

# *Open Biotechnology*

*& the*

# *BioBrick Public Agreement*

*Prepared by Drew Endy  
Stanford University & The BioBricks Foundation*

*18 October 2009*

*These slides are freely available under a Creative Commons Attribution 3.0 United States License:  
<http://creativecommons.org/licenses/by/3.0/us/>*

# Property Rights are Important



The United States

To all to whom these Presents shall come, Greeting,

X000001  
July 31, 1790

**1. Define and scale relationships among parties**

**2. Support investment and returns**

**3. Rights frameworks change over time**

Whereas Samuel Hopkins of the City of Philadelphia and State of Pennsylvania hath discovered an Improvement, not known or used before, and being in the making of Pot ash and Pearl ash by a new Apparatus and Process, that is to say, in the making of Pot ash 1<sup>o</sup> by burning the new Ashes in a Furnace, 2<sup>o</sup> by digesting and boiling them when so burnt in Water, 3<sup>o</sup> by drawing off and setting the Lye and 4<sup>o</sup> by boiling the Lye into Salt which then are the true Pot ash, and also in the making of Pot ash by placing the Pot ash as made as aforesaid, which Operation of burning the new Ashes in a Furnace, digesting and boiling in Water, is new, bears this Resemblance, and produces a much greater Quantity of Salt: These are therefore in pursuance of the Act, entitled "An Act to promote the Progress of useful Arts", to grant to the said Samuel Hopkins, his Heirs, Administrators and Assigns, for the Term of fourteen Years, the sole and exclusive Right and Liberty of using and vending to others the said Discovery of burning the new Ashes previous to their being digested and boiled in Water, according to the true Intent and Meaning of the Act aforesaid. In Testimony whereof there is under these Letters under the Great Seal of the United States the hereunto affixed Great Seal of the City of New York this thirty first Day of July in the Year of our Lord one thousand seven hundred and Ninety.

G. Washington

City of New York July 31<sup>o</sup> 1790.

I do hereby certify that the foregoing Letters Patent was delivered to me in pursuance of the Act, entitled "An Act to promote the Progress of useful Arts", that I have examined the same and find them conformable to the said Act.

Edm. Randolph Attorney General for the United States.

The first U.S. patent, issued to Samuel Hopkins on July 31, 1790, for an innovative way of making "pot ash and pearl ash" -- source, Wikipedia

# Property Rights Change

## **The Copyright Act of 1976 stipulates (section 102):**

(b) In no case does copyright protection for an original work of authorship extend to any idea, procedure, process, system, method of operation, concept, principle, or discovery, regardless of the form in which it is described, explained, illustrated, or embodied in such work.

## **Congress attempted to clarify the situation for computer programs (Rep. No. 473, 94th Cong., 1st Sess. 54 (1975)):**

Section 102(b) is intended, among other things, to make clear that the expression adopted by the programmer is the copyrightable element in a computer program, and that the actual processes or methods embodied in the program are not within the scope of the copyright law.

## **and the National Commission on New Technological Uses of Copyrighted Works (CONTU), wrote in its final report (1978):**

Where could a meaningful line of demarcation be drawn? Between flow chart and source code? Between source code and object code? . . . The Commission believes that none of these is appropriate. The line which must be drawn is between the expression and the idea, between the writing and the process which is described.

From MIT Course 6.805/STS085: Software and copyright law

***E.g., copyright law was extended to cover software decades ago.  
More recently software patents have been pursued.***

