclamation Act of 1977 (30 U.S.C. 1226(d); 91 Stat. 455); [1]

(18) section 21(d) of the Federal Fire Prevention and Control Act of 1974 (15 U.S.C. 2218(d); 88 Stat. 1548);

(19) section 6(b) of the Solar Photovoltaic Energy Research Development and Demonstration Act of 1978 (42 U.S.C. 5585(b); 92 Stat. 2516);

(20) section 12 of the Native Latex Commercialization and Economic Development Act of 1978 (7 U.S.C. 178j; 92 Stat. 2533); and

(21) section 408 of the Water Resources and Development Act of 1978 (42 U.S.C. 7879; 92 Stat. 1360).

The Act creating this chapter shall be construed to take precedence over any future Act unless that Act specifically cites this Act and provides that it shall take precedence over this Act.

(b) Nothing in this chapter is intended to alter the effect of the laws cited in paragraph (a) of this section or any other laws with respect to the disposition of rights in inventions made in the performance of funding agreements with persons other than nonprofit organizations or small business firms.

(c) Nothing in this chapter is intended to limit the authority of agencies to agree to the disposition of rights in inventions made in the performance of work under funding agreements with persons other than nonprofit organizations or small business firms in accordance with the Statement of Government Patent Policy issued on February 18, 1983, agency regulations, or other applicable regulations or to otherwise limit the authority of agencies to allow such persons to retain ownership of inventions except that all funding agreements, including those with other than small business firms and nonprofit organizations, shall include the requirements established in section 202(c)(4) and section 203 of this title. Any disposition of rights in inventions made in accordance with the Statement or implementing regulations, including any disposition occurring before enactment of this section, are hereby authorized.

(d) Nothing in this chapter shall be construed to require the disclosure of intelligence sources or methods or to otherwise affect the authority granted to the Director of Central Intelligence by statute or Executive order for the protection of intelligence sources or methods.

(e) The provisions of the Stevenson-Wydler Technology Innovation Act of 1980 shall take precedence over the provisions of this chapter to the extent that they permit or require a disposition of rights in subject inventions which is inconsistent with this chapter.

(Added Pub. L. 96–517, § 6(a), Dec. 12, 1980, 94 Stat. 3026; amended Pub. L. 98–620, title V, § 501(13), Nov. 8, 1984, 98 Stat. 3367; Pub. L. 99–502, § 9(c), Oct. 20, 1986, 100 Stat. 1796; Pub. L. 103–272,

[1] See References in Text note below.

§ 5(j), July 5, 1994, 108 Stat. 1375; Pub. L. 104–113, § 7, Mar. 7, 1996, 110 Stat. 779; Pub. L. 105–393, title II, § 220(c)(2), Nov. 13, 1998, 112 Stat. 3625; Pub. L. 107–273, div. C, title III, § 13206(a)(16), Nov. 2, 2002, 116 Stat. 1905; Pub. L. 109–58, title X, § 1009(a)(2), Aug. 8, 2005, 119 Stat. 934.)

REFERENCES IN TEXT

The Act and this Act, referred to in subsec. (a), is Pub. L. 96–517, Dec. 12, 1980, 94 Stat. 3015, which enacted sections 200 to 211 and 301 to 307 of this title, amended sections 41, 42, and 154 of this title, section 1113 of Title 15, Commerce and Trade, sections 101 and 117 of Title 17, Copyrights, and sections 2186, 2457, and 5908 of Title 42, The Public Health and Welfare, and enacted provisions set out as notes under sections 13 and 41 of this title. For complete classification of this Act to the Code, see Tables.

Section 12 of the National Science Foundation Act of 1950 (42 U.S.C. 1871(a); 82 Stat. 360), referred to in subsec. (a)(5), was amended by Pub. L. 99–159, title I, § 109(c), Nov. 22, 1985, 99 Stat. 889, by striking out subsec. (b) and designating subsec. (a) as the entire section.

Section 3 of the Act of April 5, 1944 (30 U.S.C. 323; 58 Stat. 191), referred to in subsec. (a)(13), was omitted from the Code.

Section 306(d) of the Surface Mining and Reclamation Act, referred to in subsec. (a)(17), was classified to section 1226(d) of Title 30, Mineral Lands and Mining, prior to enactment of Pub. L. 98–409, which enacted a new section 1226 of Title 30. See section 1226(c) of Title 30.

The Native Latex Commercialization and Economic Development Act of 1978, referred to in subsec. (a)(20), is Pub. L. 95–592, Nov. 4, 1978, 92 Stat. 2529, as amended, which, as amended by Pub. L. 98–284, May 16, 1984, 98 Stat. 181, is known as the Critical Agricultural Materials Act and is classified principally to subchapter II (§ 178 et seq.) of chapter 8A of Title 7, Agriculture. For complete classification of this Act to the Code, see Short Title note set out under section 178 of Title 7 and Tables.

Section 408 of the Water Resources and Development Act of 1978 (42 U.S.C. 7879; 92 Stat. 1360), referred to in subsec. (a)(21), was repealed by Pub. L. 98–242, title I, § 110(a), Mar. 22, 1984, 98 Stat. 101. See section 10308 of Title 42, The Public Health and Welfare.

The Stevenson-Wydler Technology Innovation Act of 1980, referred to in subsec. (e), is Pub. L. 96–480, Oct. 21, 1980, 94 Stat. 2311, as amended, which is classified generally to chapter 63 (§ 3701 et seq.) of Title 15, Commerce and Trade. For complete classification of this Act to the Code, see Short Title note set out under section 3701 of Title 15 and Tables.

AMENDMENTS

2005—Subsec. (a)(8). Pub. L. 109–58 substituted ''Coal Research and Development Act of 1960'' for ''Coal Research Development Act of 1960''.

2002—Subsec. (a)(11). Pub. L. 107–273, § 13206(a)(16)(A)(i), substituted ''5908'' for ''5901''.

Subsec. (a)(20). Pub. L. 107–273, § 13206(a)(16)(A)(ii), substituted ''178j'' for ''178(j)''.

Subsec. (c). Pub. L. 107–273, § 13206(a)(16)(B), substituted ''section 202(c)(4)'' for ''paragraph 202(c)(4)'' and struck out second period after ''title''.

1998—Subsec. (a)(11) to (22). Pub. L. 105–393 redesignated pars. (12) to (22) as (11) to (21), respectively, and struck out former par. (11) which read as follows: ''subsection (e) of section 302 of the Appalachian Regional Development Act of 1965 (40 U.S.C. App. 302(e); 79 Stat. 5);''.

1996—Subsec. (e). Pub. L. 104–113 struck out '', as amended by the Federal Technology Transfer Act of 1986,'' after ''1980''.

1994—Subsec. (a)(4). Pub. L. 103–272 substituted ''section 30168(e) of title 49'' for ''section 106(c) of the National Traffic and Motor Vehicle Safety Act of 1966 (15 U.S.C. 1395(c); 80 Stat. 721)''.

1986—Subsec. (e). Pub. L. 99–502 added subsec. (e).

1984—Subsec. (c). Pub. L. 98–620 substituted ''February 18, 1983'' for ''August 23, 1971 (36 Fed. Reg. 16887)'' and inserted provision that all funding agreements, including those with other than small business firms and nonprofit organizations, shall include the requirements established in paragraph 202(c)(4) and section 203 of this title.

CHANGE OF NAME

Reference to the Director of Central Intelligence or the Director of the Central Intelligence Agency in the Director's capacity as the head of the intelligence community deemed to be a reference to the Director of National Intelligence. Reference to the Director of Central Intelligence or the Director of the Central Intelligence Agency in the Director's capacity as the head of the Central Intelligence Agency deemed to be a reference to the Director of the Central Intelligence Agency. See section 1081(a), (b) of Pub. L. 108–458, set out as a note under section 401 of Title 50, War and National Defense.

§ 211. Relationship to antitrust laws

Nothing in this chapter shall be deemed to convey to any person immunity from civil or criminal liability, or to create any defenses to actions, under any antitrust law.

(Added Pub. L. 96–517, § 6(a), Dec. 12, 1980, 94 Stat. 3027.)

§ 212. Disposition of rights in educational awards

No scholarship, fellowship, training grant, or other funding agreement made by a Federal agency primarily to an awardee for educational purposes will contain any provision giving the Federal agency any rights to inventions made by the awardee.

(Added Pub. L. 98–620, title V, § 501(14), Nov. 8, 1984, 98 Stat. 3368.)

PART III—PATENTS AND PROTECTION OF PATENT RIGHTS

AMENDMENTS

2002—Pub. L. 107–273, div. C, title III, § 13206(a)(17), Nov. 2, 2002, 116 Stat. 1905, inserted a comma after ''Patent'' in item for chapter 29.

1999—Pub. L. 106–113, div. B, § 1000(a)(9) [title IV, § 4604(b)], Nov. 29, 1999, 113 Stat. 1536, 1501A–570, as amended by Pub. L. 107–273, div. C, title III, § 13202(c)(2), Nov. 2, 2002, 116 Stat. 1902, substituted ''Ex Parte Reexamination of Patents'' for ''Reexamination of Patents'' in item for chapter 30 and added item for chapter 31.

1982—Pub. L. 97–256, title I, § 101(7), Sept. 8, 1982, 96 Stat. 816, added item for chapter 30.

[1] So in original. Does not conform to chapter heading.

PART 401—RIGHTS TO INVENTIONS MADE BY NONPROFIT ORGANIZATIONS AND SMALL BUSINESS FIRMS UNDER GOVERNMENT GRANTS, CONTRACTS, AND COOPERATIVE AGREEMENTS

Sec.

AUTHORITY: 35 U.S.C. 206 and the delegation of authority by the Secretary of Commerce to the Assistant Secretary of Commerce for Technology Policy at sec. 3(g) of DOO 10–18.

SOURCE: 52 FR 8554, Mar. 18, 1987, unless otherwise noted.

§401.1 Scope.

(a) Traditionally there have been no conditions imposed by the government on research performers while using private facilities which would preclude them from accepting research funding from other sources to expand, to aid in completing or to conduct separate investigations closely related to research activities sponsored by the government. Notwithstanding the right of research organizations to accept supplemental funding from other sources for the purpose of expediting or more comprehensively accomplishing the research objectives of the government sponsored project, it is clear that the ownership provisions of these regulations would remain applicable in any invention ''conceived or first actually reduced to practice in performance'' of the project. Separate accounting for the two funds used to support the project in this case is not a determining factor.

(1) To the extent that a non-government sponsor established a project which, although closely related, falls outside the planned and committed activities of a government-funded project and does not diminish or distract from the performance of such activities, inventions made in performance of the non-government sponsored project would not be subject to the conditions of these regulations. An example of such related but separate projects would be a government sponsored project having research objectives to expand scientific understanding in a field and a closely related industry sponsored project having as its objectives the application of such new knowledge to develop usable new technology. The time relationship in conducting the two projects and the use of new fundamental knowledge from one in the performance of the other are not important determinants since most inventions rest on a knowledge base built up by numerous independent research efforts extending over many years. Should such an invention be claimed by the performing organization to be the product of non-government sponsored research and be challenged by the sponsoring agency as being reportable to the government as a ''subject invention'', the challenge is appealable as described in §401.11(d).

(2) An invention which is made outside of the research activities of a government-funded project is not viewed as a ''subject invention'' since it cannot be shown to have been ''conceived or first actually reduced to practice'' in performance of the project. An obvious example of this is a situation where an instrument purchased with government funds is later used, without interference with or cost to the government-funded project, in making an invention all expenses of which involve only non-government funds.

(b) This part inplements 35 U.S.C. 202 through 204 and is applicable to all Federal agencies. It applies to all funding agreements with small business firms and nonprofit organizations executed after the effective date of this part, except for a funding agreement

made primarily for educational purposes. Certain sections also provide guidance for the administration of funding agreements which predate the effective date of this part. In accordance with 35 U.S.C. 212, no scholarship, fellowship, training grant, or other funding agreement made by a Federal agency primarily to an awardee for educational purposes will contain any provision giving the Federal agency any rights to inventions made by the awardee.

(c) The *march-in* and appeals procedures in §§ 401.6 and 401.11 shall apply to any march-in or appeal proceeding under a funding agreement subject to Chapter 18 of Title 35, U.S.C., initiated after the effective date of this part even if the funding agreement was executed prior to that date.

(d) At the request of the contractor, a funding agreement for the operation of a government-owned facility which is in effect on the effective date of this part shall be promptly amended to include the provisions required by §§ 401.3(a) unless the agency determines that one of the exceptions at 35 U.S.C. 202(a)(i) through (iv) § 401.3(a)(8) through (iv) of this part) is applicable and will be applied. If the exception at § 401.3(a)(iv) is determined to be applicable, the funding agreement will be promptly amended to include the provisions required by § 401.3(c).

