THE NATIONAL ACADEMIES

MEETING SUMMARY

OWNERSHIP AND SHARING

SETTING THE PATENT FRAMEWORK FOR INNOVATION IN SYNTHETIC BIOLOGY

Committee on Science, Technology, and Law
July 15-16, 2013

INTRODUCTION

On June 13, 2013, in a much anticipated decision, the U.S. Supreme Court issued a unanimous opinion in *Association for Molecular Pathology v. Myriad Genetics.* Ending a 30 year practice of issuing patents on human genes, the Court ruled that, as a "product of nature," naturally occurring DNA segments (and the information encoded within that DNA) are patent ineligible. The Court stated, however, that while isolated naturally occurring DNA is *not* patentable, *synthetically* created complementary DNA (cDNA) *is* patent eligible, as it is not naturally occurring.[1]

The *Myriad* decision fortuitously coincided with a London workshop organized by the U.S. National Academy of Sciences' Committee on Science, Technology, and Law's (CSTL) Forum on Synthetic Biology and Imperial College London. The July 15-16 event, entitled *Ownership and Sharing: Setting the Patent Framework for Innovation in Synthetic Biology*, was organized with support from the Alfred P. Sloan Foundation and the British Consulate-General San Francisco. The workshop was convened to explore ownership and barriers to sharing that might retard innovation in synthetic biology – a key issue identified during previous meetings with the academies of sciences and engineering of the United Kingdom, China, and the United States.[2]

[1] The Court qualified this view with the following "…except insofar as very short series of DNA may have no intervening introns to remove when creating cDNA."

[2] See http://sites.nationalacademies.org/PGA/stl/Synthetic_Biology/index.htm.

THE BIOECONOMY AND THE EMERGENCE OF SYNTHETIC BIOLOGY

The workshop began with a discussion of the bioeconomy and the role that synthetic biology might play in offering scientific and technological solutions to the range of environmental, social, and economic challenges that society will face as world demand for food, materials, medicine, water, and energy increases. Biotechnology, **Robert Wells** [formerly Organisation for Economic Co-operation and Development (OECD)] observed, is expected to supply materials to meet these demands. Recent OECD discussions about the bioeconomy,[3] Wells said, have included discussions about synthetic biology, as both are often linked when member countries envision a future where manufacturing and economic growth are decoupled from greenhouse gas emissions. Wells identified several areas where OECD delegates see the greatest opportunities for short to medium term success in synthetic biology. These include energy security, climate change, industrial biotechnology (bio-based products and biofuels), environmental biotechnology and green growth, and marine biotechnology.

[3] The bioeconomy will likely involve: 1) the use of advanced knowledge of genes and complex cell processes to develop new processes and products; 2) the use of renewable biomass and efficient bioprocesses to support sustainable production, and 3) the integration of biotechnology knowledge and applications across sectors. See http://www.oecd.org/futures/long-termtechnologicalsocietalchallenges/thebioeconomyto2030designingapolicyagenda.htm

Wells encouraged participants to consider OECD guidelines for licensing inventions[4] as a model that recognizes the importance of invention and the rights of the inventor but moves away from an "own and protect" to a "protect and share" model.

Rob Carlson (Biodesic LLC) discussed the difficulty that exists in trying to quantify the U.S. bioeconomy, noting that current assessments do not capture the full range of biotechnology activities. Nonetheless, Carlson estimates that biotechnology from three sectors – pharmaceuticals, crops, and industrial products – accounts for about 2% of the U.S. economy. He valued the bioeconomy in 2010 at $300B.[5]

Carlson stated that the goal of synthetic biology is to create predictive models of real biological systems. He offered a vision of the future wherein it is possible to synthesize cells capable of producing other cells and the structures that cells make (e.g. proteins or organs from stem cells). Carlson contrasted the performance trajectory of enabling biotechnology tools and approaches relevant to recombinant DNA technology to the trajectory of synthetic biology techniques. The latter, he said, is on a trajectory that far outstrips that of the former. Carlson noted that various enabling technologies (i.e., DNA synthesis and sequencing) are improving rapidly while their cost continuously decreases.

Carlson observed that the current state of production of biologically synthesized biofuels is akin to the microbrewery industry where: 1) there is "low or no barrier to entry and small-scale, distributed biological production can emerge and compete against an installed large-scale infrastructure base"; and 2) "small producers can command a premium in a commodity marketplace, i.e. can receive a *disproportionate share of revenues*." Carlson noted that progress is increasingly driven by innovation and open access to the knowledge, tools, and materials needed to advance individual initiatives.