# *What About Biotech Today?*

*Example: UC Berkeley, Amyris Inc., & One World Health team up against malaria!*



VS

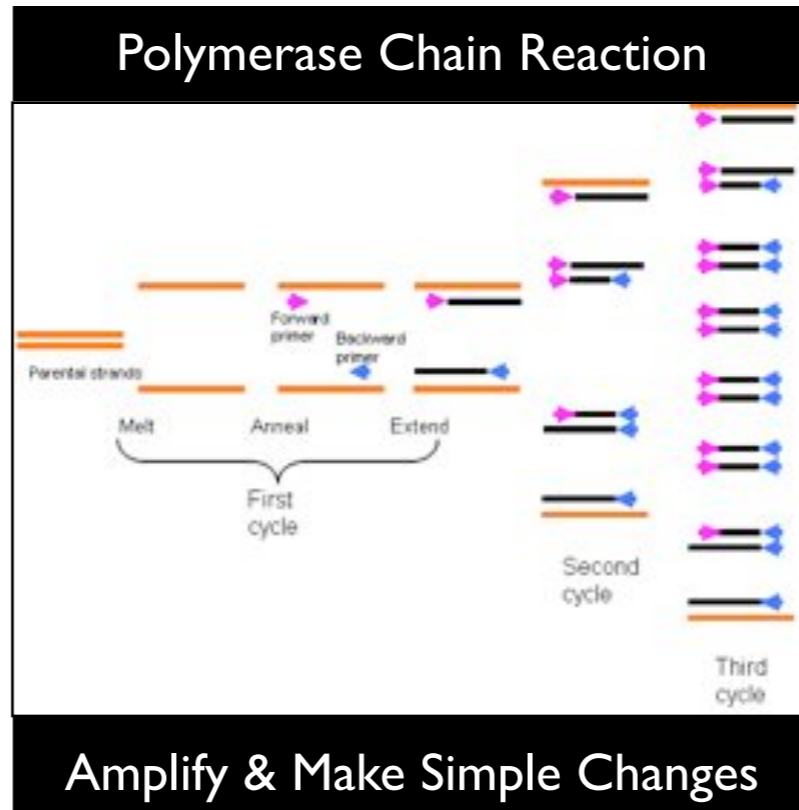
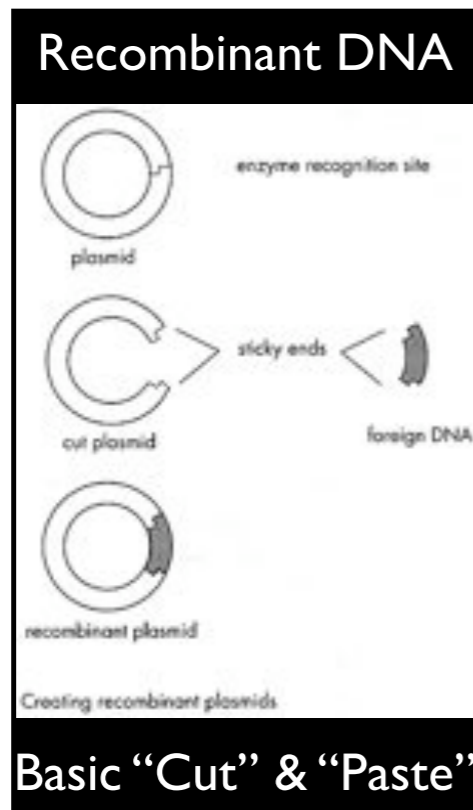


- 1. ~10 step biosynthesis project leading to artemisinin***
- 2. ~\$25 million research and development budget***
- 3. Strong, traditional patent-based property rights program***
- 4. Prepare defense against possible poor quality counterfeit products, preserve freedom to operate***

# Synthetic Biology as Tools Revolution

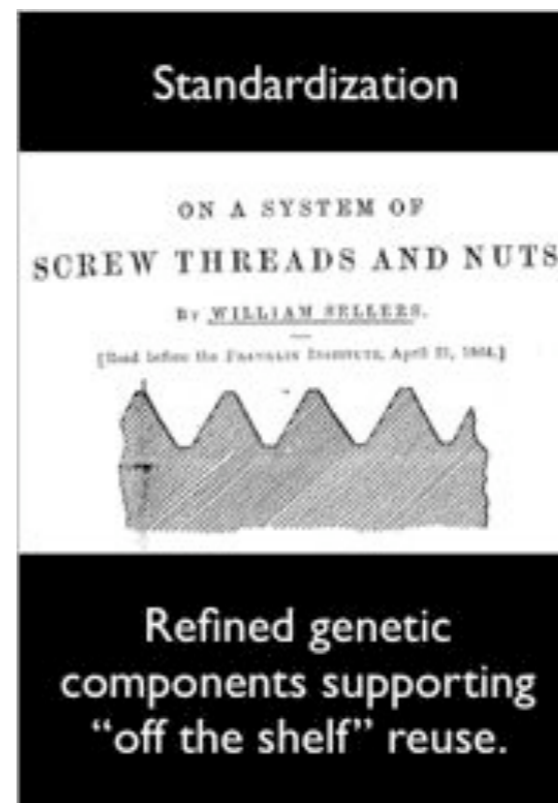
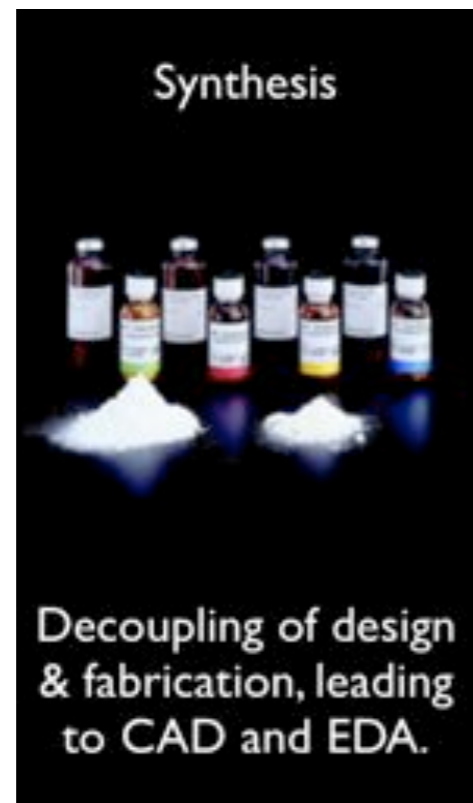
**First Gen. Biotech**