(e) This regulation supersedes OMB Circular A–124 and shall take precedence over any regulations dealing with ownership of inventions made by small businesses and nonprofit organizations which are inconsistent with it. This regulation will be followed by all agencies pending amendment of agency regulations to conform to this part and amended Chapter 18 of Title 35. Only deviations requested by a contractor and not inconsistent with Chapter 18 of Title 35, United States Code, may be made without approval of the Secretary. Modifications or tailoring of clauses as authorized by §§ 401.5 or 401.3, when alternative provisions are used under § 401.3(a)(1) through (4), are not considered deviations requiring the Secretary's approval. Three copies of proposed and final agency regulations supplementing this part shall be submitted to the Secretary at the office set out in § 401.16 for approval for consistency with this part before they are submitted to the Office of Management and Budget (OMB) for review under Executive Order 12291 or, if no submission is required to be made to OMB, before their submission to the FEDERAL REGISTER for publication.

(f) In the event an agency has outstanding prime funding agreements that do not contain patent flow-down provisions consistent with this part or earlier Office of Federal Procurement Policy regulations (OMB Circular A–124 or OMB Bulletin 81–22), the agency shall take appropriate action to ensure that small business firms or nonprofit organizations that are subcontractors under any such agreements and that received their subcontracts after July 1, 1981, receive rights in their subject inventions that are consistent with Chapter 18 and this part.

(g) This part is not intended to apply to arrangements under which nonprofit organizations, small business firms, or others are allowed to use government-owned research facilities and normal technical assistance provided to users of those facilities, whether on a reimbursable or nonreimbursable basis. This part is also not intended to apply to arrangements under which sponsors reimburse the government or facility contractor for the contractor employee's time in performing work for the sponsor. Such arrangements are not considered ''funding agreements'' as defined at 35 U.S.C. 201(b) and § 401.2(a) of this part.

§ 401.2 Definitions.

As used in this part—

(a) The term *funding agreement* means any contract, grant, or cooperative agreement entered into between any Federal agency, other than the Tennessee Valley Authority, and any contractor for the performance of experimental, developmental, or research work funded in whole or in part by the Federal government. This term also includes any assignment, substitution of parties, or subcontract of any type entered into for the performance of experimental, developmental, or research work under a funding agreement as defined in the first sentence of this paragraph.

(b) The term *contractor* means any person, small business firm or nonprofit organization which is a party to a funding agreement.

(c) The term *invention* means any invention or discovery which is or may be patentable or otherwise protectable under Title 35 of the United States Code, or any novel variety of plant which is or may be protectable under the Plant Variety Protection Act (7 U.S.C. 2321 *et seq.*).

(d) The term *subject invention* means any invention of a contractor conceived or first actually reduced to practice in the performance of work under a funding agreement; provided that in the case of a variety of plant, the date of determination (as defined in section 41(d) of the Plant Variety Protection Act, 7 U.S.C. 2401(d)) must also occur during the period of contract performance.

(e) The term *practical application* means to manufacture in the case of a composition of product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are, to the extent permitted by law or government regulations, available to the public on reasonable terms.

(f) The term *made* when used in relation to any invention means the conception or first actual reduction to practice of such invention.

(g) The term *small business firm* means a small business concern as defined at section 2 of Pub. L. 85–536 (15 U.S.C. 632) and implementing regulations of the Administrator of the Small Business Administration. For the purpose of this part, the size standards for small business concerns involved in government procurement and subcontracting at 13 CFR 121.5 will be used.

(h) The term *nonprofit organization* means universities and other institutions of higher education or an organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1954 (26 U.S.C. 501(c) and exempt from taxation under section 501(a) of the Internal Revenue Code (26 U.S.C. 501(a)) or any nonprofit scientific or educational organization qualified under a state nonprofit organization statute.

(i) The term *Chapter 18* means Chapter 18 of Title 35 of the United States Code.

(j) The term *Secretary* means the Assistant Secretary of Commerce for Technology Policy.

(k) The term *electronically filed* means any submission of information transmitted by an electronic or optical-electronic system.

(l) The term *electronic or optical-electronic system* means a software-based system approved by the agency for the transmission of information.

(m) The term *patent application* or ''application for patent'' includes a provisional or nonprovisional U.S. national application for patent as defined in 37 CFR 1.9 (a)(2) and (a)(3), respectively, or an application for patent in a foreign country or in an international patent office.

(n) The term *initial patent application* means a nonprovisional U.S. national application for patent as defined in 37 CFR 1.9(a)(3).

[52 FR 8554, Mar. 18, 1987, as amended at 60 FR 41812, Aug. 14, 1995]

§ 401.3 Use of the standard clauses at § 401.14.

(a) Each funding agreement awarded to a small business firm or nonprofit organization (except those subject to 35 U.S.C. 212) shall contain the clause found in § 401.14(a) with such modifications and tailoring as authorized or required elsewhere in this part. However, a funding agreement may contain alternative provisions—

(1) When the contractor is not located in the United States or does not have a place of business located in the United States or is subject to the control of a foreign government; or

(2) In exceptional circumstances when it is determined by the agency that restriction or elimination of the right to retain title to any subject invention will better promote the policy and objectives of Chapter 18 of Title 35 of the United States Code; or

(3) When it is determined by a government authority which is authorized

by statute or executive order to conduct foreign intelligence or counterintelligence activities that the restriction or elimination of the right to retain title to any subject invention is necessary to protect the security to such activities; or

(4) When the funding agreement includes the operation of the government-owned, contractor-operated facility of the Department of Energy primarily dedicated to that Department's naval nuclear propulsion or weapons related programs and all funding agreement limitations under this subparagraph on the contractor's right to elect title to a subject invention are limited to inventions occurring under the above two programs.

(5) If any part of the contract may require the contractor to perform work on behalf of the Government at a Government laboratory under a Cooperative Research and Development Agreement (CRADA) pursuant to the statutory authority of 15 U.S.C. 3710a, the contracting officer may include alternate paragraph (b) in the basic patent rights clause in §401.14. Because the use of the alternate is based on a determination of exceptional circumstances under §401.3(a)(2), the contracting officer shall ensure that the appeal procedures of §401.4 are satisfied whenever the alternate is used.

(b) When an agency exercises the exceptions at §401.3(a)(2) or (3), it shall use the standard clause at §401.14(a) with only such modifications as are necessary to address the exceptional circumstances or concerns which led to the use of the exception. For example, if the justification relates to a particular field of use or market, the clause might be modified along lines similar to those described in §401.14(b). In any event, the clause should provide the contractor with an opportunity to receive greater rights in accordance with the procedures at §401.15. When an agency justifies and exercises the exception at §401.3(a)(2) and uses an alternative provision in the funding agreement on the basis of national security, the provision shall provide the contractor with the right to elect ownership to any invention made under such funding agreement as provided by the Standard Patent Rights Clause found at §401.14(a) if the invention is not classified by the agency within six months of the date it is reported to the agency, or within the same time period the Department of Energy does not, as authorized by regulation, law or Executive order or implementing regulations thereto, prohibit unauthorized dissemination of the invention. Contracts in support of DOE's naval nuclear propulsion program are exempted from this paragraph.

(c) When the Department of Energy exercises the exception at §401.3(a)(4), it shall use the clause prescribed at §401.14(b) or substitute thereto with such modification and tailoring as authorized or required elsewhere in this part.

(d) When a funding agreement involves a series of separate task orders, an agency may apply the exceptions at §401.3(a)(2) or (3) to individual task orders, and it may structure the contract so that modified patent rights provisions will apply to the task order even though the clauses at either §401.14(a) or (b) are applicable to the remainder of the work. Agencies are authorized to negotiate such modified provisions with respect to task orders added to a funding agreement after its initial award.

(e) Before utilizing any of the exceptions in §401.3(a) of this section, the agency shall prepare a written determination, including a statement of facts supporting the determination, that the conditions identified in the exception exist. A separate statement of facts shall be prepared for each exceptional circumstances determination, except that in appropriate cases a single determination may apply to both a funding agreement and any subcontracts issued under it or to any funding agreement to which such an exception is applicable. In cases when §401.3(a)(2) is used, the determination shall also include an analysis justifying the determination. This analysis should address with specificity how the alternate provisions will better achieve the objectives set forth in 35 U.S.C. 200. A copy of each determination, statement of facts, and, if applicable, analysis shall be promptly provided to the contractor or prospective contractor

along with a notification to the contractor or prospective contractor of its rights to appeal the determination of the exception under 35 U.S.C. 202(b)(4) and § 401.4 of this part.

(f) Except for determinations under § 401.3(a)(3), the agency shall also provide copies of each determination, statement of fact, and analysis to the Secretary. These shall be sent within 30 days after the award of the funding agreement to which they pertain. Copies shall also be sent to the Chief Counsel for Advocacy of the Small Business Administration if the funding agreement is with a small business firm. If the Secretary of Commerce believes that any individual determination or pattern of determinations is contrary to the policies and objectives of this chapter or otherwise not in conformance with this chapter, the Secretary shall so advise the head of the agency concerned and the Administrator of the Office of Federal Procurement Policy and recommend corrective actions.

(g) To assist the Comptroller General of the United States to accomplish his or her responsibilities under 35 U.S.C. 202, each Federal agency that enters into any funding agreements with nonprofit organizations or small business firms shall accumulate and, at the request of the Comptroller General, provide the Comptroller General or his or her duly authorized representative the total number of prime agreements entered into with small business firms or nonprofit organizations that contain the patent rights clause in this part or under OMB Circular A–124 for each fiscal year beginning with October 1, 1982.

(h) To qualify for the standard clause, a prospective contractor may be required by an agency to certify that it is either a small business firm or a nonprofit organization. If the agency has reason to question the status of the prospective contractor as a small business firm, it may file a protest in accordance with 13 CFR 121.9. If it questions nonprofit status, it may require the prospective contractor to furnish evidence to establish its status as a nonprofit organization.

[52 FR 8554, Mar. 18, 1987, as amended at 69 FR 17301, Apr. 2, 2004]

§ 401.4 Contractor appeals of exceptions.

(a) In accordance with 35 U.S.C. 202(b)(4) a contractor has the right to an administrative review of a determination to use one of the exceptions at § 401.3(a) (1) through (4) if the contractor believes that a determination is either contrary to the policies and objectives of this chapter or constitutes an abuse of discretion by the agency. Paragraph (b) of this section specifies the procedures to be followed by contractors and agencies in such cases. The assertion of such a claim by the contractor shall not be used as a basis for withholding or delaying the award of a funding agreement or for suspending performance under an award. Pending final resolution of the claim the contract may be issued with the patent rights provision proposed by the agency; however, should the final decision be in favor of the contractor, the funding agreement will be amended accordingly and the amendment made retroactive to the effective date of the funding agreement.

(b)(1) A contractor may appeal a determination by providing written notice to the agency within 30 working days from the time it receives a copy of the agency's determination, or within such longer time as an agency may specify in its regulations. The contractor's notice should specifically identify the basis for the appeal.

(2) The appeal shall be decided by the head of the agency or by his/her designee who is at a level above the person who made the determination. If the notice raises a genuine dispute over the material facts, the head of the agency or the designee shall undertake, or refer the matter for, fact-finding.

(3) Fact-finding shall be conducted in accordance with procedures established by the agency. Such procedures shall be as informal as practicable and be consistent with principles of fundamental fairness. The procedures should afford the contractor the opportunity to appear with counsel, submit documentary evidence, present witnesses and confront such persons as the agency may rely upon. A transcribed record shall be made and shall be available at cost to the contractor upon request. The requirement for a transcribed

record may be waived by mutual agreement of the contractor and the agency.

(4) The official conducting the fact-finding shall prepare or adopt written findings of fact and transmit them to the head of the agency or designee promptly after the conclusion of the fact-finding proceeding along with a recommended decision. A copy of the findings of fact and recommended decision shall be sent to the contractor by registered or certified mail.

(5) Fact-finding should be completed within 45 working days from the date the agency receives the contractor's written notice.

(6) When fact-finding has been conducted, the head of the agency or designee shall base his or her decision on the facts found, together with any argument submitted by the contractor, agency officials or any other information in the administrative record. In cases referred for fact-finding, the agency head or the designee may reject only those facts that have been found to be clearly erroneous, but must explicitly state the rejection and indicate the basis for the contrary finding. The agency head or the designee may hear oral arguments after fact-finding provided that the contractor or contractor's attorney or representative is present and given an opportunity to make arguments and rebuttal. The decision of the agency head or the designee shall be in writing and, if it is unfavorable to the contractor shall include an explanation of the basis of the decision. The decision of the agency or designee shall be made within 30 working days after fact-finding or, if there was no fact-finding, within 45 working days from the date the agency received the contractor's written notice. A contractor adversely affected by a determination under this section may, at any time within sixty days after the determination is issued, file a petition in the United States Claims Court, which shall have jurisdiction to determine the appeal on the record and to affirm, reverse, remand, or modify as appropriate, the determination of the Federal agency.

§ 401.5 Modification and tailoring of clauses.