How Synthetic Biology Differs from Genetic Engineering and Biotechnology

Drew Endy (Stanford University and The BioBricks Foundation) discussed how synthetic biology differs from genetic engineering and biotechnology. Endy referred to the 2003 DARPA Synthetic Biology Study wherein he and his fellow authors were asked "to specify enabling technologies that, if developed, would provide a general foundation for the engineering of biology and make routine the creation of synthetic biological systems that behave as predicted."[6] The report concluded that specific process improvements in the design-build-test cycle should be pursued.[7] Endy's subsequent remarks focused on the importance of 1) DNA synthesis; 2) the development of standards; and 3) the role that abstraction plays in managing complexity. Endy noted that the ability to design and sequence DNA and transmit the sequence for synthesis is tremendously important, as it allows for high value distributed manufacturing of biological materials. Endy explained that standards allow for the coordination of work among parties and will enable, over time, more rapid progress than would otherwise be possible.[8] Endy observed that the idea of biological standards is controversial because there is tremendous context sensitivity within biology. He stated that the notion that it is not possible to achieve standardization in biology is being disproved.[9] Endy then discussed abstraction and the idea that, conceptually, a designer of a biological system would not need to know much about the mechanics of a particular biological component within a system in order to design a system. Endy observed that the tools of genetic engineering are recombinant DNA, polymerase chain reaction, and DNA sequencing but that the tools of synthetic biology include synthesis, abstraction, and standardization. For Endy, synthetic biology represents an encapsulation of discrete changes in the approach to biology.

[4] See http://www.oecd.org/sti/biotech/36198812.pdf.

[5] $110B from genetically modified crops, $75B from biologics, and $115B from industrial products.

[6] See Endy, Drew, 2007. "Synthetic Biology Study." Online at http://dspace.mit.edu/handle/1721.1/38455, accessed October 2, 2013.

[7] Ibid. In particular, "(i) component standardization, (ii) substrate and component abstraction, and (iii) design and fabrication decoupling."

[8] Endy noted that there are four areas of technical standards in development: 1) physical layout of molecules; 2) functional composition; 3) metrology inside cells (measurement and reference materials); and 4) representation (e.g. how something is transmitted pictorially, etc.).

[9] See, for example: "Precise and reliable gene expression via standard transcription and translation initiation elements" by Mutalik et al. (2013, PMID: 23474465) recently reported how to make standard parts, including for prokaryotic ribosome binding sites, a type of part that had been a particularly challenging to make reliably reusable; "Rewritable digital data storage in live cells via engineered control of recombination directionality" by Bonnet et al. (2012, PMID 22615351) detailed challenges associated with traditional engineering approaches; e.g., 750 attempts to get one bit of rewritable genetic data storage. However, following Bonnet et al. 2012, there was successful abstraction of analog-to-digital genetic switches that, when combined with reusable parts from Mutalik et al., allowed Bonnet et al. 2013 ("Amplifying genetic logic gates", PMID: 23539178) to design DNA that, using pre-existing abstracted devices and reusable parts, worked the first time.

THE PATENT LANDSCAPE AND RECENT U.S. SUPREME COURT DECISIONS

Daniel J. Kevles (Yale University) suggested that the *Myriad* case may be indicative of a sea change in biomedical patenting. He argued that the range of plaintiffs in the case signals that stakeholders outside the biotechnology industry and the patent bar – scientists, patients, physicians, and health advocates – expect and would act to achieve standing in decisions concerning control of DNA. Kevles stated that the Court's opinion placed unmodified genomic DNA in the same category as the naturally occurring elements – unpatentable products of nature which had been discovered nevertheless and had been used to create innumerable patented inventions. Kevles said that the Supreme Court rejected the United States Patent and Trademark Office's interpretation of U.S. patent law as permitting DNA patenting, emphasizing that natural laws and substances must be freely available to everyone and reserved to no one.

Kevles believes that, when synthetic biology products appear on a large scale, the scope of the community of stakeholders (given the social, economic, and ethical ramifications in areas such as agriculture, energy, medicine, and the environment) suggests that property right claims might not prevail in any absolute sense over all other claims.

