BioBricks FOUNDATION

How Synthetic Biology Challenges Current Patenting/Ownership Frameworks

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Ownership & Sharing Workshop
Imperial College London
July15, 2013

TM

Make biology easier to engineer.


Make biology easier to engineer.


Make property rights easier to navigate.


ABSTRACTION
DECOUPLING
STANDARDIZATION

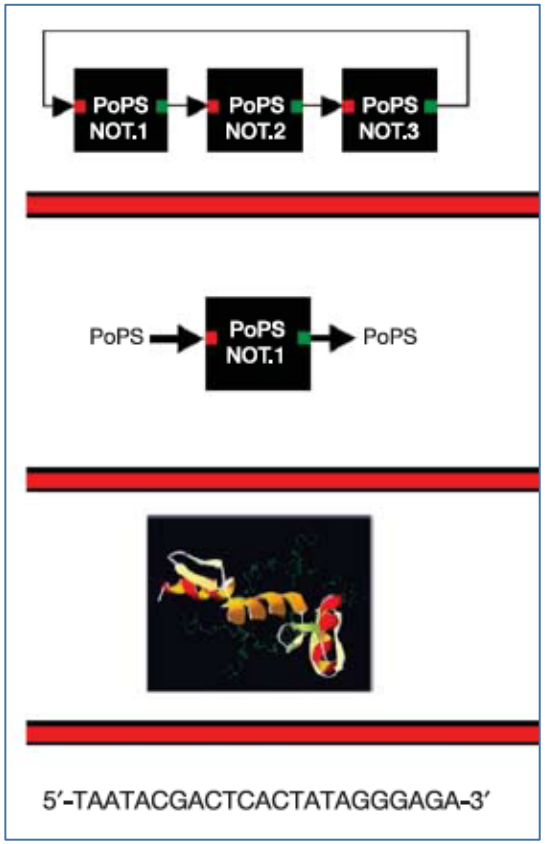
ABSTRACTION
a tool for managing complexity

SYSTEM

DEVICE

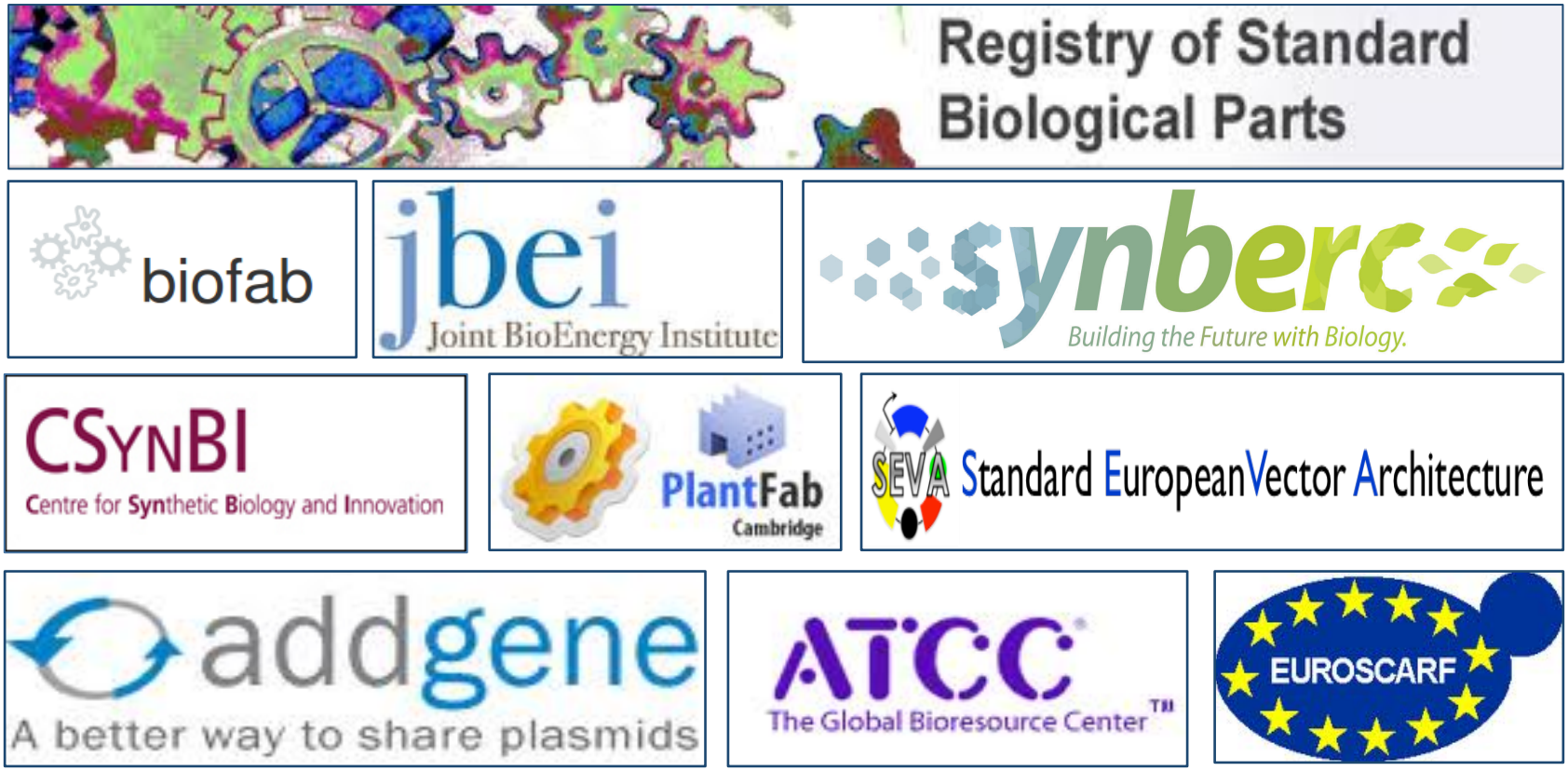
PART

DNA



Technical Advantage: A system engineer could program a tumor destroying bacterium without needing to know that DNA is comprised of four bases.