(a) Agencies should complete the blank in paragraph (g)(2) of the clauses at § 401.14 in accordance with their own or applicable government-wide regulations such as the Federal Acquisition Regulation. In grants and cooperative agreements (and in contracts, if not inconsistent with the Federal Acquisition Regulation) agencies wishing to apply the same clause to all subcontractors as is applied to the contractor may delete paragraph (g)(2) of the clause and delete the words ''to be performed by a small business firm or domestic nonprofit organization'' from paragraph (g)(1). Also, if the funding agreement is a grant or cooperative agreement, paragraph (g)(3) may be deleted. When either paragraph (g)(2) or paragraphs (g) (2) and (3) are deleted, the remaining paragraph or paragraphs should be renumbered appropriately.

(b) Agencies should complete paragraph (l), ''Communications'', at the end of the clauses at § 401.14 by designating a central point of contact for communications on matters relating to the clause. Additional instructions on communications may also be included in paragraph (l).

(c) Agencies may replace the italicized words and phrases in the clauses at § 401.14 with those appropriate to the particular funding agreement. For example, ''contracts'' could be replaced by ''grant,'' ''contractor'' by ''grantee,'' and ''contracting officer'' by ''grants officer.'' Depending on its use, ''Federal agency'' can be replaced either by the identification of the agency or by the specification of the particular office or official within the agency.

(d) When the agency head or duly authorized designee determines at the time of contracting with a small business firm or nonprofit organization that it would be in the national interest to acquire the right to sublicense foreign governments or international organizations pursuant to any existing treaty or international agreement, a sentence may be added at the end of paragraph (b) of the clause at § 401.14 as follows:

This license will include the right of the government to sublicense foreign governments, their nationals, and international organizations, pursuant to the following treaties or international agreements:

_____.

The blank above should be completed with the names of applicable existing treaties or international agreements, agreements of cooperation, memoranda of understanding, or similar arrangements, including military agreements relating to weapons development and production. The above language is not intended to apply to treaties or other agreements that are in effect on the date of the award but which are not listed. Alternatively, agencies may use substantially similar language relating the government's rights to specific treaties or other agreements identified elsewhere in the funding agreement. The language may also be modified to make clear that the rights granted to the foreign government, and its nationals or an international organization may be for additional rights beyond a license or sublicense if so required by the applicable treaty or international agreement. For example, in some exclusive licenses or even the assignment of title in the foreign country involved might be required. Agencies may also modify the language above to provide for the direct licensing by the contractor of the foreign government or international organization.

(e) If the funding agreement involves performance over an extended period of time, such as the typical funding agreement for the operation of a government-owned facility, the following language may also be added:

The *agency* reserves the right to unilaterally amend this *funding agreement* to identify specific treaties or international agreements entered into or to be entered into by the government after the effective date of this *funding agreement* and effectuate those license or other rights which are necessary for the government to meet its obligations to foreign governments, their nationals and international organizations under such treaties or international agreements with respect to subject inventions made after the date of the amendment.

(f) Agencies may add additional subparagraphs to paragraph (f) of the clauses at § 401.14 to require the contractor to do one or more of the following:

(1) Provide a report prior to the close-out of a funding agreement listing all subject inventions or stating that there were none.

(2) Provide, upon request, the filing date, patent application number and title; a copy of the patent application; and patent number and issue date for any subject invention in any country in which the contractor has applied for a patent.

(3) Provide periodic (but no more frequently than annual) listings of all subject inventions which were disclosed to the agency during the period covered by the report.

(g) If the contract is with a nonprofit organization and is for the operation of a government-owned, contractor-operated facility, the following will be substituted for paragraph (k)(3) of the clause at § 401.14(a):

(3) After payment of patenting costs, licensing costs, payments to inventors, and other expenses incidental to the administration of subject inventions, the balance of any royalties or income earned and retained by the *contractor* during any fiscal year on subject inventions under this or any successor *contract* containing the same requirement, up to any amount equal to five percent of the budget of the facility for that fiscal year, shall be used by the contractor for scientific research, development, and education consistent with the research and development mission and objectives of the facility, including activities that increase the licensing potential of other inventions of the facility. If the balance exceeds five percent, 75 percent of the excess above five percent shall be paid by the contractor to the Treasury of the United States and the remaining 25 percent shall be used by the *contractor* only for the same purposes as described above. To the extent it provides the most effective technology transfer, the licensing of subject inventions shall be administered by *contractor* employees on location at the facility.

(h) If the contract is for the operation of a government-owned facility, agencies may add the following at the end of paragraph (f) of the clause at § 401.14(a):

(5) The contractor shall establish and maintain active and effective procedures to ensure that subject inventions are promptly identified and timely disclosed and shall submit a description of the procedures to the

contracting officer so that the *contracting officer* may evaluate and determine their effectiveness.

[52 FR 8554, Mar. 18, 1987, as amended at 60 FR 41812, Aug. 14, 1995]

§ 401.6 Exercise of march-in rights.

(a) The following procedures shall govern the exercise of the march-in rights of the agencies set forth in 35 U.S.C. 203 and paragraph (j) of the clause at § 401.14.

(b) Whenever an agency receives information that it believes might warrant the exercise of march-in rights, before initiating any march-in proceeding, it shall notify the contractor in writing of the information and request informal written or oral comments from the contractor as well as information relevant to the matter. In the absence of any comments from the contractor within 30 days, the agency may, at its discretion, proceed with the procedures below. If a comment is received within 30 days, or later if the agency has not initiated the procedures below, then the agency shall, within 60 days after it receives the comment, either initiate the procedures below or notify the contractor, in writing, that it will not pursue march-in rights on the basis of the available information.

(c) A march-in proceeding shall be initiated by the issuance of a written notice by the agency to the contractor and its assignee or exclusive licensee, as applicable and if known to the agency, stating that the agency is considering the exercise of march-in rights. The notice shall state the reasons for the proposed march-in in terms sufficient to put the contractor on notice of the facts upon which the action would be based and shall specify the field or fields of use in which the agency is considering requiring licensing. The notice shall advise the contractor (assignee or exclusive licensee) of its rights, as set forth in this section and in any supplemental agency regulations. The determination to exercise march-in rights shall be made by the head of the agency or his or her designee.

(d) Within 30 days after the receipt of the written notice of march-in, the contractor (assignee or exclusive licensee) may submit in person, in writing, or through a representative, information or argument in opposition to the proposed march-in, including any additional specific information which raises a genuine dispute over the material facts upon which the march-in is based. If the information presented raises a genuine dispute over the material facts, the head of the agency or designee shall undertake or refer the matter to another official for fact-finding.

(e) Fact-finding shall be conducted in accordance with the procedures established by the agency. Such procedures shall be as informal as practicable and be consistent with principles of fundamental fairness. The procedures should afford the contractor the opportunity to appear with counsel, submit documentary evidence, present witnesses and confront such persons as the agency may present. A transcribed record shall be made and shall be available at cost to the contractor upon request. The requirement for a transcribed record may be waived by mutual agreement of the contractor and the agency. Any portion of the march-in proceeding, including a fact-finding hearing that involves testimony or evidence relating to the utilization or efforts at obtaining utilization that are being made by the contractor, its assignee, or licensees shall be closed to the public, including potential licensees. In accordance with 35 U.S.C. 202(c)(5), agencies shall not disclose any such information obtained during a march-in proceeding to persons outside the government except when such release is authorized by the contractor (assignee or licensee).

(f) The official conducting the fact-finding shall prepare or adopt written findings of fact and transmit them to the head of the agency or designee promptly after the conclusion of the fact-finding proceeding along with a recommended determination. A copy of the findings of fact shall be sent to the contractor (assignee or exclusive licensee) by registered or certified mail. The contractor (assignee or exclusive licensee) and agency representatives will be given 30 days to submit written arguments to the head of the agency or

designee; and, upon request by the contractor oral arguments will be held before the agency head or designee that will make the final determination.

(g) In cases in which fact-finding has been conducted, the head of the agency or designee shall base his or her determination on the facts found, together with any other information and written or oral arguments submitted by the contractor (assignee or exclusive licensee) and agency representatives, and any other information in the administrative record. The consistency of the exercise of march-in rights with the policy and objectives of 35 U.S.C. 200 shall also be considered. In cases referred for fact-finding, the head of the agency or designee may reject only those facts that have been found to be clearly erroneous, but must explicitly state the rejection and indicate the basis for the contrary finding. Written notice of the determination whether march-in rights will be exercised shall be made by the head of the agency or designee and sent to the contractor (assignee of exclusive licensee) by certified or registered mail within 90 days after the completion of fact-finding or 90 days after oral arguments, whichever is later, or the proceedings will be deemed to have been terminated and thereafter no march-in based on the facts and reasons upon which the proceeding was initiated may be exercised.

(h) An agency may, at any time, terminate a march-in proceeding if it is satisfied that it does not wish to exercise march-in rights.

(i) The procedures of this part shall also apply to the exercise of march-in rights against inventors receiving title to subject inventions under 35 U.S.C. 202(d) and, for that purpose, the term ''contractor'' as used in this section shall be deemed to include the inventor.

(j) An agency determination unfavorable to the contractor (assignee or exclusive licensee) shall be held in abeyance pending the exhaustion of appeals or petitions filed under 35 U.S.C. 203(2).

(k) For purposes of this section the term *exclusive licensee* includes a partially exclusive licensee.

(l) Agencies are authorized to issue supplemental procedures not inconsistent with this part for the conduct of march-in proceedings.

§ 401.7 Small business preference.

(a) Paragraph (k)(4) of the clauses at § 401.14 Implements the small business preference requirement of 35 U.S.C. 202(c)(7)(D). Contractors are expected to use efforts that are reasonable under the circumstances to attract small business licensees. They are also expected to give small business firms that meet the standard outlined in the clause a preference over other applicants for licenses. What constitutes reasonable efforts to attract small business licensees will vary with the circumstances and the nature, duration, and expense of efforts needed to bring the invention to the market. Paragraph (k)(4) is not intended, for example, to prevent nonprofit organizations from providing larger firms with a right of first refusal or other options in inventions that relate to research being supported under long-term or other arrangements with larger companies. Under such circumstances it would not be resonable to seek and to give a preference to small business licensees.

(b) Small business firms that believe a nonprofit organization is not meeting its obligations under the clause may report their concerns to the Secretary. To the extent deemed appropriate, the Secretary will undertake informal investigation of the concern, and, if appropriate, enter into discussions or negotiations with the nonprofit organization to the end of improving its efforts in meeting its obligations under the clause. However, in no event will the Secretary intervene in ongoing negotiations or contractor decisions concerning the licensing of a specific subject invention. All the above investigations, discussions, and negotiations of the Secretary will be in coordination with other interested agencies, including the Small Business Administration; and in the case of a contract for the operation of a government-owned, contractor operated research or production facility, the Secretary will coordinate with the agency responsible for the facility prior to any discussions or negotiations with the contractor.

§ 401.8 Reporting on utilization of subject inventions.

(a) Paragraph (h) of the clauses at § 401.14 and its counterpart in the clause at Attachment A to OMB Circular A–124 provides that agencies have the right to receive periodic reports from the contractor on utilization of inventions. Agencies exercising this right should accept such information, to the extent feasible, in the format that the contractor normally prepares it for its own internal purposes. The prescription of forms should be avoided. However, any forms or standard questionnaires that are adopted by an agency for this purpose must comply with the requirements of the Paperwork Reduction Act. Copies shall be sent to the Secretary.

(b) In accordance with 35 U.S.C. 202(c)(5) and the terms of the clauses at § 401.14, agencies shall not disclose such information to persons outside the government. Contractors will continue to provide confidential markings to help prevent inadvertent release outside the agency.

§ 401.9 Retention of rights by contractor employee inventor.

Agencies which allow an employee/inventor of the contractor to retain rights to a subject invention made under a funding agreement with a small business firm or nonprofit organization contractor, as authorized by 35 U.S.C. 202(d), will impose upon the inventor at least those conditions that would apply to a small business firm contractor under paragraphs (d)(1) and (3); (f)(4); (h); (i); and (j) of the clause at § 401.14(a).

§ 401.10 Government assignment to contractor of rights in invention of government employee.

In any case when a Federal employee is a co-inventor of any invention made under a funding agreement with a small business firm or nonprofit organization and the Federal agency employing such co-inventor transfers or reassigns the right it has acquired in the subject invention from its employee to the contractor as authorized by 35 U.S.C. 202(e), the assignment will be made subject to the same conditions as apply to the contractor under the patent rights clause of its funding agreement. Agencies may add additional conditions as long as they are consistent with 35 U.S.C. 201–206.

§ 401.11 Appeals.

(a) As used in this section, the term *standard clause* means the clause at § 401.14 of this part and the clauses previously prescribed by either OMB Circular A–124 or OMB Bulletin 81–22.

(b) The agency official initially authorized to take any of the following actions shall provide the contractor with a written statement of the basis for his or her action at the time the action is taken, including any relevant facts that were relied upon in taking the action.

(1) A refusal to grant an extension under paragraph (c)(4) of the standard clauses.

(2) A request for a conveyance of title under paragraph (d) of the standard clauses.

(3) A refusal to grant a waiver under paragraph (i) of the standard clauses.