Following Kevles' presentation, **Jane Calvert** (University of Edinburgh) and **Nikolas Rose** (King's College London) reflected upon his comments. Dr. Calvert structured her remarks around three areas: 1) the chemical-informational duality of genes; 2) the inclusion of a broader range of social groups in the patent process; and 3) the types of arguments that were mobilized against Myriad's patents. Calvert said that how we think of genes – i.e., as chemicals or as pieces of information – leads to different conclusions about ownership. With regard to the inclusion of a broader range of social groups, Calvert suggested that by focusing on the informational rather than the chemical, the discussion becomes less technical and therefore accessible to a broader group of stakeholders. With regard to arguments raised against Myriad, Calvert suggested that there are two perspectives at work: 1) the notion that intellectual property regimes must be encouraging of innovation and protective of innovators, and 2) the idea of values – that natural substances should be in the public domain. Rose observed that the law in action, in books, and as formulated in legal judgments is infused with social, moral, political and economic beliefs. He noted that patents are not always enforced even in jurisdictions where they are obtained and that restrictions on access don't work once knowledge is in the public domain. A participant asked when, in the interest of advancing innovation, should information be controlled and when should it be freely available: what is the best scenario for advancing innovation? Another participant asked how judgments/decisions made now will affect the practice/processes of engineering biology in the future. If basic processes are patented, it was asked, how will this affect the intellectual landscape? How, it was asked, might conflicts between differing intellectual property frameworks be resolved? Carlson noted that industrial biotechnology is already fast and inexpensive and that there is economic pressure to invest in biotechnology around the world. By focusing on patents, Carlson suggested, the United States may drive innovation elsewhere.

Rochelle Cooper Dreyfuss (New York University School of Law and Engelberg Center on Innovation Law and Policy) discussed the implications of the *Myriad* ruling for synthetic biology and whether the fundamental building blocks of synthetic biology could be retained in a shared public domain or whether they would be subject to patenting and the attendant possibilities of fragmented ownership rights, high transaction costs, and high monetary rewards. Dreyfuss noted that, Justice Clarence Thomas, in his majority opinion, stated that products of nature are not patentable while "synthetic creations" are patent-eligible. As all products of synthetic biology are synthetic, they would thus be subject to patenting. Dreyfuss noted, however, that the *Myriad* opinion hid many complexities. The Court suggested that sequences that mirror nature are not patentable, she said, even if synthesized. She asked whether there are synthetic biology products that should similarly be regarded as non-patentable. Further, she asked whether the distinction between "natural" and "synthetic" is sufficient to safeguard competitive development of broad scientific prospects. She noted that, in dissenting from a decision by the Supreme Court to refrain from reviewing *Lab Corp. v. Metabolite*, Justice Stephen Breyer wrote, "Sometimes patent protection can impede rather than promote the progress of science and useful arts." In a separate case, *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, the Court noted that, when steps in processes "involve well-understood, routine, conventional activity previously engaged in by researchers in the field… upholding…patents would risk disproportionately tying up the use of the underlying natural laws, inhibiting their use in the making of further discoveries." Dreyfuss asked whether creating DNA is "a well-understood, routine, conventional way to work with sequences" and if so, would that mean

that *Myriad* overrules *Mayo*? She asked about the implications of these cases for synthetic biology, raising three questions: 1) What is protectable? 2) What are the limits on infringement (freedom to operate)? and 3) What are the self-help possibilities? With regard to what is protectable, she suggested that new molecules with specific end-uses, building blocks/parts/systems, research tools, assembly techniques, and design and evaluation techniques might all be subject to patents. With regards to limits on infringement, she suggested that exceptions to infringement liability might be granted for research, diagnostics, and interoperability. She noted that freedom-to-operate problems might be mitigated through the assignment of compulsory licenses, limitations on patent scope, the institution of special rules for blocking patents, and subjecting entities to antitrust (competition law) scrutiny. In terms of self-help possibilities for the synthetic biology community, she suggested that the building blocks of synthetic biology might be put into the public domain, patented and then licensed or pooled with conditions, placed in a database (information commons), or licensed with restrictions.

R. Alta Charo (University of Wisconsin – Madison) opened discussion by asking "How much of the issue is about property rights and how much of the issue is about hostility to corporate or business interests converging with property rights?" Kevles suggested that social resistance will arise from the consequences of what is invented, who controls it, and what impact the control has on various segments of society. Patents are required in order to obtain investment, but access to patents is necessary in order to develop a product. Kevles suggested that exclusivity may make sense in the developmental stage but may decrease in significance based on the importance of the product and how essential it is to other considerations.