Public registries of biological parts are important for synthetic biology research



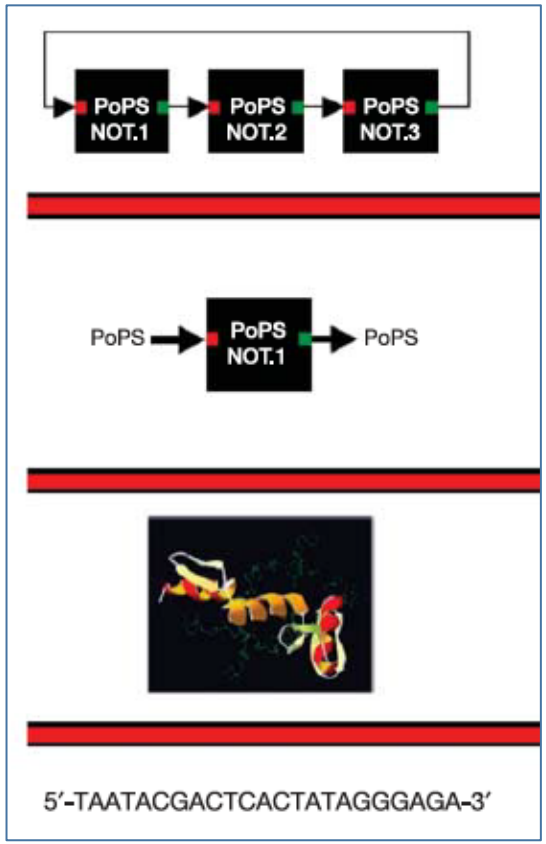
Establishing Freedom-to-Operate for biological parts is expensive

	Green Fluorescent Protein	Yellow Fluorescent Protein
A search for all U.S. patents that include "green" and "fluorescent" and "protein" (appropriately truncated) in the same claim	~1000 hits	~1000 hits

$8,000 = cost for this information

>$50,000 = cost for FTO opinion

Royalty stacking can make it difficult/impossible to bring products to market



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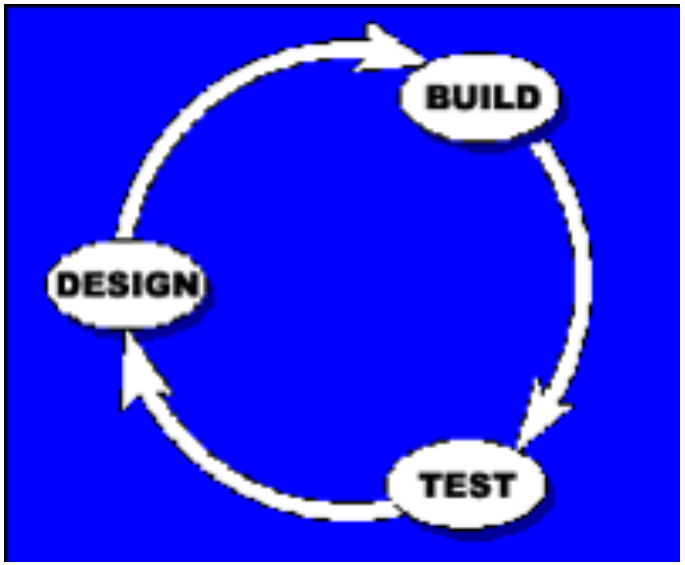
DECOUPLING
separate design from fabrication

Computer aided-design of DNA sequences



Synthesis and assembly of DNA molecules

Functional test of DNA in living systems

Technical Advantage: Decoupling DNA sequence design from DNA synthesis exponentially increases the rate at which DNA molecules are produced & tested.

Decoupling DNA sequence design from DNA synthesis alters market dynamics

Computer-Aided Design (CAD) of DNA sequences

geneious

GeneDesigner

GenoCAD

MathWorks

RBS Calculator v1.1
tunable control of the translation initiation rate

j5

GENOME COMPILER

DNA synthesis and assembly

BlueHeron
The Gene Synthesis Company

Desktop Genetics

DNA 2.0

IDT
INTEGRATED DNA TECHNOLOGIES

GenScript

Gen9

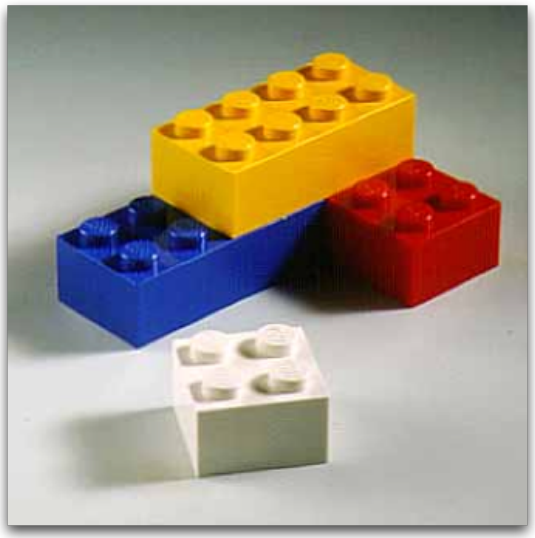
GENABLER

DNA synthesis companies may unknowingly infringe patents

35 U.S.C. 271 Infringement of patent

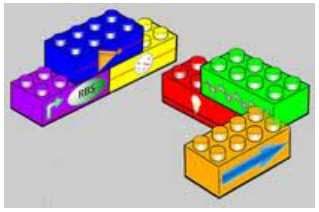
…whoever without authority makes, uses, offers to sell, or sells any patented invention...