=



**Next Gen. Biotech Adds New Tools**

=



...

# Connection or Collision?

*(synthetic biology meets property rights)*

*Example:*

*2008 iGEM competition resulted in 1,500 new BioBrick Parts being developed last year, produced by students across 30 countries.*



**1. 2008 iGEM budget worldwide ~\$4 million**

**2. Commercial freedom to operate unclear**

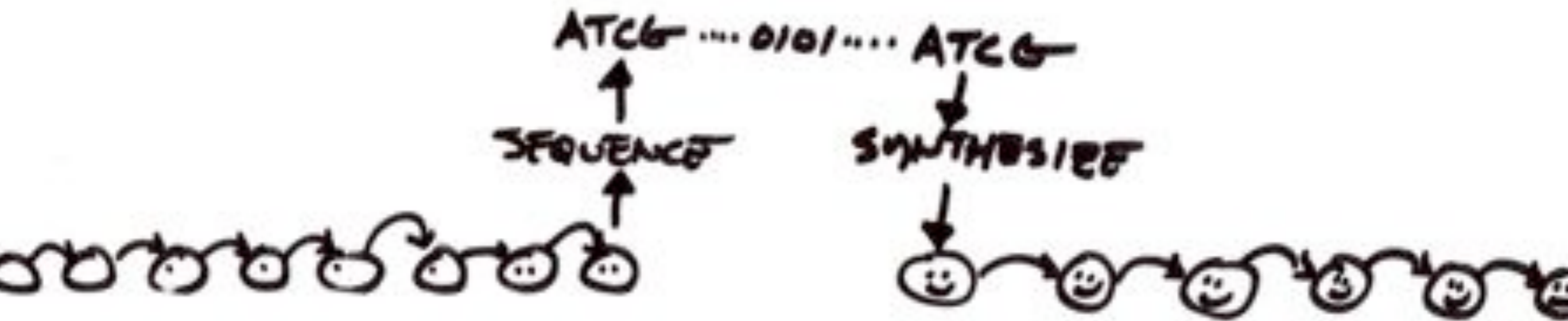
**3. Patent filings on all new 2008 parts would cost up to \$37.5 million**

**4. iGEM and the parts collections continue to grow (geometric)**

# Connection or Collision?

(synthetic biology meets property rights)

Second Example:



- 1. DNA sequencing and synthesis technologies make genetic information and material interconvertible**
- 2. Material transfer agreements are thus becoming less relevant**
- 3. Sequencing and synthesis tools improving geometrically**
- 4. Construction of 1000+ component systems now possible; conducting FTO searches on 1000s of components non-trivial.**

# Collision!!!

OPEN ACCESS Freely available online

PLoS BIOLOGY

Essay

## Synthetic Biology: Caught between Property Rights, the Public Domain, and the Commons

Arti Rai<sup>1</sup>, James Boyle

**N**ovel artificial genetic systems with twelve bases instead of four [1]. Bacteria that can be programmed to take photographs [2] or form visible patterns [3]. Cells that can count the number of times they divide [4]. A live polio virus “created from scratch using mail-order segments of DNA and a viral genome map that is freely available on the Internet” [5]. These are some of the remarkable, and occasionally disturbing, fruits of “synthetic biology,” the attempt to construct life starting at the genetic level. In terms of their scale and ambition, these efforts go beyond traditional recombinant DNA technology. Rather than simply transferring a pre-existing gene from one species to another, synthetic biologists aim to make biology a true engineering discipline.