Dreyfuss suggested that the function of *Myriad* and related cases was to test the question of whether there are things that belong in the public domain, i.e. accessible to all researchers or diagnosticians. Dreyfuss expressed the opinion that if there were a research exemption in the United States, many of the property rights issues would go away. Discussion moved to the idea of a "research on" vs. a "research with" exemption – research into a patented subject matter (investigating/improving/ validating it) or using something that is patented as a tool for some other purpose. Dreyfuss expressed the opinion that the *Myriad* decision opened the way for discussions on strengthening patent rights on the condition that research exemptions would be recognized. She expressed a hope that the decision would lead to more thoughtful discussions about the merits of putting materials into the public domain.

IP AND OWNERSHIP OF SYNTHETIC BIOLOGY

Linda Kahl [Synthetic Biology Engineering Resource Center (SynBERC)] noted that making biology easier to engineer exacerbates tensions within current property rights frameworks. She identified three concepts important to the consideration of IP issues in synthetic biology: Abstraction, Decoupling, and Standardization. She noted four discrete compositional elements that contribute to the formation of a synthetic biology product: DNA, parts, devices, and systems. The technical advantage of *abstraction* is that a researcher could engineer a tumor destroying bacterium without needing to know that DNA is composed of four base pairs. Kahl noted that registries of "standard" biological parts are under development, but that the commercial use of parts registries is hindered by freedom-to operate (FTO) expenses.[10] Kahl stated that costs associated with royalty stacking can make it difficult if not impossible to bring products to market. Kahl then described *decoupling*: separating design from fabrication. She noted that the technical advantage of decoupling DNA sequence design from DNA synthesis exponentially increases the rate at which DNA molecules are produced and tested but noted that, in synthesizing DNA, companies may unknowingly infringe patents. Kahl noted that *standardization* allows for the coordination of labor over space and time. She said that standardization leads to geometric increases in the quantity of biological parts being produced, distributed, and re-used. She stated that technical standards are under development in the areas of physical composition, functional composition, units of measure, and data exchange. Kahl observed that some technical standards might be subject to background patents and that the costs associated with doing an examination of the relevant patent landscape may be immense.[11] Even when a standard is widely adopted, she said, patent "hold-ups" may occur without an agreement to license under Fair/Reasonable and Nondiscriminatory (F/RAND) terms. Without F/RAND, patent owners could charge disproportionate, exorbitant fees.

Kahl concluded her remarks by offering a vision of the future where researchers have access to a collection of genetically encoded functions that they are free to use and compose without: 1) fear of liability for property rights infringement;

[10] In an example, Kahl provided an FTO figure of $58K - $8K for a patent search and $50K for a FTO opinion

[11] As an example, Kahl provided the case of indirect measure of promoter activity using Green Fluorescent Protein (GFP). She noted that uses of GFP are patent protected and that hundreds of patents covering variants of GFP have been issued in the U.S. and Europe.

2) encumbrances limiting novel constructive uses; and 3) overwhelming transaction costs associated with use.

APPROACHES TO ACCESS, TRANSFERS, USE, AND LIABILITY

Joanne Kamens (Addgene), described Addgene, a non-profit, mission-driven plasmid repository that archives and distributes plasmids to researchers. Researchers deposit plasmids with Addgene for free. The key to Addgene's success, Kamens said, is the company's innovative electronic material transfer agreement (eMTA), which is based upon the National Institutes of Health's Uniform Biological Material Transfer Agreement (UBMTA). While ancillary agreements are used for special cases, Kamens said that there is no blue penciling: the Addgene MTA is used as is. She noted that scientists have shown broad support for the Addgene model and that the number of scientists who work with Addgene is increasing both nationally and internationally.

Reshma Shetty (Gingko Bioworks, Inc.) discussed intellectual property from the perspective of Gingko Bioworks, Inc.; a small company that makes and sells engineered organisms primarily to customers who are interested in using fermentation processes in lieu of traditional chemically-based manufacturing methods. Shetty observed that patents are especially important to small companies because patent portfolios are a key component of their corporate valuation. From Shetty's perspective, patents are valuable for two types of intellectual property; those protecting engineering processes and those protecting rights over physical organisms. As a seller of organisms, the most valuable patents for Gingko Bioworks are those that relate to the organisms themselves. For Shetty, it is critical that biological parts that perform essential functions (e.g. regulatory functions, facilitation of the production of enzymes, metabolism) are available in the public domain.