STANDARDIZATION
coordination of labor over time & space



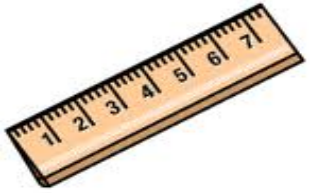
Technical Advantage: Standardization leads to geometric increases in the quantity of biological parts being produced, distributed, and reused.

Technical standards for synthetic biology are under development

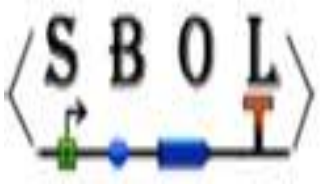


PHYSICAL COMPOSITION
BioBricks assembly, BglBricks assembly, etc.

FUNCTIONAL COMPOSITION
Expression Operating Unit (EOU)



UNITS OF MEASURE
Relative Promoter Unit (RPU)



DATA EXCHANGE
SBOL, DICOM-SB, JBEI

Technical standards may be covered by background patents

Request for Comment (RFC) process

BBF RFC 19: Relative measure of promoter activity

- BBa_J23101 – *in vivo* reference promoter
- indirect measure using Green Fluorescent Protein (GFP)

Uses of GFP are patent-protected

US Patent 5,491,084
Inventors: Martin Chalfie & Douglas Prasher
Filed: September 10, 1993

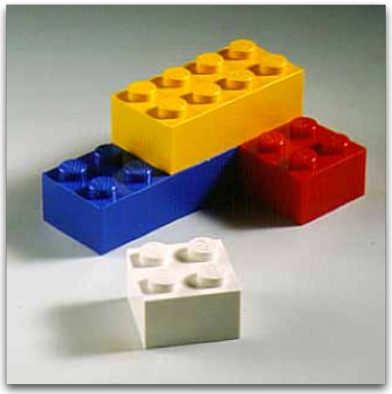
What is claimed is:

1. A host cell comprising a DNA molecule having a regulatory element from a gene, other than a gene encoding an *Aequorea victoria* green-fluorescent protein operatively linked to a DNA sequence encoding the fluorescent *Aequorea victoria* green-fluorescent protein.

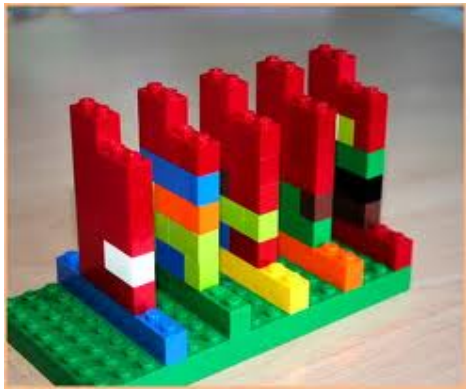
2. A cell of claim **1**, wherein the cell is selected from a group consisting of bacterial cell, yeast cell, fungal cell, plant cell or animal cell.

3. A cell of claim **1**, wherein the regulatory element is a promoter.

Once a standard is widely adopted, patent "hold-up" may occur



Standard



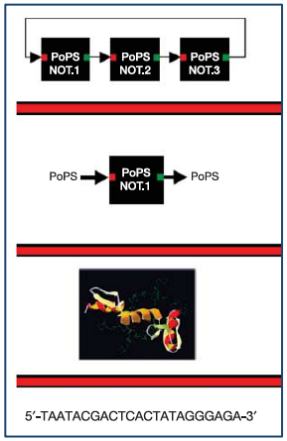
Pre-competitive innovation

Commercial product

Without agreement to license under F/RAND terms (Fair/Reasonable And Nondiscriminatory), patent owners could charge disproportionate, exorbitant fees.

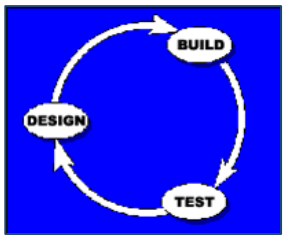
Engineering biology exacerbates tensions within the existing property rights framework.