(4) A refusal to approve an assignment under paragraph (k)(1) of the standard clauses.

(5) A refusal to grant an extension of the exclusive license period under paragraph (k)(2) of the clauses prescribed by either OMB Circular A–124 or OMB Bulletin 81–22.

(c) Each agency shall establish and publish procedures under which any of the agency actions listed in paragraph (b) of this section may be appealed to the head of the agency or designee. Review at this level shall consider both the factual and legal basis for the actions and its consistency with the policy and objectives of 35 U.S.C. 200–206.

(d) Appeals procedures established under paragraph (c) of this section shall include administrative due process procedures and standards for fact-finding at least comparable to those set forth in § 401.6 (e) through (g) whenever there is a dispute as to the factual basis for an agency request for a conveyance of title under paragraph (d) of the standard clause, including any dispute as to whether or not an invention is a subject invention.

(e) To the extent that any of the actions described in paragraph (b) of this section are subject to appeal under the

Contract Dispute Act, the procedures under the Act will satisfy the requirements of paragraphs (c) and (d) of this section.

§ 401.12 Licensing of background patent rights to third parties.

(a) A funding agreement with a small business firm or a domestic nonprofit organization will not contain a provision allowing a Federal agency to require the licensing to third parties of inventions owned by the contractor that are not subject inventions unless such provision has been approved by the agency head and a written justification has been signed by the agency head. Any such provision will clearly state whether the licensing may be required in connection with the practice of a subject invention, a specifically identified work object, or both. The agency head may not delegate the authority to approve such provisions or to sign the justification required for such provisions.

(b) A Federal agency will not require the licensing of third parties under any such provision unless the agency head determines that the use of the invention by others is necessary for the practice of a subject invention or for the use of a work object of the funding agreement and that such action is necessary to achieve practical application of the subject invention or work object. Any such determination will be on the record after an opportunity for an agency hearing. The contractor shall be given prompt notification of the determination by certified or registered mail. Any action commenced for judicial review of such determination shall be brought within sixty days after notification of such determination.

§ 401.13 Administration of patent rights clauses.

(a) In the event a subject invention is made under funding agreements of more than one agency, at the request of the contractor or on their own initiative the agencies shall designate one agency as responsible for administration of the rights of the government in the invention.

(b) Agencies shall promptly grant, unless there is a significant reason not to, a request by a nonprofit organization under paragraph (k)(2) of the clauses prescribed by either OMB Circular A–124 or OMB Bulletin 81–22 inasmuch as 35 U.S.C. 202(c)(7) has since been amended to eliminate the limitation on the duration of exclusive licenses. Similarly, unless there is a significant reason not to, agencies shall promptly approve an assignment by a nonprofit organization to an organization which has as one of its primary functions the management of inventions when a request for approval has been necessitated under paragraph (k)(1) of the clauses prescribed by either OMB Circular A–124 or OMB Bulletin 81–22 because the patent management organization is engaged in or holds a substantial interest in other organizations engaged in the manfacture or sale of products or the use of processes that might utilize the invention or be in competition with embodiments of the invention. As amended, 35 U.S.C. 202(c)(7) no longer contains this limitation. The policy of this subsection should also be followed in connection with similar approvals that may be required under Institutional Patent Agreements, other patent rights clauses, or waivers that predate Chapter 18 of Title 35, United States Code.

(c) The President's Patent Policy Memorandum of February 18, 1983, states that agencies should protect the confidentiality of invention disclosure, patent applications, and utilization reports required in performance or in consequence of awards to the extent permitted by 35 U.S.C. 205 or other applicable laws. The following requirements should be followed for funding agreements covered by and predating this part 401.

(1) To the extent authorized by 35 U.S.C. 205, agencies shall not disclose to third parties pursuant to requests under the Freedom of Information Act (FOIA) any information disclosing a subject invention for a reasonable time in order for a patent application to be filed. With respect to subject inventions of contractors that are small business firms or nonprofit organizations, a reasonable time shall be the time during which an initial patent application may be filed under paragraph (c) of the standard clause found at § 401.14(a) or such other clause may be

used in the funding agreement. However, an agency may disclose such subject inventions under the FOIA, at its discretion, after a contractor has elected not to retain title or after the time in which the contractor is required to make an election if the contractor has not made an election within that time. Similarly, an agency may honor a FOIA request at its discretion if it finds that the same information has previously been published by the inventor, contractor, or otherwise. If the agency plans to file itself when the contractor has not elected title, it may, of course, continue to avail itself of the authority of 35 U.S.C. 205.

(2) In accordance with 35 U.S.C. 205, agencies shall not disclose or release for a period of 18 months from the filing date of the patent application to third parties pursuant to requests under the Freedom of Information Act, or otherwise, copies of any document which the agency obtained under this clause which is part of an application for patent with the U.S. Patent and Trademark Office or any foreign patent office filed by the contractor (or its assignees, licensees, or employees) on a subject invention to which the contractor has elected to retain title. This prohibition does not extend to disclosure to other government agencies or contractors of government agencies under an obligation to maintain such information in confidence.

(3) A number of agencies have policies to encourage public dissemination of the results of work supported by the agency through publication in government or other publications of technical reports of contractors or others. In recognition of the fact that such publication, if it included descriptions of a subject invention could create bars to obtaining patent protection, it is the policy of the executive branch that agencies will not include in such publication programs copies of disclosures of inventions submitted by small business firms or nonprofit organizations, pursuant to paragraph (c) of the standard clause found at § 401.14(a), except that under the same circumstances under which agencies are authorized to release such information pursuant to FOIA requests under paragraph (c)(1) of this section, agencies may publish such disclosures.

(4) Nothing in this paragraph is intended to preclude agencies from including in the publication activities described in the first sentence of paragraph (c)(3), the publication of materials describing a subject invention to the extent such materials were provided as part of a technical report or other submission of the contractor which were submitted independently of the requirements of the patent rights provisions of the contract. However, if a small business firm or nonprofit organization notifies the agency that a particular report or other submission contains a disclosure of a subject invention to which it has elected title or may elect title, the agency shall use reasonable efforts to restrict its publication of the material for six months from date of its receipt of the report or submission or, if earlier, until the contractor has filed an initial patent application. Agencies, of course, retain the discretion to delay publication for additional periods of time.

(5) Nothing in this paragraph is intended to limit the authority of agencies provided in 35 U.S.C. 205 in circumstances not specifically described in this paragraph.

[52 FR 8554, Mar. 18, 1987, as amended at 60 FR 41812, Aug. 14, 1995]

§ 401.14 Standard patent rights clauses.

(a) The following is the standard patent rights clause to be used as specified in § 401.3(a).

Patent Rights (Small Business Firms and Nonprofit Organizations)

(a) Definitions

(1) *Invention* means any invention or discovery which is or may be patentable or otherwise protectable under Title 35 of the United States Code, or any novel variety of plant which is or may be protected under the Plant Variety Protection Act (7 U.S.C. 2321 *et seq.*).

(2) *Subject invention* means any invention of the *contractor* conceived or first actually reduced to practice in the performance of work under this *contract,* provided that in the case of a variety of plant, the date of determination (as defined in section 41(d) of the Plant Variety Protection Act, 7 U.S.C. 2401(d))

must also occur during the period of *contract* performance.

(3) *Practical Application* means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are, to the extent permitted by law or government regulations, available to the public on reasonable terms.

(4) *Made* when used in relation to any invention means the conception or first actual reduction to practice of such invention.

(5) *Small Business Firm* means a small business concern as defined at section 2 of Pub. L. 85–536 (15 U.S.C. 632) and implementing regulations of the Administrator of the Small Business Administration. For the purpose of this clause, the size standards for small business concerns involved in government procurement and subcontracting at 13 CFR 121.3–8 and 13 CFR 121.3–12, respectively, will be used.

(6) *Nonprofit Organization* means a university or other institution of higher education or an organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1954 (26 U.S.C. 501(c) and exempt from taxation under section 501(a) of the Internal Revenue Code (25 U.S.C. 501(a)) or any nonprofit scientific or educational organization qualified under a state nonprofit organization statute.

(b) Allocation of Principal Rights

The *Contractor* may retain the entire right, title, and interest throughout the world to each subject invention subject to the provisions of this clause and 35 U.S.C. 203. With respect to any subject invention in which the *Contractor* retains title, the Federal government shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States the subject invention throughout the world.

(c) Invention Disclosure, Election of Title and Filing of Patent Application by *Contractor*

(1) The *contractor* will disclose each subject invention to the *Federal Agency* within two months after the inventor discloses it in writing to *contractor* personnel responsible for patent matters. The disclosure to the agency shall be in the form of a written report and shall identify the *contract* under which the invention was made and the inventor(s). It shall be sufficiently complete in technical detail to convey a clear understanding to the extent known at the time of the disclosure, of the nature, purpose, operation, and the physical, chemical, biological or electrical characteristics of the invention. The disclosure shall also identify any publication, on sale or public use of the invention and whether a manuscript describing the invention has been submitted for publication and, if so, whether it has been accepted for publication at the time of disclosure. In addition, after disclosure to the *agency,* the *Contractor* will promptly notify the *agency* of the acceptance of any manuscript describing the invention for publication or of any on sale or public use planned by the *contractor.*

(2) The *Contractor* will elect in writing whether or not to retain title to any such invention by notifying the *Federal agency* within two years of disclosure to the *Federal agency.* However, in any case where publication, on sale or public use has initiated the one year statutory period wherein valid patent protection can still be obtained in the United States, the period for election of title may be shortened by the *agency* to a date that is no more than 60 days prior to the end of the statutory period.

(3) The *contractor* will file its initial patent application on a subject invention to which it elects to retain title within one year after election of title or, if earlier, prior to the end of any statutory period wherein valid patent protection can be obtained in the United States after a publication, on sale, or public use. The *contractor* will file patent applications in additional countries or international patent offices within either ten months of the corresponding initial patent application or six months from the date permission is granted by the Commissioner of Patents and Trademarks to file foreign patent applications where such filing has been prohibited by a Secrecy Order.

(4) Requests for extension of the time for disclosure, election, and filing under subparagraphs (1), (2), and (3) may, at the discretion of the *agency,* be granted.

(d) Conditions When the Government May Obtain Title

The *contractor* will convey to the *Federal agency,* upon written request, title to any subject invention—

(1) If the *contractor* fails to disclose or elect title to the subject invention within the times specified in (c), above, or elects not to retain title; provided that the *agency* may only request title within 60 days after learning of the failure of the *contractor* to disclose or elect within the specified times.

(2) In those countries in which the *contractor* fails to file patent applications within the times specified in (c) above; provided, however, that if the *contractor* has filed a patent application in a country after the times specified in (c) above, but prior to its receipt of the written request of the *Federal agency,* the *contractor* shall continue to retain title in that country.

(3) In any country in which the *contractor* decides not to continue the prosecution of

any application for, to pay the maintenance fees on, or defend in reexamination or opposition proceeding on, a patent on a subject invention.

(e) Minimum Rights to *Contractor* and Protection of the *Contractor* Right to File

(1) The *contractor* will retain a nonexclusive royalty-free license throughout the world in each subject invention to which the Government obtains title, except if the *contractor* fails to disclose the invention within the times specified in (c), above. The *contractor's* license extends to its domestic subsidiary and affiliates, if any, within the corporate structure of which the *contractor* is a party and includes the right to grant sublicenses of the same scope to the extent the *contractor* was legally obligated to do so at the time the *contract* was awarded. The license is transferable only with the approval of the *Federal agency* except when transferred to the sucessor of that party of the *contractor's* business to which the invention pertains.

(2) The *contractor's* domestic license may be revoked or modified by the *funding Federal agency* to the extent necessary to achieve expeditious practical application of the subject invention pursuant to an application for an exclusive license submitted in accordance with applicable provisions at 37 CFR part 404 and *agency* licensing regulations (if any). This license will not be revoked in that field of use or the geographical areas in which the *contractor* has achieved practical application and continues to make the benefits of the invention reasonably accessible to the public. The license in any foreign country may be revoked or modified at the discretion of the *funding Federal agency* to the extent the *contractor,* its licensees, or the domestic subsidiaries or affiliates have failed to achieve practical application in that foreign country.

(3) Before revocation or modification of the license, the *funding Federal agency* will furnish the *contractor* a written notice of its intention to revoke or modify the license, and the *contractor* will be allowed thirty days (or such other time as may be authorized by the *funding Federal agency* for good cause shown by the *contractor*) after the notice to show cause why the license should not be revoked or modified. The *contractor* has the right to appeal, in accordance with applicable regulations in 37 CFR part 404 and *agency* regulations (if any) concerning the licensing of Government-owned inventions, any decision concerning the revocation or modification of the license.

(f) *Contractor* Action to Protect the Government's Interest

(1) The *contractor* agrees to execute or to have executed and promptly deliver to the *Federal agency* all instruments necessary to (i) establish or confirm the rights the Government has throughout the world in those subject inventions to which the *contractor* elects to retain title, and (ii) convey title to the *Federal agency* when requested under paragraph (d) above and to enable the government to obtain patent protection throughout the world in that subject invention.