Randy Rettberg (iGEM Foundation) described the International Genetically Engineered Machine (iGEM) competition wherein undergraduate student teams are given a kit of biological parts from the Registry of Standard Biological Parts. Teams use these parts and new parts of their own design to build biological systems and operate them in living cells. According to Rettberg, the competition is successful due to open access to the biological parts and the team dynamic – the later educating students to view research as a collaborative endeavor and instilling a culture of responsibility. Rettberg views patents as a threat to the success of iGEM.[12] With regard to biological parts, he said universities behave as if there is a research exemption that protects open experimentation.

Dr. Endy discussed the BioBrick Public Agreement (BPA). In formulating the BPA, Endy noted that the BioBricks Foundation looked at many types of intellectual property protection schemes but determined that none were suitable for biological parts. Endy stated that the BPA is a two-party agreement between a parts contributor and a parts user (the BioBricks Foundation is not a participant in the agreement) – a collection of promises. The contributor makes an irrevocable promise not to assert property rights or threaten to assert property rights. Endy noted that misrepresentations are possible with the BPA if, for example, a parts contributor misrepresents that he is the sole owner of a part when, in fact, the part is subject to others' property rights. Further, when a user executes the agreement, it is unclear if he is free to pass usage rights onto a third party. Endy stated that there is a desire to have parts flow to commercial as well as academic laboratories but that there is a high transaction cost for commercial users. Endy offered Stanford University's patent policy as a good model. The policy allows inventors to put their inventions in the public domain: "Inventors … are free to place their inventions in the public domain if they believe that would be in the best interest of technology transfer and if doing so is not in violation of the terms of any agreements that supported or related to the work."[13]

Trevor Cook (Bird & Bird LLP) extended the scope of Endy's presentation by raising questions about the concept of "IP free" and third party rights. Cook expressed interest in a database wherein information on parties with intellectual property interests in the parts contributed under the BioBrick Public Agreement could be collected and tied to the collection. Otherwise, he said, parts users would be operating in an ecosystem that is ostensibly IP free but which might, in actuality, be very narrow in breadth because of property rights interests. Endy noted that, in some instances, contributors signing the BPA provide information that seeks to allay patent concerns but that the value of contributions lies in the quality of the contribution and the standing of the contributor with respect to property rights. At the frontline of research, Endy said, there is a feeling of being ahead of the state of the art and in a position to operate in an open IP space. The BPA, he said, is an appropriate way to move materials into

[12] The parts in the Registry of Standard Biological Parts are not patented.

[13] See http://doresearch.stanford.edu/policies/research-policy-handbook/intellectual-property/inventions-patents-and-licensing.

the public domain in support of translational research. The environment is different in industry. Companies use patents to protect and advance their business. It was observed that universities aren't often pursued for IP infringements because the economic value of the research does not justify the cost of litigation. **Paul Freemont** (Imperial College London) concluded the session by asking how a young researcher should approach IP issues in light of the various approaches discussed.

Discussion and Issues Raised:

Richard I. Kitney (Imperial College London) moderated a discussion on ways to protect the intellectual property rights associated with vital component parts and processes while simultaneously allowing the field to flourish. Discussion focused on: 1) bridging the "Valley of Death" to achieve a translation of research into economically viable products; 2) questions of a proper business model for synthetic biology; and 3) the need for best practices in sharing and ownership. Much discussion related to the questions of: 1) what makes synthetic biology different from other disciplines? and 2) does synthetic biology require different types of property protections than those currently available? It was suggested that, because practitioners sense that the field of synthetic biology is in such an early stage of development, there is a need to establish a pre-competitive space to prevent the stifling of innovation. It was argued that, in the case of synthetic biology – a collaborative discipline – there is a real need for open IP as many biological parts are useful in different applications.