ABSTRACTION



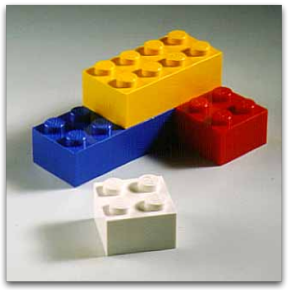
Freedom-to-Operate
Royalty Stacking

DECOUPLING

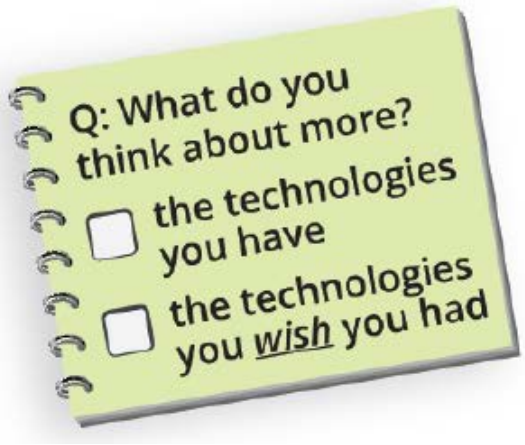


Patent Infringement
by intermediaries

STANDARDIZATION



Patent Hold-up



SB6 State-of-The-Art Survey

Defining the enabling technologies of synthetic biology

www.biobricks.org/survey

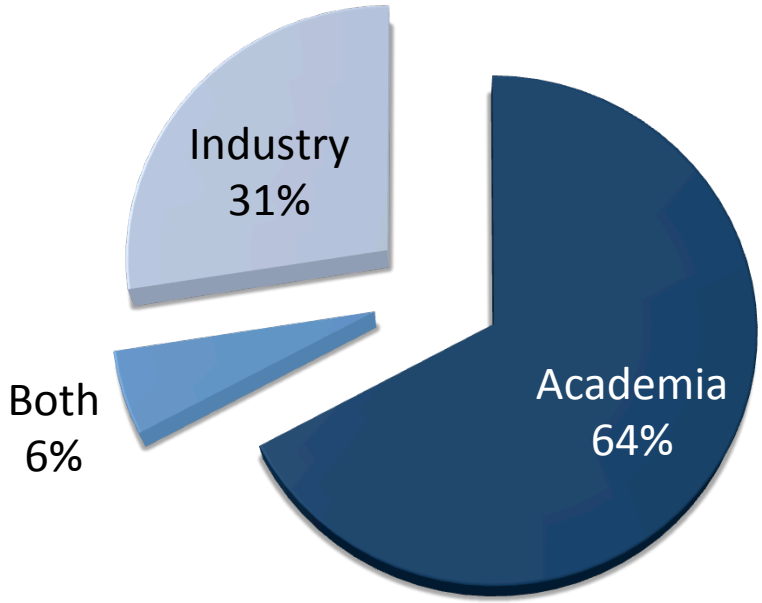
BioBricks FOUNDATION

synberc
Building the Future with Biology.

Linda Kahl and Drew Endy
J Biol Eng 2013; 7:13.
Linda@biobricks.org

A Survey of Enabling Technologies in Synthetic Biology

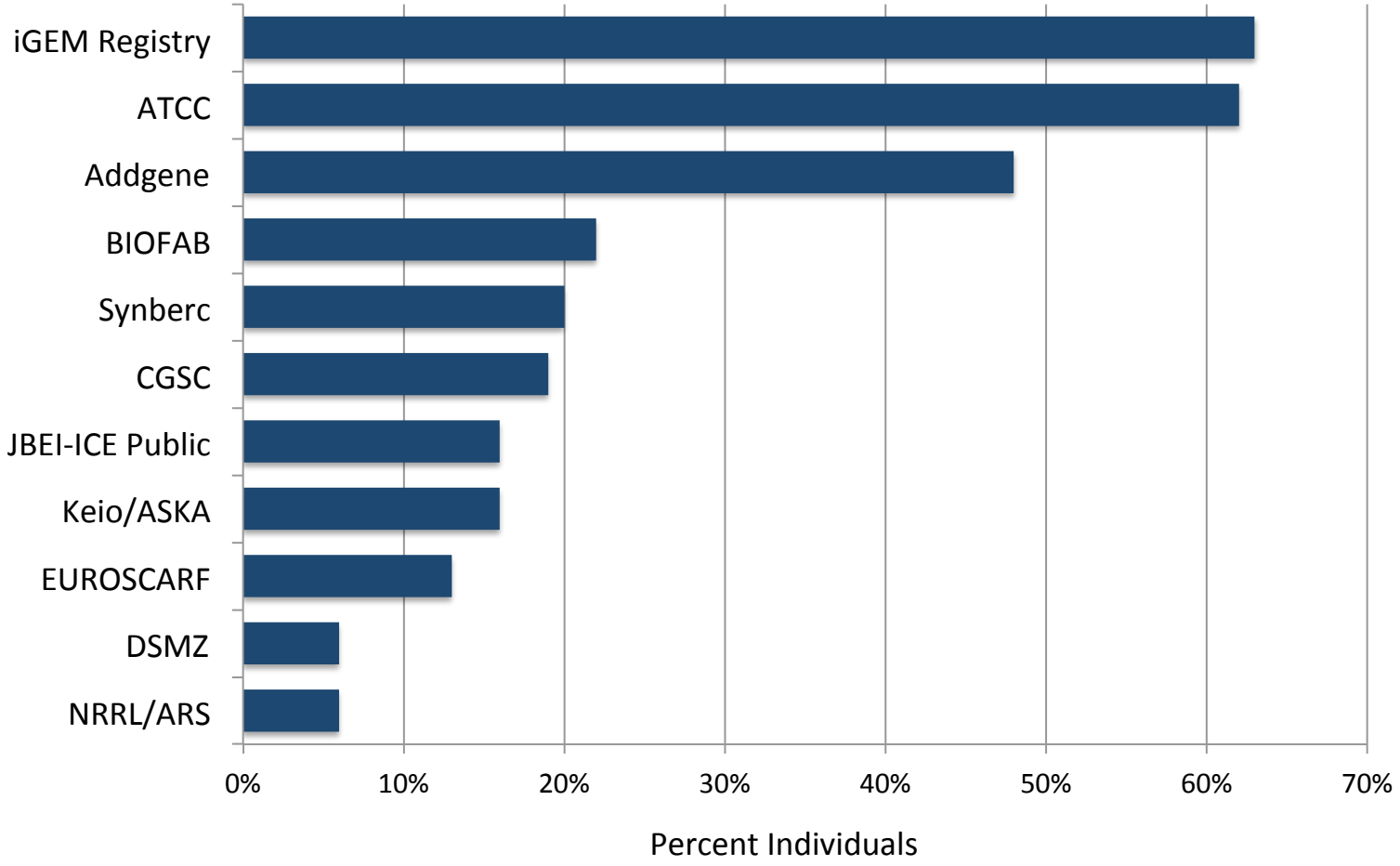
Responses collected from self-identified synthetic biologists