(2) The *contractor* agrees to require, by written agreement, its employees, other than clerical and nontechnical employees, to disclose promptly in writing to personnel identified as responsible for the administration of patent matters and in a format suggested by the *contractor* each subject invention made under *contract* in order that the *contractor* can comply with the disclosure provisions of paragraph (c), above, and to execute all papers necessary to file patent applications on subject inventions and to establish the government's rights in the subject inventions. This disclosure format should require, as a minimum, the information required by (c)(1), above. The *contractor* shall instruct such employees through employee agreements or other suitable educational programs on the importance of reporting inventions in sufficient time to permit the filing of patent applications prior to U.S. or foreign statutory bars.

(3) The *contractor* will notify the *Federal agency* of any decisions not to continue the prosecution of a patent application, pay maintenance fees, or defend in a reexamination or opposition proceeding on a patent, in any country, not less than thirty days before the expiration of the response period required by the relevant patent office.

(4) The *contractor* agrees to include, within the specification of any United States patent applications and any patent issuing thereon covering a subject invention, the following statement, ''This invention was made with government support under (identify the *contract*) awarded by (identify the Federal agency). The government has certain rights in the invention.''

(g) Subcontracts

(1) The *contractor* will include this clause, suitably modified to identify the parties, in all subcontracts, regardless of tier, for experimental, developmental or research work to be performed by a small business firm or domestic nonprofit organization. The subcontractor will retain all rights provided for the *contractor* in this clause, and the *contractor* will not, as part of the consideration for awarding the subcontract, obtain rights in the subcontractor's subject inventions.

(2) The *contractor* will include in all other subcontracts, regardless of tier, for experimental developmental or research work the patent rights clause required by (*cite section of agency implementing regulations or FAR*).

(3) In the case of subcontracts, at any tier, when the prime award with the Federal agency was a contract (but not a grant or cooperative agreement), the *agency,* subcontractor, and the contractor agree that the mutual obligations of the parties created by this clause constitute a contract between the subcontractor and the Federal agency with respect to the matters covered by the clause; provided, however, that nothing in this paragraph is intended to confer any jurisdiction under the Contract Disputes Act in connection with proceedings under paragraph (j) of this clause.

(h) Reporting on Utilization of Subject Inventions

The *Contractor* agrees to submit on request periodic reports no more frequently than annually on the utilization of a subject invention or on efforts at obtaining such utilization that are being made by the *contractor* or its licensees or assignees. Such reports shall include information regarding the status of development, date of first commerical sale or use, gross royalties received by the contractor, and such other data and information as the *agency* may reasonably specify. The *contractor* also agrees to provide additional reports as may be requested by the *agency* in connection with any march-in proceeding undertaken by the *agency* in accordance with paragraph (j) of this clause. As required by 35 U.S.C. 202(c)(5), the *agency* agrees it will not disclose such information to persons outside the government without permission of the *contractor*.

(i) Preference for United States Industry

Notwithstanding any other provision of this clause, the *contractor* agrees that neither it nor any assignee will grant to any person the exclusive right to use or sell any subject inventions in the United States unless such person agrees that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States. However, in individual cases, the requirement for such an agreement may be waived by the *Federal agency* upon a showing by the *contractor* or its assignee that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commerically feasible.

(j) March-in Rights

The *contractor* agrees that with respect to any subject invention in which it has acquired title, the *Federal agency* has the right in accordance with the procedures in 37 CFR 401.6 and any supplemental regulations of the *agency* to require the *contractor,* an assignee or exclusive licensee of a subject invention to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if the *contractor,* assignee, or exclusive licensee refuses such a request the *Federal agency* has the right to grant such a license itself if the *Federal agency* determines that:

(1) Such action is necessary because the *contractor* or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use.

(2) Such action is necessary to alleviate health or safety needs which are not reasonably satisfied by the *contractor,* assignee or their licensees;

(3) Such action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the *contractor,* assignee or licensees; or

(4) Such action is necessary because the agreement required by paragraph (i) of this clause has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of such agreement.

(k) Special Provisions for *Contracts* with Nonprofit Organizations

If the *contractor* is a nonprofit organization, it agrees that:

(1) Rights to a subject invention in the United States may not be assigned without the approval of the *Federal agency,* except where such assignment is made to an organization which has as one of its primary functions the management of inventions, provided that such assignee will be subject to the same provisions as the *contractor;*

(2) The *contractor* will share royalties collected on a subject invention with the inventor, including Federal employee co-inventors (when the agency deems it appropriate) when the subject invention is assigned in accordance with 35 U.S.C. 202(e) and 37 CFR 401.10;

(3) The balance of any royalties or income earned by the *contractor* with respect to subject inventions, after payment of expenses (including payments to inventors) incidential to the administration of subject inventions, will be utilized for the support of scientific research or education; and

(4) It will make efforts that are reasonable under the circumstances to attract licensees of subject invention that are small business firms and that it will give a preference to a small business firm when licensing a subject invention if the *contractor* determines that the small business firm has a plan or proposal for marketing the invention which, if executed, is equally as likely to bring the invention to practical application as any plans

or proposals from applicants that are not small business firms; provided, that the *contractor* is also satisfied that the small business firm has the capability and resources to carry out its plan or proposal. The decision whether to give a preference in any specific case will be at the discretion of the *contractor.* However, the *contractor* agrees that the Secretary may review the *contractor's* licensing program and decisions regarding small business applicants, and the *contractor* will negotiate changes to its licensing policies, procedures, or practices with the Secretary when the Secretary's review discloses that the *contractor* could take reasonable steps to implement more effectively the requirements of this paragraph (k)(4).

(l) Communication

(Complete According to Instructions at 401.5(b))

(b) When the Department of Energy (DOE) determines to use alternative provisions under § 401.3(a)(4), the standard clause at § 401.14(a), of this section, shall be used with the following modifications unless a substitute clause is drafted by DOE:

(1) The title of the clause shall be changed to read as follows: *Patent Rights to Nonprofit DOE Facility Operators*

(2) Add an ''(A)'' after ''(1)'' in paragraph (c)(1) and add subparagraphs (B) and (C) to paragraph (c)(1) as follows:

(B) If the subject invention occurred under activities funded by the naval nuclear propulsion or weapons related programs of *DOE,* then the provisions of this subparagraph (c)(1)(B) will apply in lieu of paragraphs (c)(2) and (3). In such cases the contractor agrees to assign the government the entire right, title, and interest thereto throughout the world in and to the subject invention except to the extent that rights are retained by the contractor through a greater rights determination or under paragraph (e), below. The contractor, or an employee-inventor, with authorization of the contractor, may submit a request for greater rights at the time the invention is disclosed or within a reasonable time thereafter. *DOE* will process such a request in accordance with procedures at 37 CFR 401.15. Each determination of greater rights will be subject to paragraphs (h)–(k) of this clause and such additional conditions, if any, deemed to be appropriate by the *Department of Energy.*

(C) At the time an invention is disclosed in accordance with (c)(1)(A) above, or within 90 days thereafter, the contractor will submit a written statement as to whether or not the invention occurred under a naval nuclear propulsion or weapons-related program of the *Department of Energy.* If this statement is not filed within this time, subparagraph (c)(1)(B) will apply in lieu of paragraphs (c)(2) and (3). The contractor statement will be deemed conclusive unless, within 60 days thereafter, the Contracting Officer disagrees in writing, in which case the determination of the Contracting Officer will be deemed conclusive unless the contractor files a claim under the Contract Disputes Act within 60 days after the Contracting Officer's determination. Pending resolution of the matter, the invention will be subject to subparagraph (c)(1)(B).

(3) Paragraph (k)(3) of the clause will be modified as prescribed at § 401.5(g).

(c) As prescribed in § 401.3, replace (b) of the basic clause with the following paragraphs (1) and (2):

(b) Allocation of principal rights. (1) The Contractor may retain the entire right, title, and interest throughout the world to each subject invention subject to the provisions of this clause, including (2) below, and 35 U.S.C. 203. With respect to any subject invention in which the Contractor retains title, the Federal Government shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States the subject invention throughout the world.

(2) If the Contractor performs services at a Government owned and operated laboratory or at a Government owned and contractor operated laboratory directed by the Government to fulfill the Government's obligations under a Cooperative Research and Development Agreement (CRADA) authorized by 15 U.S.C. 3710a, the Government may require the Contractor to negotiate an agreement with the CRADA collaborating party or parties regarding the allocation of rights to any subject invention the Contractor makes, solely or jointly, under the CRADA. The agreement shall be negotiated prior to the Contractor undertaking the CRADA work or, with the permission of the Government, upon the identification of a subject invention. In the absence of such an agreement, the Contractor agrees to grant the collaborating party or parties an option for a license in its inventions of the same scope and terms set forth in the CRADA for inventions made by the Government.

[52 FR 8554, Mar. 18, 1987, as amended at 69 FR 17301, Apr. 2, 2004]

§ 401.15 Deferred determinations.

(a) This section applies to requests for greater rights in subject inventions made by contractors when deferred determination provisions were included in the funding agreement because one

of the exceptions at §401.3(a) was applied, except that the Department of Energy is authorized to process deferred determinations either in accordance with its waiver regulations or this section. A contractor requesting greater rights should include with its request information on its plans and intentions to bring the invention to practical application. Within 90 days after receiving a request and supporting information, or sooner if a statutory bar to patenting is imminent, the agency should seek to make a determination. In any event, if a bar to patenting is imminent, unless the agency plans to file on its own, it shall authorize the contractor to file a patent application pending a determination by the agency. Such a filing shall normally be at the contractor's own risk and expense. However, if the agency subsequently refuses to allow the contractor to retain title and elects to proceed with the patent application under government ownership, it shall reimburse the contractor for the cost of preparing and filing the patent application.

(b) If the circumstances of concerns which originally led the agency to invoke an exception under §401.3(a) are not applicable to the actual subject invention or are no longer valid because of subsequent events, the agency should allow the contractor to retain title to the invention on the same conditions as would have applied if the standard clause at §401.14(a) had been used originally, unless it has been licensed.

(c) If paragraph (b) is not applicable the agency shall make its determination based on an assessment whether its own plans regarding the invention will better promote the policies and objectives of 35 U.S.C. 200 than will contractor ownership of the invention. Moreover, if the agency is concerned only about specific uses or applications of the invention, it shall consider leaving title in the contractor with additional conditions imposed upon the contractor's use of the invention for such applications or with expanded government license rights in such applications.

(d) A determination not to allow the contractor to retain title to a subject invention or to restrict or condition its title with conditions differing from those in the clause at §401.14(a), unless made by the head of the agency, shall be appealable by the contractor to an agency official at a level above the person who made the determination. This appeal shall be subject to the procedures applicable to appeals under §401.11 of this part.

§401.16 Electronic filing.

Unless otherwise requested or directed by the agency,

(a) The written report required in (c)(1) of the standard clause in §401.14(a) may be electronically filed;

(b) The written election required in (c)(2) of the standard clause in §401.14(a) may be electronically filed; and

(c) The close-out report in (f)(1) and the information identified in (f)(2) and (f)(3) of §401.5 may be electronically filed.

[60 FR 41812, Aug. 14, 1995]

§401.17 Submissions and inquiries.

All submissions or inquiries should be directed to Director, Technology Competitiveness Staff, Office of Technology Policy, Technology Administration, telephone number 202–482–2100, Room H4418, U.S. Department of Commerce, Washington, DC 20230.

[60 FR 41812, Aug. 14, 1995]

PART 404—LICENSING OF GOVERNMENT OWNED INVENTIONS

Sec.

AUTHORITY: 35 U.S.C. 207–209.

APPENDIX I: UNIVERSITY IP AND TECHNOLOGY TRANSFER IN OTHER COUNTRIES

A. Overview

Given the focus of this report on the United States legal landscape, the purpose of considering laws and regulations of other countries is to provide a broader, international context against which to compare at least some of the key principles established under U.S. law. Historically, differences across national legal traditions and academic systems have led to significant variations in how academic IP is handled. Differences largely hinge upon four fundamental factors. The first is the legal status of research universities, especially in relation to the state. Depending on the country, this can range from universities being considered agencies or sub-agencies of national or state governments, to universities being considered independent (although almost always non-profit) organization or corporations.

Second is the level of government research funding. Outside of the United States, government funding levels are typically lower and more mixed, with greater shares of (relatively smaller) research budgets coming from supranational sources (*e.g.* European Union Framework funding) and/or from industry sources. With diverse the funding sources, comes diversity in the conditions and policies governing IP.

The third fundamental determining factor is closely related to the first and second. It is the legal status or type of funds provided by the government to universities. These can range from direct government allocations (to state agency universities) or unconditional subsidies, on the one hand, to competitive service procurement contracts or research agreements, on the other hand. Depending on how government funding is regarded legally, there can be wide variation in the terms and conditions that a government places on the use of the monies in question and, particularly, in the claims that a government makes over results from the funded research. This can be influenced by the extent to which a government was historically active in procuring R&D services from industry, for military or other state-sensitive purposes, and thus has established legal precedents that are followed when funding R&D at universities.