OWNERSHIP AND INNOVATION: CASE STUDIES FROM INDUSTRY

Lionel Clarke (Shell Global Solutions) discussed a recent survey of the UK Synthetic Biology Special Interest Group. He observed that 15% of respondents indicated that IP issues were a factor that hindered progress in synthetic biology. Respondents also indicated that there was a need for an easier IP licensing process for university research. Clarke then discussed available routes to move an idea to market. He observed that, in the commercialization of an idea, many innovations and most investment occurs downstream, that costs and risks increase along the route to market, and that value is only captured upon delivery to market. Clarke considered how open source technologies factor into industrial R&D. He noted that advanced innovations might require partnerships between industry and academia and concluded that, in the case of synthetic biology, there is not a single industry but many industries and consequently, no single best point at which to switch from open to closed sourcing. He noted that there is often a disconnect between the point in time at which an original concept is conceived (and IP filed and rights acquired) and the point where most value is accumulated. He observed that in the case of a field that is developing rapidly, a potentially patentable idea or concept may lend itself towards a clearly defined output or to a range of outputs, many of which may not be recognized at the time of the original invention. The key, he suggested, is to avoid unintentionally obstructing future innovation.

Stephen Laderman (Agilent Laboratories) discussed freedom to operate (FTO) from the perspective of Agilent Technologies, a company that designs and manufactures electronic and bio-analytical instruments and equipment for measurement and evaluation. Laderman stated that Agilent won't/can't sell products without freedom to operate. He noted that factors to consider when moving a product forward include: the nature of the innovation, customer needs, infrastructure for commercialization, the intellectual property landscape (e.g. freedom to operate, blocking potential, licensing requirements, cross-license value), the competitive situation, and cost. He stated that, for Agilent, opportunities in synthetic biology exist in such areas as software platforms, measurement platforms, and synthesis platforms. Laderman noted that there are many reasons why the patent landscape is so complex, but highlighted patent thickets as a factor in the cost of bringing a product to market. He observed that, without freedom to operate, new products will not be made.

Discussion and Issues Raised:

Questions arose about intellectual property assertions in the case of synthetic biology parts registries and whether, as registries grow and more parts are incorporated, IP assertions on specific parts would increase or decrease. It was suggested that the issue is not about whether parts have been patented but the need for protections in material transfer and a need for a minimal material transfer agreement that protects researchers and intermediaries, for example. Lionel Clarke shared conclusions from a June 24-25, 2013 U.K. IP workshop: 1) although important, IP law should not be overhauled; 2) nomenclature remains a challenge since open source and open innovation are often imprecisely defined terms; 3) because synthetic biology seeks synergies among different cultures of scientific research and technology development, different attitudes towards IP and commercialization across different cultures need to be understood better before consiliences and conflicts can be

actively managed; 4) sharing contributes to scientific process but at some stage may deter investment needed for commercialization; and 5) introducing standards and regulations can either help or impede the growth of a field.

MOVING FORWARD: CREATING THE RIGHT OWNERSHIP/SHARING/ACCESS ENVIRONMENT FOR SYNTHETIC BIOLOGY

The workshop concluded with a discussion about what was needed, with regards to intellectual property, to move synthetic biology forward. Significant discussion centered on the need for a minimal/maximal MTA and the need to create momentum to use it. It was suggested that one of the biggest barriers to progress in synthetic biology relates to disagreement about what constitutes commercially reasonable terms and standards of transactions. It was suggested that the BioBrick Public Agreement (BPA) complements MTAs by facilitating translation space. It was suggested that there might be the need for some sort of hybrid arrangement, with, for example, aspects of patent and copyright protection. Discussion shifted to the culture of the synthetic biology enterprise and the notion of values. Who, it was asked, sees to it that biological parts are used responsibly? What happens once a material is transferred, e.g. who enforces controls on redistribution? Wells observed that synthetic biology was the first science to come about in an era of social networking. "What do we value," he asked, "as a global, decentralized community?"

Session moderators Linda Kahl, Drew Endy, and Richard I. Kitney noted that the flow of ideas out of the laboratory follows many paths including the education, training, and movement of highly-skilled students; industry-university collaborations; and faculty consulting. Kahl observed that the advancement of synthetic biology will not be linear, as progress is dependent on technology, the research community, and a legal structure to support both. Endy reiterated his belief that there is pressing need to create mechanisms to facilitate the sharing of materials – a type of agreement that supports the responsible flowing of parts beyond what the UBMTA can support. Kitney acknowledged that the destination we want to get to is not well-defined at the moment but that some type of roadmap would give the field something to work towards. All suggested that synthetic biology might benefit from more effective and efficient MTAs, the development of best practices, and the encouragement of shared values.