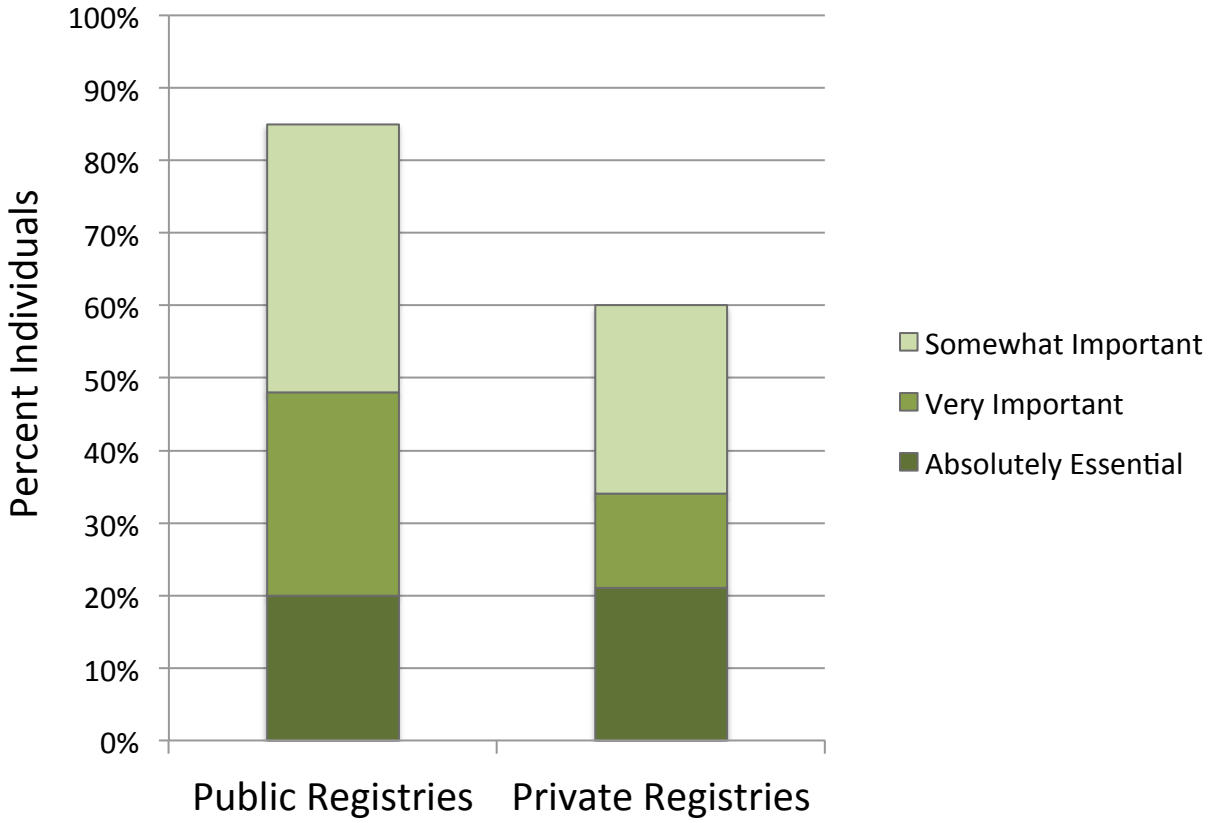
162 so far… (results from 120)

- Australia (3)
- Belgium (2)
- Brazil (2)
- Canada (6)
- China (2)
- France (5)
- Germany (10)
- Hungary (1)
- India (6)
- Israel (1),
- Italy (1)
- Japan (3)
- Malaysia (1)
- Mexico (4)
- Netherlands (3)
- New Zealand (3)
- Norway (1)
- Poland (1)
- Russian Federation (2)
- Singapore (1)
- Spain (4)
- Switzerland (3)
- Taiwan (1)
- Ukraine (1)
- United Kingdom (17)
- United States (77)
- Uzbekistan (1)