In the same way that electrical engineers rely on standard

DNA, its developers believe that, as DNA synthesis technology becomes increasingly inexpensive [7], the registry will be composed largely of information and specifications that can be executed in synthesizers just as semiconductor chip designs are executed by fabrication firms.

Synthetic biology has already produced important results, including more accurate AIDS tests and the possibility of unlimited supplies of previously scarce drugs for malaria [8]. Proponents hope to use synthetic organisms to produce not only medically relevant chemicals but also industrial materials, including biofuels such as hydrogen and ethanol [9]. At the same time, synthetic biology has engendered numerous policy concerns. From its inception, commentators have raised issues ranging from bioethical and environmental worries to fears of bioterrorism—indeed, the US Central

Intelligence Agency has expressed concern about the tension between different methods of creating “openness.” On the one hand, one standard mechanism for creating openness has involved putting material in the public domain, outside the world of property. On the other, synthetic biology researchers may want to use intellectual property rights to create a “commons,” just as developers of free and open source software use the leverage of software copyrights to impose requirements of openness on future programmers, requirements greater than those attaching to a public domain work. But synthetic biology, unlike software, is not necessarily protected by copyright. Should we rethink the boundary lines between intellectual property and the public domain as a result?

### The Perfect Storm: Flawed Biotech Law Meets Flawed Software Law?

Intellectual property law in the US has



# *Challenge or Opportunity?*



***Experiments and advancements in the business models and ownership, sharing, and innovation frameworks will be at least as important to our future biotechnology successes and competitiveness as will be the advancements of our educational programs and research laboratories.***

# Past Lessons & Inspirations

## Early 1970s



“The first Unix application would be a word-processing program to be used by AT&T's patent-writing group.”

<http://www.spectrum.ieee.org/print/1571>

## Mid 70s to Mid 90s



“Who can afford to do professional work for nothing? ... Nothing would please me more than being able to hire ten programmers and deluge the hobby market with good software.”

Bill Gates, Microsoft, Inc.

<http://www.time.com>



“Proprietary software divides the users and keeps them helpless, and that is wrong.”

Richard Stallman, Free Software Foundation

<http://www.boycottnovell.com/2009/03/14/>

## Today



# *Our Combined Opportunities*

***Develop and validate complementary legal frameworks that best support the ownership, sharing and innovation needed to power the next generation of biotechnology.***

***Enable a rich, fully diverse ecology of commercial and public benefit use from the outset (i.e., avoid “religious” and dysfunctional community polarization).***

***Address issues of equity (and perhaps also safety and responsibility) that impact broader acceptance and framing of biological technologies.***



**The BioBricks Foundation is a not-for-profit that:**

**1. Is developing and supporting new legal frameworks enabling open biotechnology (next slides).**

**2. Enabling an open, open technical standards process (inspired by IETF, USB, et cetera).**

**3. Fostering the Synthetic Biology community (e.g., SB4.0 in Hong Kong, 2008)**

**[www.biobricks.org](http://www.biobricks.org)**

# BioBricks Legal Team Leadership



## David Grewal

J.D., Yale; PhD, Harvard (2009)  
Harvard Society of Fellows  
Author, "Network Power"