PLANNING COMMITTEE ON INTELLECTUAL PROPERTY AND OWNERSHIP ISSUES FOR SYNTHETIC BIOLOGY: A WORKSHOP: **Drew Endy** (Chair), Stanford University and The BioBricks Foundation; **Richard I. Kitney**, Imperial College London; **Linda Kahl**, Stanford University. **Staff: Anne-Marie Mazza**, Director, Committee on Science, Technology, and Law; **Steven Kendall**, Program Officer, Committee on Science, Technology, and Law.

PARTICIPANTS: Spencer Adler, SynBio Investors, LLC; Monica Alandete-Saez, PIPRA, University of California; Jacqueline Allan, Organisation for Economic Co-operation and Development; Fredrik Aslund, European Patent Office; James Brown, Biosciences KTN / UK Technology Strategy Board; Ken Browne, Technology Networks Ltd.; Ian Bryan, GE Healthcare; Jane Calvert, University of Edinburgh; Michel Cannieux, Integrated DNA Technologies; Rob Carlson,* Biodesic LLC; Vicki L. Chandler,* Gordon and Betty Moore Foundation; Mark Chadwick, DSM; R. Alta Charo,* University of Wisconsin – Madison; Kevin Clancy, Life Technologies; Lionel Clarke, Shell Global Solutions; Trevor Cook, Bird & Bird LLP; Shona Cunningham, University of Edinburgh; Luke Davis, Engineering and Physical Sciences Research Council; Helen Disney, Pugatch Consilium; Rochelle Cooper Dreyfuss; Tom Ellis, Imperial College London; Drew Endy,* Stanford University and The BioBricks Foundation; Antony Evans, Growing Plant; Tim Fell, Synthace; James Field, Imperial College London; Ian Fotheringham, Ingenza Ltd.; Paul Freemont, Imperial College London; David Friedman, National Council for Reaserch and Development; William Graham, Monsanto; Richard A. Johnson,* GlobalHelix LLC; Linda Kahl, Stanford University; Joanne Kamens, Addgene; Daniel J. Kevles, Yale University; Greg Kisor, Intellectual Ventures; Richard I. Kitney, Imperial College London; Todd Kuiken, Woodrow Wilson International Center for Scholars; Stephen Laderman, Agilent Laboratories; Sarah Lau, Kilburn & Strode LLP; Fred Ledley, Bentley University; Oskar Liivak, Cornell University Law School; Oscar Lizarazo, Universidad Nacional de Colombia; Neil MacDonald, Federal Technology Watch; Claire Marris,* King's College London; Shane McHugh, Royal Academy of Engineering; Lisa Melton, Nature Biotechnology; Ana Palacios, Pugatch Consilium; Megan Palmer, SynBERC/ University of California, Berkeley; Sungshic Park, Newcastle University; Jim Philp, Organisation for Economic Co-operation and Development; Randy Rettberg, iGEM Foundation; Avi Robinson-Mosher, Harvard Medical School; Nikolas Rose, King's College London; Ben Sheridan, BSI; Reshma Shetty, Gingko Bioworks, Inc.; Christina Smolke, Stanford University; John Spiers, London Metropolitan University; Guy-Bart Stan, Imperial College London; Joyce Tait, University of Edinburgh; Siva Thambisetty, London School of Economics; Sean Ward, Synthace; Robert Wells, General Electric; Jon Wilkinson, Imperial Innovations; Emma Woods, The Royal Society.

*Member of the U.S. National Academy of Sciences' Forum on Synthetic Biology

ABOUT CSTL

The National Academy of Sciences established the Committee on Science, Technology, and Law (CSTL) in 1998 to examine the growing number of areas where science, engineering, and law intersect in this era of increasing globalization. It is the leading national committee that brings leading figures in science, engineering, and medicine together with members of the legal and policy communities for discussions about critical issues of mutual interest and concern. Through its reports and activities, CSTL brings widespread attention to issues of pressing national and international concern. The committee considers challenging issues at the nexus of science and law from three perspectives: 1) *law in the laboratory* - the law's influence on the practice of scientific, engineering and health research; 2) *science in the courts* - the role of scientists and engineers in the legal arena and the use of scientific research by the legal community; and 3) *public policy formation*, including looking at the uses and misuses of science in shaping public policy at the confluence of the scientific, engineering, medical, and legal arenas.

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