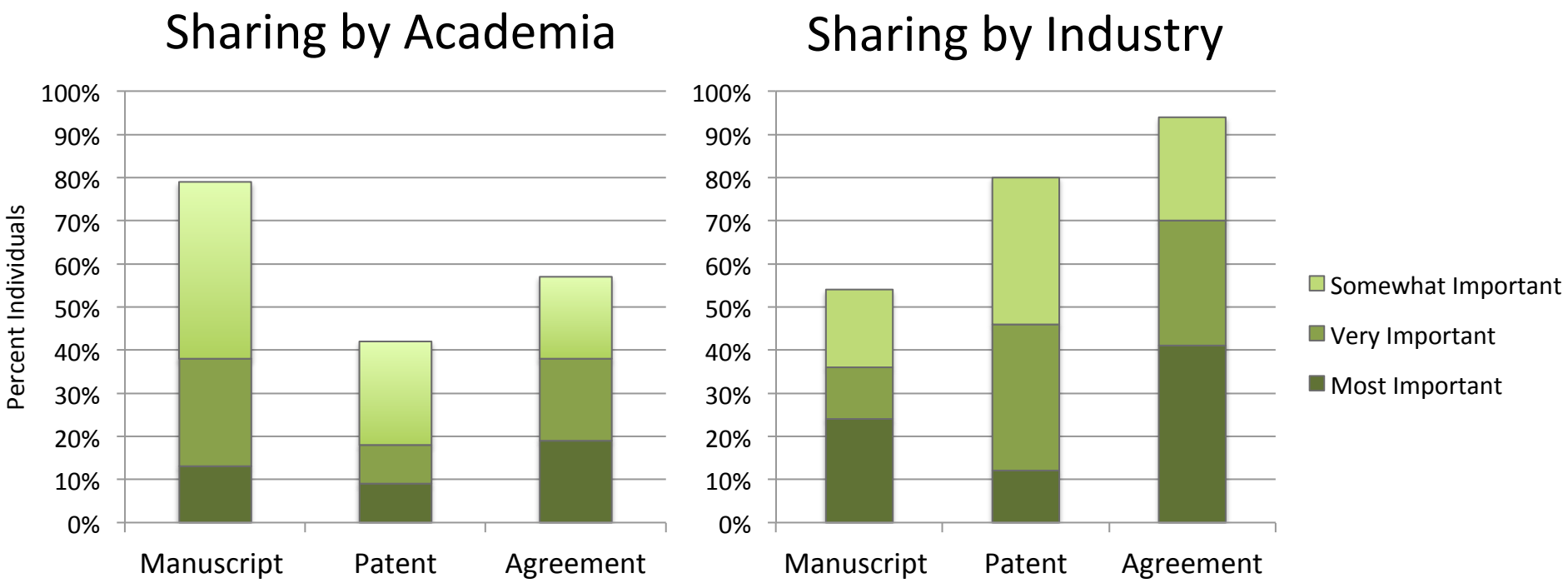
Use of Public Registries



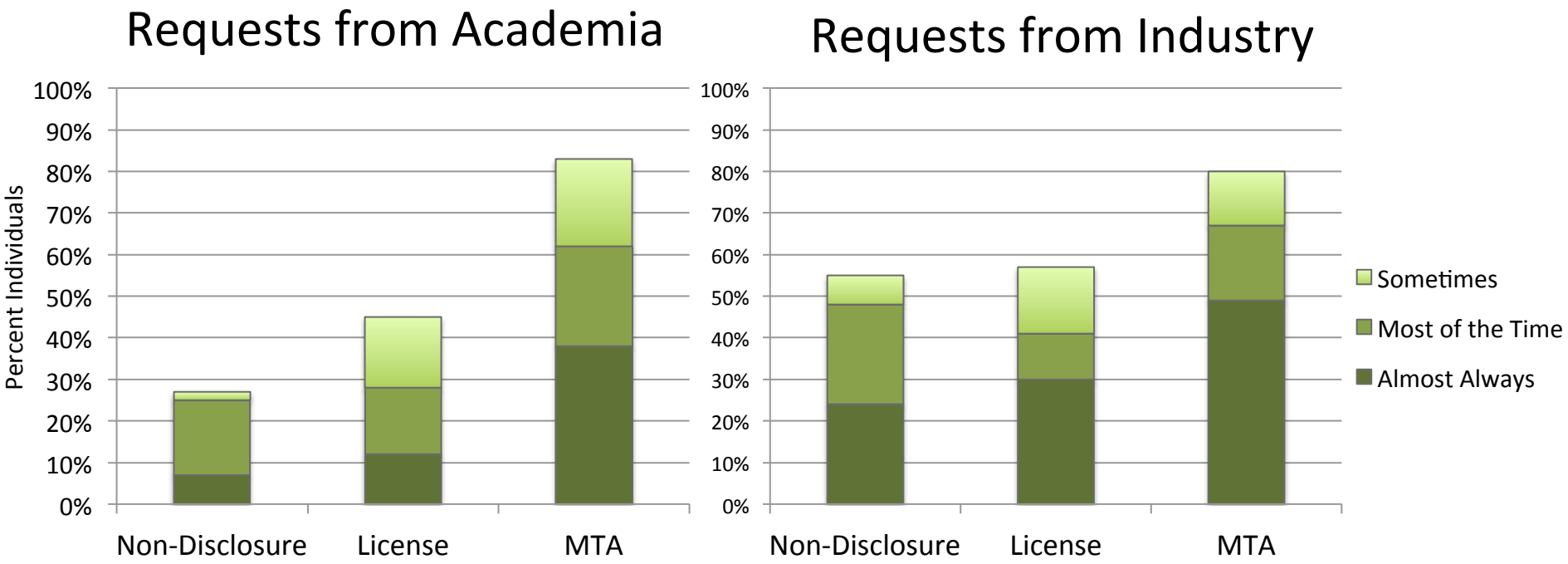
Registries of Biological Parts are Important for Synthetic Biology Research