## Lee Crews, Principal

Patents  
Life Sciences  
Medical Technologies

**FISH & RICHARDSON P.C.**  
Intellectual Property | Litigation | Corporate



## Jason Schultz

Acting Director  
Samuelson Clinic  
UC Berkeley Law  
Previously of EFF



## Mark Fischer, Principal

New Media and Entertainment  
Trademarks  
Copyrights  
Licensing

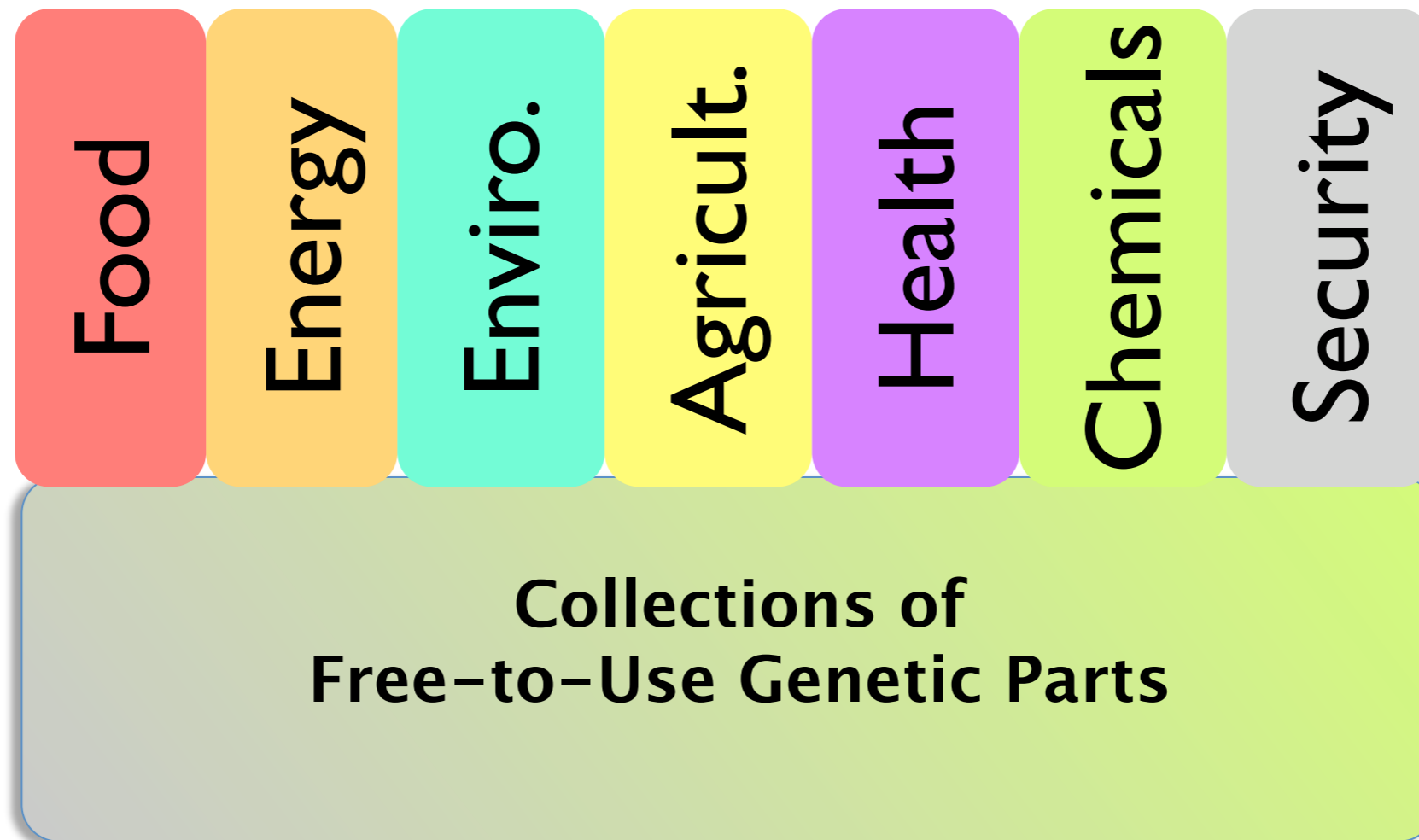
**FISH & RICHARDSON P.C.**  
Intellectual Property | Litigation | Corporate



## Jennifer Lynch

Clinic Fellow &  
Supervising Attorney  
Samuelson Clinic  
UC Berkeley Law

# First-Order Goals



- 1. Enable and support development of a community of contributors and users of free-to-use parts.***
- 2. Address issues associated with encumbrance of novel uses/reuse of parts, alone or in combination.***
- 3. Don't "irreversibly pollute" the long term, big picture.***

# *Starting from First Principles*

**Patents:**

Standard practice

Slow, expensive,  
exclusive

**Copyright:**

Cheap, easy to Use

Could be too strong.  
Not used today

**Contracts:**

Defined agreements

Leaky

**Public Domain:**

Cheap, fast

May not offer protection.  
Hard to build community

**Sui Generis:**

Could be exactly right

Expensive & political

# *First Generation Solution*

## **The BioBrick Public Agreement**

***1. Bilateral Agreement between Contributors and Users of genetic parts (optimized for BioBrick parts but not limited thereto).***