Fourth is the right of the employee, as a natural legal person, to retain title to IP as inventor or author. This can range, on the one hand, from obligations to assign IP rights (patents, plant variety protection, copyright, *etc.*) to the employer under a statutory hired-to-invent or work-made-for-hire rule, to, on the other hand, full rights of the employee to retain IP as a default under an academic exemption. In many countries, IP terms and conditions for university research personnel are defined by employment law and/or are subject to collective bargaining by public employee or academic unions.

These four fundamental factors can vary independently of one another, thus generating the patchwork pattern of policy and practice observed in countries around the world. Of course, other factors matter as well—such as the scope and the practical availability of IP protections (including filing and maintenance costs), the extent of dedicated infrastructure and expert personnel to manage IP, rules allowing or constraining direct sale or assignment of IP to third parties, rules allowing or constraining outside commercial activities of university researchers, employee rights to reasonable compensation if their inventions and creations generate commercial revenues, government rights to practice an invention it funds but does not own, conditions of compulsory licensing for public benefit, preferences for domestic manufacture or regional economic impact, as well as questions of exceptions/exemptions for use of background IP in the course of research. But, all of these tend to follow from the alignment of the more

fundamental factors.

In interest of space, and because it is central to many national debates, we will review in this section just *academic patent ownership policies* across countries and how they depend upon these four fundamental factors. Comparative analysis of the full legal landscapes of other countries is well beyond the scope of this report. Regardless, an international assessment of this one key policy variable can help cast the historical development and current alignment of the United States legal landscape for university IP and technology transfer in fuller light.

B. Variations in IP ownership rules across different academic traditions

Legal and normative academic traditions concerning ownership of university-created IP have varied significantly. Without too much oversimplification, internationally these traditions can be divided into those that have tended to favor the rights of government, those that have tended to favor the rights of the employer (*i.e.*, the university), and those that have tended to favor the rights of the individual as author or inventor. Interestingly, *all three* have been invoked or embraced as supporting the interests of national industry, the promotion of economic development, and the service of the public interest.

In the United States, throughout much of the twentieth century, federal agencies tended to treat their extramural funding of research at universities as a type of procurement activity, as opposed to a direct subsidy, largely because significant portions of their extramural R&D funding was also being directed at private corporate contractors under terms that required the results of that R&D to be provided to or assigned back to the government. As a result of this precedent, federal agencies were inclined to include similar conditions in their research agreements with universities. But, to the extent that this was the rule, there certainly were exceptions, and by the 1970s depending upon the particular federal agency, statute, or program under which university research was funded, title to resulting IP could go to the government, to the individual inventor, or to the institution.

Other countries that have also had fairly clear legal traditions of IP ownership rights defaulting to the government include Canada, France, Russia, and Japan. Outside of these countries, whether because less of the overall research funding came from government and/or because government funding was viewed more as a direct budget allocation or subsidy and less as a payment for services rendered, the legal tradition placed default ownership of IP with the employer, under employment statutes or common law shop rights, regardless of the sector of that employer. By contrast, the Germanic and Nordic countries formalized a "professor's privilege" between the 1940s and the 1960s, as an exemption from those very employment laws and the shop rights doctrine. Thus, by default, ownership rights belonged to individual academic inventor.

However, in recent years, there has been a noticeable international trend of convergence in national policies around a core principle of title ownership going—at least initially—to the research institution that employs the inventor. [1] Convergence towards this principle of

[1] See *Turning Science into Business: Patenting and Licensing at Public Research Organizations* , Organization for Economic Co-operation and Development (OECD): Paris, 2003; *How Universities Promote Economic Growth*, Shahid Yusuf and Kaoru Nabeshima, Eds. (The World Bank: Washington DC), 2007; Gregory D. Graff (2007) "Echoes of Bayh Dole? A survey of IP and technology transfer policies in emerging and developing economies," in A. Krattiger, R. Mahoney, L. Nelsen, et al, Editors, *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* . MIHR: Oxford, UK, and PIPRA: Davis, CA, USA. pp. 169-195.

institutional ownership has in turn raised questions among the secondary set of policy questions, including employee rights to reasonable compensation, government rights to practice the invention, conditions of compulsory licensing for public benefit, obligations for domestic economic benefit, as well as questions of academic research use exceptions/exemptions. [2]

The observed convergence or alignment of legal principles, in country after country, around a default rule of institutional IP ownership likely stems from several exogenous economic and political forces. First, the economic environment within which universities operate is changing. The simultaneous knowledge intensification and globalization of national economies—as reflected in ever higher ratios of intangible to tangible assets held by companies, increased international flows of technologies embedded in capital, increased cross-border ownership of companies, international diversification of increasingly complex supply chains, and increased trade in final goods and services that embody intellectual assets—are affecting regional and national economies around the world in similar ways. At the core, intangibles are of increasingly greater value to industry relative to traditional physical and financial assets. [3] In this changing economic environment national and regional governments are increasingly turning to universities as sources of national or regional economic competitiveness. [4] The goal of many governments has been to increase the "economic utilization" of already existing research capacity. But, rather than simply seeking such utilization through transfer of academic results to existing industry, the desire has been to stimulate the creation of new high-technology (and thus presumably high-growth) companies through entrepreneurial activities based on those academic research results. [5] A key requirement for driving venture creation is the investment of risk capital, which is highly sensitive to the assurances provided by IP protections. Second, the emergence of certain fields like biotechnology—in which industry tends to be more reliant on formal IP protections and in which academia has a high level of research expertise—has generally increased the demand for IP from academics. Third, the apparent success of the legal framework in the United States has carried force of example. Policymakers around the world have taken notice of the Bayh-Dole policies. [6] Some countries have used Bayh-Dole directly as a template in designing a complete rewriting of their own laws. Others have merely shifted their existing frameworks in the direction of its principles.

The observed policy changes in multiple countries do not, in themselves, provide any direct verification of the efficacy of the underlying principle of institutional ownership, relative to government or individual ownership, for driving technology transfer and the commercial

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[2] *See supra* Part III for treatment of these in current United States federal law.

[3] Leonard I. Nakamura, "What is the US gross investment in intangibles? (At least) One trillion dollars a year," Working Paper No. 01-15, *Federal Reserve Bank of Philadelphia*, October 2001.

[4] Relative to U.S. states, see David B. Audretsch and Ronnie J. Phillips, "Entrepreneurship, State Economic Development Policy, and the Entrepreneurial University," CEPR Discussion Paper No. DP6242, (April 2007).

[5] For example, an official statement by the French government that "…the number of companies created every year using the results of research funded by the public sector remains too low," as quoted in Alain Gallochat (2003) "French Technology Transfer and IP Policies," in *Turning Science into Business: Patenting and Licensing at Public Research Organizations*, OECD: Paris, at page 141.

[6] "Innovation's Golden Goose" *The Economist*, December 12, 2002; David C. Mowery and Bhaven N. Sampat (2004) "The Bayh-Dole Act of 1980 and University-Industry Technology Transfer: A Model for Other OECD Governments," *Journal of Technology Transfer*, 30(1-2), pp 115-127; Anthony D. So, Bhaven N. Sampat, Artie K. Rai, Robert Cook-Deegan, Jerome H. Reichman, et al. (2008) "Is Bayh-Dole Good for Developing Countries? Lessons from the U.S. Experience" *PLoS Biology* 6(10): e262; Graff (2007) "Echoes of Bayh Dole" *supra* note 1.

development of academic inventions. The preponderance of changes does, however, reveal at least two important facts of logic. First, some set of political interests in each country to introduce such reforms must have had reason to actively champion new rules, considering them to be sufficiently advantageous to be worth expending political effort to advance and support the proposal. And second, those changes, if they have indeed been implemented, were acceptable to a broad enough set of constituents or political interests to have been approved and enacted. In sum, they met the necessary condition of being championed by someone and they met the sufficient condition of finding broad support (or, at least, lack of opposition) across enough others.

Considerations of the various starting points from which IP ownership policies are later changed are important for several reasons. First, whether a proposed reform seeks to extend rights or to take away rights (in essence, to engage in "privatization" versus "nationalization") has very real bearing over its political feasibility. For example, if ownership rights traditionally have resided with government, and that government proposes to devolve or privatize those rights to university institutions, then there is likely to be less organized political opposition. In particular contrast, if ownership rights have traditionally gone to individual inventors and the government then proposes to strip individuals of those rights (to "nationalize" them) and allocate them instead to university institutions, there stands a much larger constituency that is likely to object politically due to economic losses or losses of rights and liberties. Second, a country's starting point matters insofar as it likely suggests the specific areas of law in which changes in university IP and technology transfer policy are most likely to be enacted: whether in the legal/institutional status of universities, IP law, employment law, or government procurement regulations. Third, the legal tradition from which a country comes suggests what other attendant or secondary concerns are likely to be addressed in new legislation or regulations, such as retention of government rights or research use exemptions. Finally, the legal tradition of a country reveals its underlying cultural norms, which will likely affect actual disposition of academic IP, even after reforms have changed the letter of the law.

Table I.1. Countries enacting or considering legal changes with effects on ownership allocation of academic IP [7]

Country	Date	Name and/or nature of the legal change
Argentina	1995	• Amendment to patent law clarified that right of ownership of inventions by employers includes public sector institutions and universities
Austria	2002	• Repealed "professor's privilege" system and established default rule of institutional ownership of inventions
Brazil	1996	• Amendment to patent law clarified that right of ownership of inventions by employers includes public sector institutions and universities
Canada	1991	• Treasury policy on *Title to IP Arising under Crown Contracts* allowed contractors to own IP created in course of work under

[7] Sources for table: OECD, *supra* note 1; Graff, *supra* note 1; Marie-Christine Janssens (2005) "Regulatory Framework Regarding Ownership of Inventions Conceived at Universities," in Andre Spithoven & Peter Teirlinck Eds., *Beyond Borders: Internationalization of R&D and Policy Implications for Small Open Economies* , Elsevier: Amsterdam, 2005; and others cited throughout the following sub-sections for specific countries.

	2000	procurement contracts • Revision of the treasury policy on *Title to IP Arising under Crown Procurement Contracts*
Chile	1991	• Patent law established university ownership of inventions
China	1996 2002	• *Act for Promotion of Technology Transfer* gave institutions right to ownership of IP for inventions funded by the government • Ministry of Science and Technology and Ministry of Education joint *Opinion on Exerting the role of Universities in Science and Technological Innovation* clarified rights of IP ownership by institutions under government funding
Denmark	2000	• *Act on Inventions at Public Research Institutes* repealed "professor's privilege" system and established institutional ownership of inventions by universities, hospitals, and public research institutes
Finland	2007	• *Act on the Right in Inventions Made at Higher Education Institutions* modified "professor's privilege" system, abolishing it for all "contract" and "collaborative" research
France	1980 1996	• Decree that general rules, in IP Code, article L.611-7, concerning inventions made by employees in course of employment shall belong to the employer with compensation determined by contract, applies to civil servants and public employees including university employees. • Law on innovation and research gives civil servants (including professors) ability to found companies.
Germany	1999 2002	• Federal Ministry of Education and Research (BMBF) regulations over commercial exploitation of IP generated under its research grants and contracts. • Reform of Employee-Employer Law repealed 'professor's privilege' (*Hochschullehrerprivileg*) system.
India	2000 pending	• Ministry of Science and Technology ruling gave title to IP to the institution if created under Ministry funding. • Bill on Protection and Utilization of Publicly Funded Intellectual Property (PUPFIP) in parliamentary committee.
Italy	2001 2005	• National law 383 established that title of inventions goes to researchers. • Title of invention from externally funded research goes to the institution, with title to researchers only if research is internally funded.
Japan	1998 1999 2000 2004	• Law to Promote the Transfer of University Technologies established technology licensing offices and gave university inventors the option to use those offices to commercialize their IP. • Law of Special Measures to Revive Industrial Vitality (the "Japanese Bayh-Dole Act") gave independent universities default right to take title to IP. • Law to Strengthen Industrial Technology clarified rules on sponsored research and academic consulting. • National University Corporation Law de-nationalized the national universities and established them as independent legal

		entities, thus enabling them to take title to IP under the 1999 law.
Norway	2003	• Law repealed 'professor's privilege' system.
South Africa	pending	• Bill titled *Intellectual Property Rights from Publicly Financed Research.*
Spain	1986 1988	• Patent law, article 15-20, assigns ownership of IP to employer (including universities) but assures "fair compensation" to the employee inventor. • *National R&D Plan* promoted creation of university technology transfer offices.
United Kingdom	1977 1998 2000	• Patent Act indicates generally that inventions made in normal course of employment belong to the employer. • National Health Service Circular HSC1998/106: IP from funded research normally resides the organization carrying out the R&D • Patent Office guidelines *Intellectual Property in Government Research Contracts*: "ownership of the IP generated in publicly funded research should in general be vested in organisations that actually do the research rather than being held by a public sector purchaser"

1. Government Ownership

Government ownership of IP resulting from university research is most straightforward in countries where universities are legally a branch of government or directly controlled by government. Government ownership of IP resulting from government sponsored R&D has also been a fairly common legal principle where universities are legally independent entities. Agencies charged with funding extramural research can often manage it as a kind of procurement of services for the government. This has been all the more so for research of a more sensitive nature, such as atomic energy or defense related R&D, but the principle can be generalized to national policy. For example, in Canada prior to 1991, ownership of IP over inventions made under government contracts went to the government as a matter of procurement policy. [8] This changed with a 1991 policy "Intellectual Property in Crown Procurement Contracts" which modified the principle through an adjustment in regulations, giving the default right of ownership of IP conducted under government contract to the contractor. This was followed in 2000 by a further set of regulatory refinements to extend the rule to IP created under all procurement contracts, not just research contracts, clarifying ownership exceptions in cases such as national defense, defining the government's rights in contractor assigned IP, and providing for the reporting and monitoring of inventions made under government contract. [9]

In Japan, prior to significant reforms of the country's university system in 1998-2004, most research universities—the so-called "national" universities—were legally established as sub-agencies of the government and not independent legal entities. As such, they were effectively

[8] Jeanne Inch, Donovan Vernon, Elizabeth Blackburn, and Michel Grenier (2003) "Policy on Title to Intellectual Property under Crown Procurement Contracts in Canada," in *Turning Science into Business: Patenting and Licensing at Public Research Organizations* , (OECD: Paris), pp. 113-128.