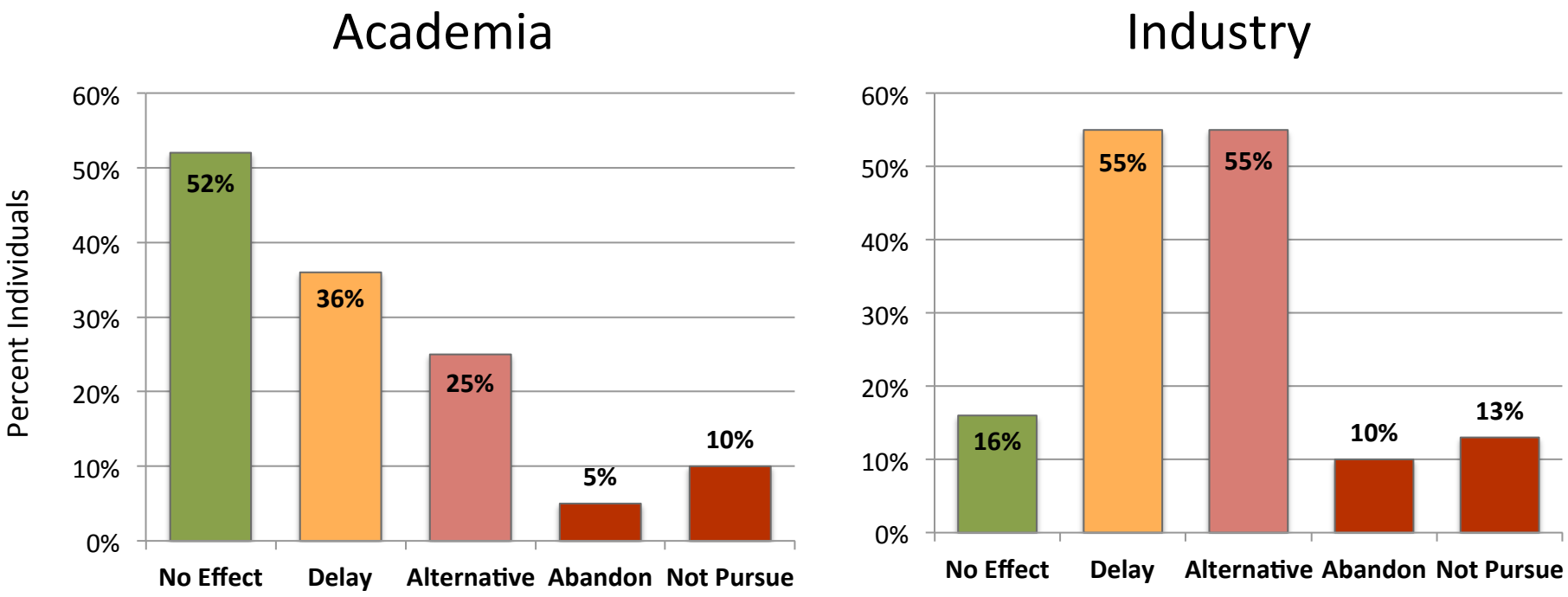
Sharing Biological Parts: Manuscripts, Patents and Agreements



Requesting Parts from Others: Non-Disclosures, MTAs and Licensing



Impact on Research due to Difficulties obtaining MTAs or Licenses:



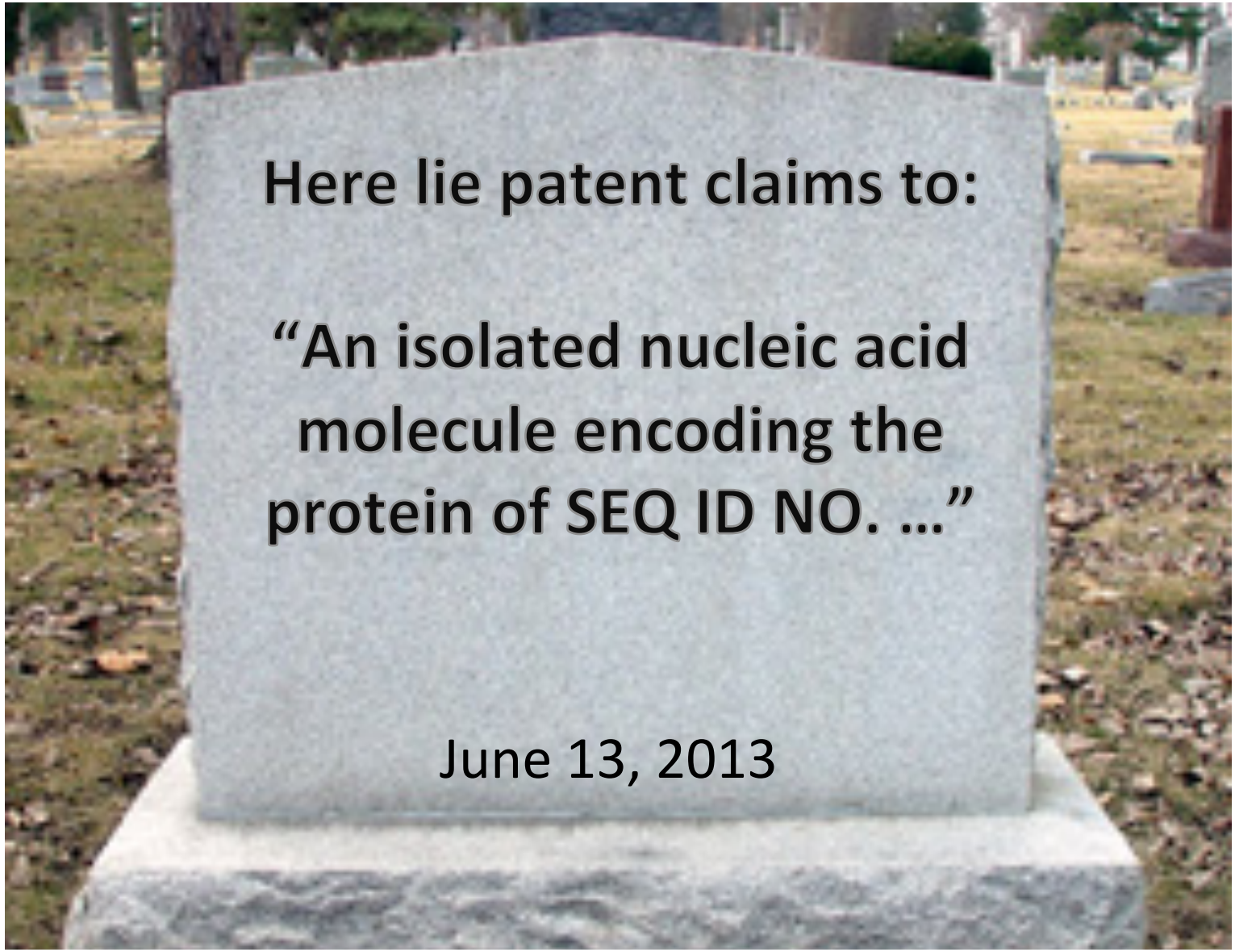
KEEP CALM
AND
IMAGINE

a collection of genetically encoded functions that are free to use and compose.