***2. Contributors make irrevocable promise to not assert any property rights they hold that would limit use of their “contributed materials” against Users.***

***3a. Contributions are “freedom to use” for specified materials.***

***3b. Users agree once, getting access to all contributed materials***

***3b. Framework is backwards & forwards compatible with patenting.***

***3c. Framework is opt-in (i.e., non prescriptive).***



# *BPA v1 DRAFT is available for public distribution and comment.*

The BioBrick™ Contributor Agreement

DRAFT Version 1 (October 2009)

The "Materials" are the particular standardized genetic material and associated functional information described as follows: \_\_\_\_\_

[Please include BioBrick part number(s), if appropriate. Contributor may list as many different parts as Materials as Contributor wishes.]

The "Contributor" is (name, address, contact information): \_\_\_\_\_

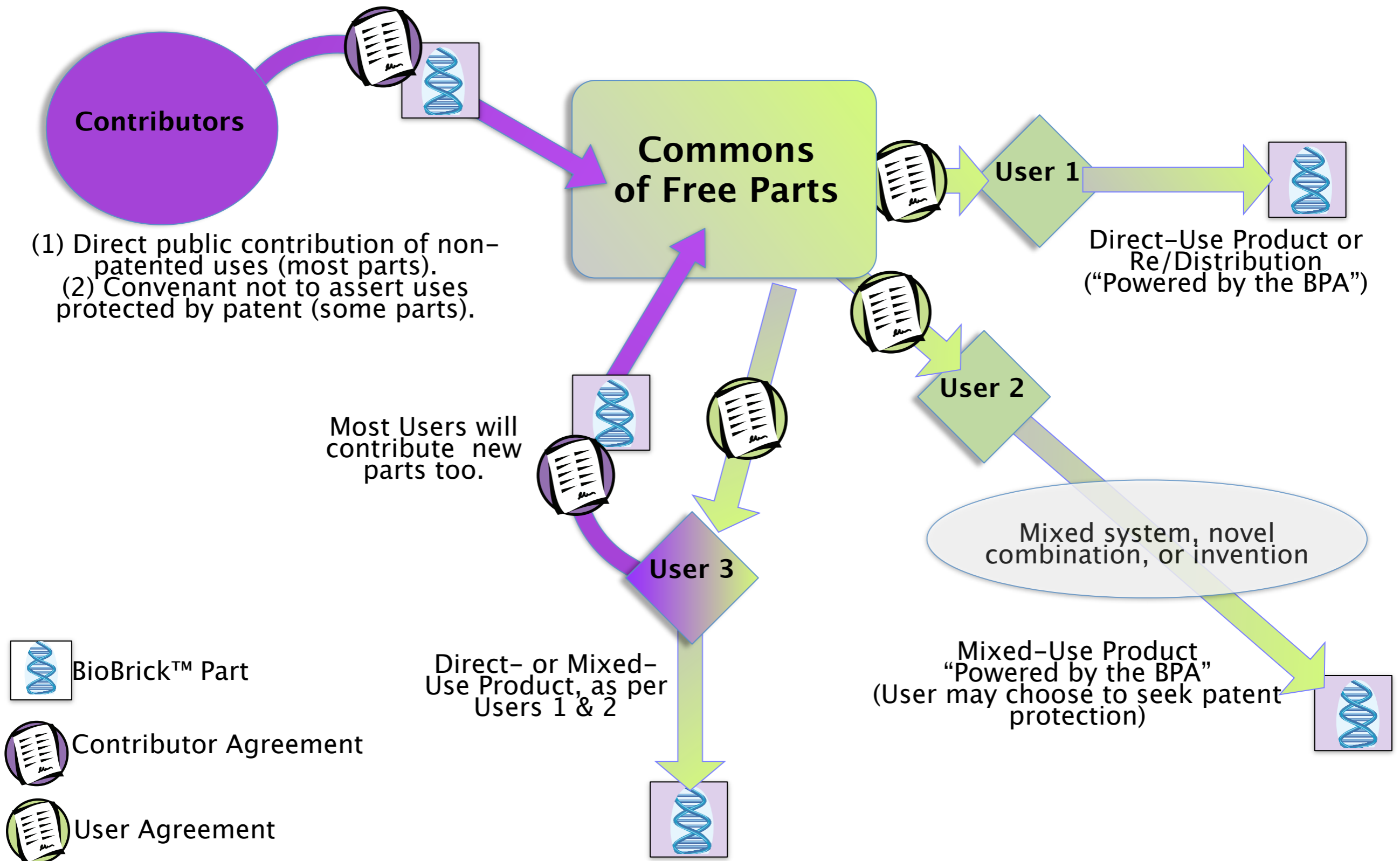
Applicable BioBrick™ Standard(s): \_\_\_\_\_