[9] *Id.*

unable to take title to IP; any ownership would have vested directly with the government. Moreover, when university research was funded for a specific government project or purpose, the resulting inventions, if properly disclosed to the responsible agency, could be classified as "national" inventions and title would be assigned to the government. [10] There was in practice an extremely low rate of disclosures and thus classification of such 'national' inventions relative to the overall IP output of Japanese academics, which commentators have attributed to the ineffectiveness of the centralized government-led commercialization efforts. [11] Most inventions made at universities were not reported to the government and were instead made exclusively available to industry collaborators under assignment by individual inventors. [12]

In the legal tradition of France, universities were similarly considered public institutions and researchers were considered civil servants, employed by the state and under obligation to assign title over inventions to the state. An added complication was that specific regulations governing IP depended upon the legal classification of the public institution at which an inventor was employed (whether a "national institute," a "public commissariat," or a "public establishment" the latter of which included universities). [13] In fact, many laboratories were jointly managed by institutions of different classification (frequently a "national institute" together with a "public establishment" university), in which case the national institute would, by default, take title and manage the IP. In practice, requirements were neither clear nor well enforced. Again, similar to the situation in Japan, the result was that a significant number of inventions made at universities were instead assigned directly by the inventors to companies in French industry. [14] The question of ownership is addressed in the French Intellectual Property Code (Article L611-7) which follows fairly common shop rights doctrine to stipulate that inventions made in the course of employment shall belong to the employer, with compensation to the inventor to be determined by contract. However, because French university employees were considered civil servants, policy had to be made (in a 1996 decree) to provide specific guidelines for calculating compensation to research employees from exploitation of their inventions. Finally, a 1999 law modified the civil service status of academics to give them more latitude to conduct outside work with industry collaborators and startup companies.

The government of the Russian Federation inherited both a legal structure and a tradition of defense-related research from the Soviet Union. As stronger forms of IP were introduced in 1992 to bring Russia into compliance with its international obligations under TRIPS, private sector patenting increased commensurately. However, conflicting standards between Russia's civil code (giving preference to contractors to obtain rights to IP arising from federally funded R&D) and new legislation (establishing the government as owner of the results of research it has funded) resulted in little patenting activity by universities and public research institutes. [15] A pair

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[10] Robert Kneller (1999) "Ownership Rights to University Inventions in Japan and China," in *Streamlining International Intellectual Property* , CASRIP Publication Series No. 5, pp. 160-164.

[11] *Id.*

[12] *Id.*

[13] Gallochat (2003), *id*., at 139.

[14] Francesco Lissoni, Patrick Llerena, Maureen McKelvey, and Bulat Sanditov (2007) "Academic Patenting in Europe: New Evidence from the KEINS Database," RIDE/IMIT Working Paper No. 84426-019, Chalmers, Sweden, at pages 17-18.

[15] Natalia Zolotykh (2003) "Legal Regulation of Protection and Commercialization of Intellectual Property Created by Russian Public Research Organizations," in *Turning Science into Business: Patenting and Licensing at Public*

of presidential decrees issued in1998 assert that results of research, military and otherwise, funded by the Russian federal government are property of the government. Yet, given that mechanisms for actual implementation were not developed for several years, rates of patenting activity by university researchers, on behalf of the Russian federal government or its agencies, has remained low. An amendment to Russian patent law in 2003 establishes that rights to IP developed under state funding belongs to the university, but only if not otherwise assigned to the government in the funding contract.

2. Employer Ownership

In many countries the legal traditions result in a default rule of employer ownership. This typically arises from two interacting conditions. First, employment statues or inventorship/assignment provisions in IP statues establish the rights of an employer to take title—or at least to include terms in employment contracts to assign title—over inventions and creative works made by employees in the normal course of employment, establishing the "hired to invent" rule of the shop rights doctrine. Second, is that any IP obligations that accompany government funding of research defers to this law, rather than presuming the research to be a "procured" service where there would be an obligation to render the results back to the government. In many cases the relative freedom of this second condition (including freedom from prohibition against assigning to third parties), combined with the relative control gained by the institutions under the first condition, creates a fairly fluid or flexible environment. The university is essentially free to transfer or commercialize the IP through a wide range of possible conveyances of rights.

In the U.K. the Patent Act historically has allocated title according to shop rights doctrine, with inventions made in normal course of employment belonging to the employer, without specific regard to the type of that employer. Government funded research has had additional procurement-type conditions attached to it. A 1998 National Health Service Circular (HSC1998/106) indicated that IP from research funded by that agency should normally reside in the organization carrying out the R&D. In 2000 general Patent Office guidelines reinforced this rule, stating, "ownership of the IP generated in publicly funded research should in general be vested in organisations that actually do the research ("the research providers") rather than being held by a public sector purchaser." [16]

Spain and several countries of Latin America, including Argentina, Chile, and Brazil, likewise have shop rights traditions embedded in their patent laws, assigning ownership of IP created in the normal course of employment to the employer. In Spain in 1986, Chile in 1991, Argentina in 1995, and Brazil in 1996 amendments were made to patent law to clarify that this employer assignment rule applied to universities as well. Additional clauses in patent or conditions in employment law serve to place limits on the contractual assignments of IP that employers can require of employees and to assure "fair compensation" is made to employee inventors.

Research Organizations, (Organization for Economic Co-operation and Development: Paris), pp. 153-166.

[16] *Intellectual Property in Government Research Contracts*, UK Patent Office, 2000. Available online at www.ipo.gov.uk/ipresearch.pdf.

3. Inventor Ownership

Ownership of IP, with some exceptions, generally vests initially to its inventor or creator, and, as noted in Part II, academics had since the institutionalization of science in the seventeenth century taken title as individuals to their own inventions and writings. This arrangement was a natural default, given that the "shop rights" doctrine whereby inventions were legally required to be assigned to an employer only emerged in the mid-nineteenth century and entered the academy, in a limited way, in the early twentieth century. But by the middle of the twentieth century, a default statutory rule had emerged in some countries as a solution, intended to address both market and government failures in the development and utilization of new technologies arising from academic research. In Europe, beginning shortly after the World War II and culminating in the 1960s, Sweden, Germany, Austria, Denmark, Norway, and Finland all put in place a legal principle whose name roughly translates as "the professor's privilege" (*Hochschullehrerprivileg* in German), denoting the exemption of academics from the typical IP clauses of employment law obligating them as employees to disclose and assign inventions to their employers. In Asia, comparable systems could be found in Japan and to a lesser extent in China, which also allowed for default ownership by individual university inventors. [17] The professor's privilege system appears to have been well suited for encouraging informal or ongoing collaborative ties between individual faculty researchers and established firms in domestic industry, as academic inventors could straightforwardly assign their IP to their industry collaborator. Such relationships typically arose via informal exchanges between industry scientists and academic experts or were a continuation of the professor-graduate student relationship after the student was hired by industry. Such relationships could lead to longstanding research sponsorship agreements with a *quid pro quo* that involved assignment of IP on the academic's results to the commercial partner in exchange for continued research funding to the academic partner. While, in principle, the system did not preclude entrepreneurial activity by professors who were inclined to launch a startup company, in practical terms, the costs and risks of entrepreneurship typically outweighed the inclination of most academic inventors to do so as individuals. Even when they have done so, professor-owned companies are often vehicles for holding title to and licensing IP rather than being directly engaged in developing and selling products.[18]

In fairly rapid succession over the last decade, most of the countries with a legal tradition of individual ownership under the professor's privilege had reformed or repealed it: Denmark in 2000, Germany in 2002, Austria in 2002, Norway in 2003, Japan in 2004, and Finland in 2006. [19] Italy first implemented a version of the professor's privilege in 2002, only to repeal it three years later in cases of external research funding. As of 2010, only Sweden has retained the professor's privilege system, and even there it has come under increasing question in recent years.

Article 5 of the (originally, West) German constitution, which in assuring basic freedoms of expression included freedom of "science, research, and teaching", was the legal basis for the *Hochschullehrerprivileg,* formally exempting (West) German academics from the obligations of the 1957 Employer-Employee Law (*Arbeitnehmererfindungsgesetz*) to disclose inventions to

[17] *See supra* note 5.

[18] Lissoni (2007), *supra* note 14 at page 18.

[19] Niklas Bruun (2007) "Innovation Policy, Academia, and Intellectual Property," *Georgia State University Law Review*, Vol. 23, No. 4, pp. 913-935.

their employer.[20] This exemption began to change in 1999, at least for federally funded research, when the Federal Ministry of Education and Research (BMBF) implemented new regulations over the commercial exploitation of IP generated under its research grants and contracts. Then a 2002 law repealed the *Hochschullehrerprivileg* by reforming a section of the Employer-Employee Law,[21] thus requiring academics to disclose inventions and assign title to their employers, similar to other employees. Yet distinctions remain. Inventions are qualified based upon whether they were supported by outside funding (so called "service" inventions) or were internally funded (which remain "free" inventions and thereby belong to the inventor as under the previous rules). While an academic inventor must disclose both kinds of inventions to the institution, it is incumbent upon the institution to declare within four months whether it has intentions of pursuing patent for "service" inventions. Beyond that, rights over even a "service" invention revert to the individual inventor. The law also introduced requirement that academic institutions share 30 percent of revenues from commercial exploitation of an invention with the inventor(s).[22] There appears to be no provision, under German law, for any retention of government rights or public uses of patented academic inventions.

Academics in Denmark were also exempted since 1957 under a professor's privilege law from the IP requirements of Danish employment law. [23] In 1998 the Ministry for Research and Technology proposed a new law, the Act on Inventions at Public Research Institutions, to repeal the professor's privilege and give to the university a first right to take title. Similar to German law, it gave a short time period, in this case two months from the date of notification, for the institution to decide whether to take title, after which ownership rights revert to the inventor. It also requires the institution, if the invention is exploited commercially, to make "reasonable remuneration" to the inventor. An actual percentage of revenues is not stipulated but is rather left to the institution to negotiate. The bill was passed into law by the Danish parliament in 1999, entered into force in 2000, and has been amended several times since. [24]

In considering the political forces that maintained the professor's privilege in Denmark through the 1990s, Sven Milthers observes:

> The reasons [no significant changes were made in the professor's privilege until 1998] include protests from the researchers' trade unions (who considered the proposals to be equivalent to nationalization of commercial rights), universities' resistance to the rather bureaucratic and distant body proposed to handle the . . . IPR, and lack of political will to get the necessary legislation through parliament. In public, industry representatives were very anxious to have the regulations changed "in order to have one institutional counterpart instead of up to ten individual researchers." In private, a number often

[20] Christian Kilger and Kurt Bartenbach (2002), "New Rules for German Professors," *Science*, 298 (5596), pg. 1173; Thomas Gering and Ulrich Schmoch, (2003) "Management of Intellectual Assets by German Public Research Organizations," in *Turning Science into Business: Patenting and Licensing at Public Research Organizations* , Organization for Economic Co-operation and Development (OECD): Paris, pp. 169-187.

[21] Gering and Schmoch (2003), *id.*

[22] Kilger and Bartenbach (2002) *supra*, note 11.

[23] Sven Milthers (2003) "Changing IPR Regulations for Researchers in Denmark," in *Turning Science into Business: Patenting and Licensing at Public Research Organizations* , (Organization for Economic Co-operation and Development: Paris), pp. 129-138.

[24] *Act on Inventions at Public Research Institutions* , No. 347, 2 June 1999.