FREE of

- ✧ fear of liability for property rights infringement
- ✧ encumbrances limiting constructive, commercial use
- ✧ overwhelming transaction costs associated with use

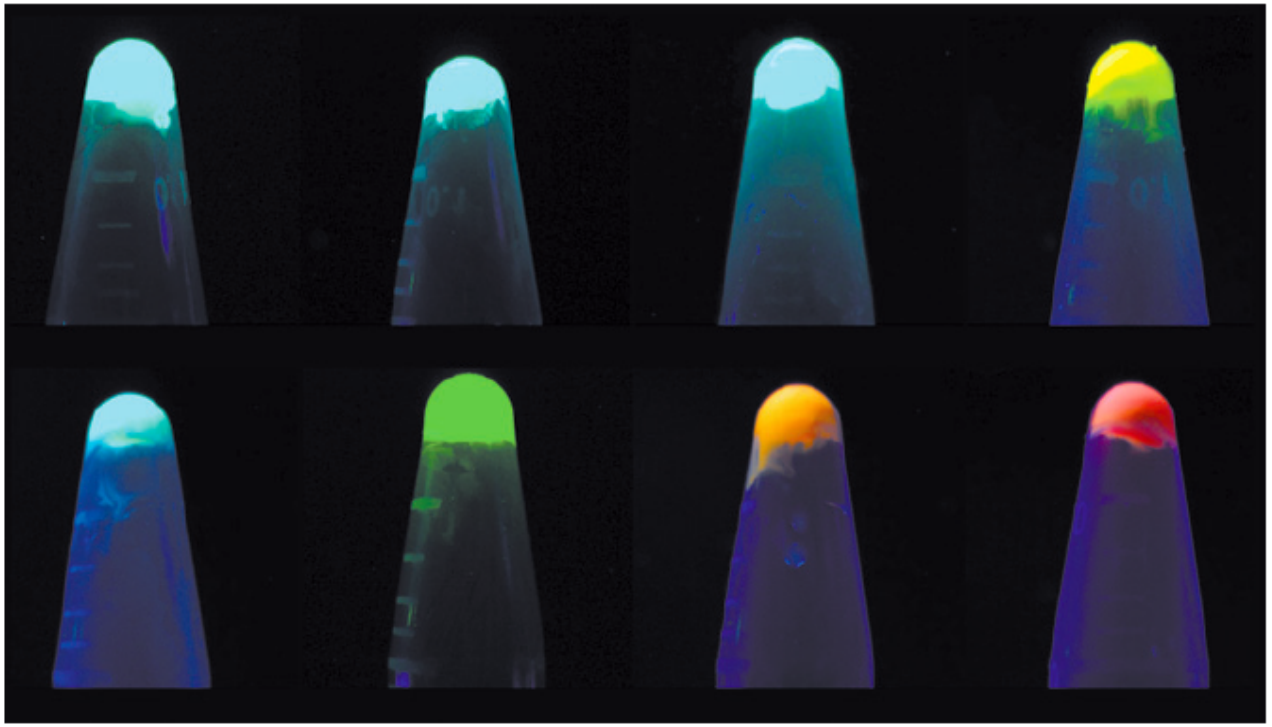
ASSOCIATION FOR MOLECULAR PATHOLOGY ET AL.
v. MYRIAD GENETICS, INC., ET AL.



Paragraph 3, Stanford Patent Policy:

The inventors, acting collectively where there is more than one, **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.

nature news
Volume 499, Issue 7456
Heidi Ledford
03 July 2013



Some synthetic fluorescent proteins made by DNA2.0 are now freely available to researchers.

BIOTECHNOLOGY

Bioengineers look beyond patents


Mars Shares Scientific Research
We continue to share the results of our scientific research, from mapping the cocoa genome to more efficient farming practices, often foregoing competitive advantage for the common good.


I couldn't be prouder.

The BioBrick™ Public Agreement

Liberating the language for programming life ... one part at a time

Synthetic Genes for Non-Natural Fluorescent Proteins

Jeremy Minshull | BPA Contribution #60

Boolean Integrase Logic (BIL) gates and amplifiers

Drew Endy | BPA Contribution #57

Terminators (BIOFAB E. coli C.dog v1 release)

Drew Endy | BPA Contribution #56

Translation Initiation Elements (BIOFAB E. coli C.dog v1 release)

Drew Endy | BPA Contribution #24

Promoters (BIOFAB E. coli C.dog v1 release)

Drew Endy | BPA Contribution #22

K1-5 transcription system

Drew Endy | BPA Contribution #2

E. coli constitutive promoter with strong ribosome binding site

Joseph H. Davis | BPA Contribution #1

*Share your parts at **biobricks.org/bpa***

BioBricks FOUNDATION


Make property rights easier to navigate.

THANK YOU!

Linda@biobricks.org