> admitted that they did not want any major changes in the system, as it was often much easier to get a good deal with an individual once-in-a-lifetime inventor than it might be with a system of professional licensing offices . . . [25]

There was apparent alignment of political interests between researchers, university administrations, and, at least in private, domestic industry for maintaining a system under which inventions publicly funded by the Danish taxpayers were directly assigned to Danish industry. But by 1998 the politics had changed. It is notable that in both Denmark and Germany the initial proposal for weakening the academic exemption arose from the ministry that funds research.

Austria and Norway have each repealed the "professor's privilege" system and established a default rule of institutional ownership of inventions, in 2002 and 2003 respectively. Finland is the most recent European country to have modified its professor's privilege system. It had established the professor's privilege in a 1967 reform intended to harmonize patent laws across Nordic countries. A new law passed in 2006, and entered into force in 2007, [26] makes a distinction similar to German law between "open" or "free" research, over the results of which academic researchers would maintain the privilege to take ownership, and "commissioned" or "contract" research, for which the professor's privilege was abolished.

According to observations by Niklas Bruun, professor of law and Director of the University IPR Center at University of Helsinki, some of the political issues involved in making the change have been similar to the experiences of its neighbors:

> The changes in Finnish legislation have been strongly promoted by universities and by authorities in charge of R&D policies, but industry has been quite skeptical. One reason for the long period of discussion regarding the changes was that industry did not applaud the changes. Some examples of clash between university interests and industry regarding contractual terms already exist. Generally, the industry argues that it is easier to negotiate with researchers… than with tech-transfer officers that are more interested in following general policy and creating a surplus for the university. In some cases, large Finnish companies have announced they will not continue their cooperation with universities if the new policy is not adjusted. With this it seems that the arguments for the teachers' exemption resemble those heard in Sweden. [27]

Sweden is widely recognized as the last country in Europe to be maintaining, as of 2010, its legal tradition of a "professor's privilege." The formalization of the right was created in Sweden in 1949, even earlier than attributed in Germany, by Act 345 "On the Right to Employee Inventions," which established general rules for companies in Sweden, and under which, it was stated, academics were not to be considered as Employees. [28] Since the Act only covers inventions and not other forms of IP, the exemption is specific to patents. [29] Recently, the

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[25] Milthers (2003) *supra*, note 16, at page 129.

[26] *The Act on the Right in Inventions Made at Higher Education Institutions* , 369/2006.

[27] Bruun (2007) *supra*, note 19, at 922.

[28] Edward Farrington & Richard Wolff, "The professor's privilege" *Managing Intellectual Property* , July/August 2008, pp. 1-4.

[29] *Id.*

changes in neighboring Germany, Denmark, Norway, and Finland have certainly not gone unnoticed in Sweden, and there have been protracted discussions within Swedish universities and relevant ministries as to whether it would be in Sweden's interest to remove the academic exemption and begin to give default rights of patent ownership to academic institutions. [30] The Swedish ministry of innovation, VINNOVA, instituted a comprehensive program in 2006 titled "University Key Actors" to fund the development of technology transfer offices at leading Swedish universities, based largely on concerns due to the professor's privilege over lack of transparency in existing academic-industry partnerships, the range of " *different cultures, different requirements, and varying degrees of professionalism* " characterizing technology transfer from within even a single university, the difficulty for a university administration to coordinate institutional-level strategic plans for commercialization or industry-collaboration, and challenges of coordinating commercially oriented research collaborations internationally. [31] An inquiry published in 2005 (SOU 2005:95) proposed abolishing or amending the professor's privilege in Sweden and was introduced to early discussions in the legislature. [32] It would not be unlikely for legislative action to be taken within the next few years.

Italy is unique in having recently *created* a professor's privilege, under 2001 legislation (Article 7 of National Law 383) that went into force in 2002. Prior to this, the legal environment for academic IP in Italy was best defined by a typical employer assignment clause found in Italian patent law (R.D. n. 1127/1939), which was considered to apply to university employees as well.[33] Yet, due to a relative lack of administrative autonomy of universities and an almost complete lack of IP management and technology transfer expertise, only a very small proportion of patents over academic inventions were assigned to universities; the balance were assigned about equally to government, companies, and individuals. [34] Law 383 was introduced by a new government with a clear intention of spurring regional economic development by creating direct incentives for individual researchers themselves to commercialize their inventions. [35] It was met almost immediately, however, with objections:

> . . . constituencies from industry associations (e.g. Confindustria), to universities (e.g. Conference of the Rectors of Italian Universities, NetVal), to PROs (e.g. ENEA, CNR), and political parties . . . . [d]espite being profoundly different, all . . . voiced for the elimination of Law n. 383, claiming that the law discriminated between private and public employees, it increased complexity and uncertainty on IPR negotiations on jointly private-public projects, and provided no incentives to universities and PROs to

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[30] Ulf Petrussen, Professor of Law and director of the Center for Intellectual Property, University of Gothenberg, *personal communication*, September 20, 2009.

[31] Christina Johannesson, "University strategies for knowledge transfer and commercialization: An overview based on peer reviews at 24 Swedish universities 2006", VINNOVA Report VR 2008:17, VINNOVA - Swedish Governmental Agency for Innovation Systems, September 2008, at 11-14.

[32] Farrington & Wolff (2008) *supra*, note 28, at 4.

[33] Nicola Baldini, Rosa Grimaldi, & Maurizio Sobrero, "Diffusion of organisational practices in turbulent environments: an empirical analysis of university-level patent regulations" (August 2007). Available at SSRN: http://ssrn.com/abstract=1030049

[34] Lissoni (2007) *supra*, note 14, at Figure 9.

[35] Baldini (2007) *supra*, note 33.

strategically manage inventions developed in their labs. [36]

As a result, the Italian professor's exemption was modified in 2005 (by an amendment to IP law D.Lgs. n. 10/2005) in a manner similar to the ownership law changes made in Germany, Denmark, and Finland, by distinguishing between "commissioned" research (i.e. any research supported by outside funding, whether from industry, provincial or Italian governments, or the E.U.) and "free" research (research supported just by internal university budgets), with the professor's exemption repealed for the former, but maintained for the latter.

The prevailing Japanese system prior to 1998, while legally one of government default ownership of academic IP, in fact coalesced around a set of norms defining an academia-industry collaboration model strikingly similar to that undergirded by professor's privilege laws in Europe. In fact, Japan's *de facto* system of inventor ownership was, in most regards, a result of the ineffectual legal framework for granting ownership of designated National Inventions to the government. According to the explanation of Robert Kneller, an expert on Japanese technology transfer policy at University of Tokyo:

> In an "inventor retains ownership" system, where the inventors fear the classifying of an invention as a National Invention, the inventors pass their inventions without documentation to industry. The inventions are passed to companies with whom professors have long-standing relations based on donations and the hiring of their students. There are no contract agreements between the company and the professor, only a gentleman's agreement that the inventor will get some remuneration if the company chooses to develop and market the invention. [37]

In the mid 1990s Japan began an extensive legal reform of the national university system in an effort to stimulate innovation and revive the country's stagnating economy. Reallocation of IP rights to university institution, while integral to this, was only one part of a much larger set of changes. Prior to these reforms, the legal status of National Universities, consisting of most of the elite educational and research institutions in Japan, was as part of the national government, specifically as sub-branches of the Ministry of Education, Culture, Sports, Science, and Technology (MEXT). As such, these universities were themselves unable to take title to IP. Rather, it would merely entail granting title to MEXT, no different effectively than designation as a National Invention.

It was decided that the first deficiency in the system to be addressed should be the lack of institutional capacity for IP management. Thus, the first legal change, taken in 1998, was the *Law to Promote the Transfer of University Technologies* which created offices of technology transfer that would serve, initially, those university inventors who voluntarily sought their IP management services, and thereby would begin to develop institutional expertise in IP management. Next, in 1999, the *Law of Special Measures to Revive Industrial Vitality* (sometimes described as the "Japanese Bayh-Dole Act") gave independent universities default right to take title to IP. However, this did not at the time apply to the national universities, as they were still not independent of the government. Next, in 2000, came the *Law to Strengthen Industrial Technology* which clarified for industry's sake the rules on sponsored research and

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[36] *Id.* at 12.

[37] Kneller (1999) *supra,* note 10 at 161.

academic consulting. Finally, and only after all of these conditions were put into place, the 2004 *National University Corporation Law* de-nationalized the national universities and established them as independent legal entities, thus enabling them to take title to IP under the 1999 law and to utilize the growing professional IP management expertise of the technology transfer offices that had been established under the 1998 law.

C. The apparent convergence of ownership rules

In concluding this international review of assignment laws for university generated patents, we should note how the three general patterns of ownership result from rules over (1) the legal status of universities, (2) the extent of government funding of university research, (3) the legal character of that funding and conditions placed upon it, and (4) the rights/obligations of an employee to retain/assign title to an invention to his or her employer.

Traditionally, government ownership has been a default rule in countries where either (1) the university was considered part of a government agency and university personnel were thus employees of the government or (2) government funding of university research was considered a procurement contract, under the terms of which assignment to the government was required of the contractor. The first of these two proved in practice to be rather impractical and at odds with the incentives created under the patent system, with academic inventors merely avoiding disclosure to the government and instead retaining title as individuals or assigning title to companies. Reforms giving title to the university have been observed in both types of systems. In the former, reforms have been undertaken to make the university (or its employees) legally independent of the government, as has been the case in Japan (or France). In the latter, government procurement standards were simply relaxed and universities allowed more leeway to take title to inventions made by their employees, as has been the case of the U.S. or Canada.

Traditional employer ownership most naturally arose from the straightforward application of a traditional "shop rights" rules of IP assignment to universities and other public sector employers. This was only viable, of course, where the university was not an integral part of the government. Interestingly, this was actually a necessary provision to support government ownership under procurement contracts, where assignment to the contractor (i.e. the employer) by the employee was a necessary precondition for assignment by the contractor to the government. Reforms that have been observed in most countries with an employer ownership default have merely involved clarification that the "shop rights" rules of IP law indeed also apply to universities as employers. Examples have been the U.K., Spain, and Brazil.

Inventor ownership has been, in all countries where it was implemented, an explicit exemption from traditional "shop rights" rules of IP assignment by employee to employer. The ideology of the professor's privilege arose in post-war Sweden and West Germany and spread to other Germanic and Nordic neighbors. To the extent that the universities in these countries were "state" universities, this exemption served to keep assignment of inventions "free" of government bureaucracies, and thus more likely to enter commerce due to the power of private incentives. Moreover, to the extent that members of these societies were suspicious of the powers of Government (fully understandable, living in the wake of Fascism and in constant confrontation with Communism) vesting rights over new ideas with scientist-scholars rather than with the State or with institutions closely associated with the State was likely viewed as the most favorable option available. But governments have reformed these rules, in most cases with the exemption being at least partially repealed, allocating options of ownership between either the

university as employer or the inventor as employee. The rights of inventors remain much stronger in these countries than they do in either of the other two, even after typical reforms.

The observed convergence has by no means been complete. Empirical analyses of national patent databases reveal the shares of academic patents assigned to universities, firms, individuals, and Governments in the U.S., France, Italy, and Sweden. [38] Systematic differences during the time period 1994 to 2001 follow, to some extent, as expected. In the U.S. under the Bayh-Dole Act the greatest share of academic patents (68.7 percent) were assigned to universities, with a large minority share (24.2 percent) assigned to companies, and small minorities to individual inventors (5.3 percent) and the U.S. Government (1.7 percent). In France, a reforming government rights system, the French government or its agencies own a significantly greater share of academic patents (at 24.8 percent) than in any of the other countries. Companies are also assigned a large share (61.4 percent) of French academic patents. The difference comes with French universities retaining title to very few (10.2 percent) of the inventions made at them. The pattern in Italy, a nominal employer rights system during this time period but without a viable technology transfer infrastructure, is quite similar to that in France, with the main exception being a smaller share assigned to the Italian Government (8.6 percent) and a greater share to Italian companies (72.0 percent). Individual Italian inventors also retained title to somewhat more (8.9 percent) relative to U.S. or French professors. In Sweden, under an intact inventor's (professor's privilege) system, still only a minority of patents were assigned to professors (13.5 percent). Rather the lion share of Swedish academic patents was assigned to companies (81.1 percent). Very few were assigned to Swedish universities (4.9 percent) and virtually none to the Swedish government (0.5 percent). [39]

The rates of patenting by academic inventors in all four countries were roughly comparable in this time period (academic accounting for between 4 and 6 percent of all patents issued by their respective patent offices). The real distinction in the results between the strong university assignment standards implemented under Bayh-Dole in the U.S. and all three of the European countries turns out to be between ownership ending up with the university (and thus subsequent conveyance of rights to industry by means of licensing) or ownership ending up within industry. Despite the extensive deliberations about government rights and professor's privileges, few patents were in fact assigned to these two parties. The two primary default options for IP title allocation, under any system in practice, it appears are either the university itself or a private sector company.

[38] Lissoni (2007) *supra*, note 14.

[39] All shares reported in Lissoni (2007), *id.*