Attribution to the Contributor: Should Users attribute the Materials to the Contributor when the Materials are commercialized or otherwise distributed?  Yes  No

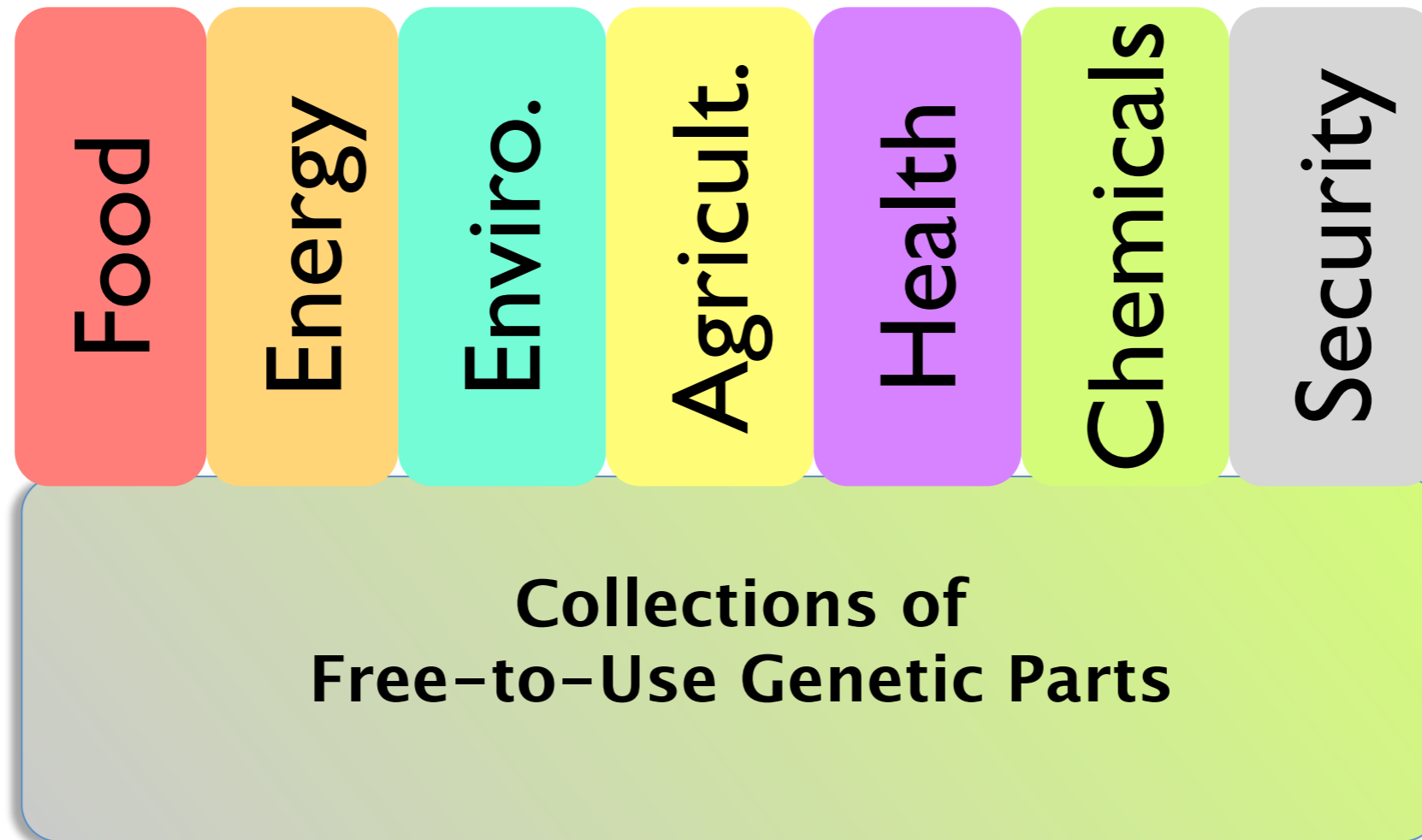
Describe attribution (if any): \_\_\_\_\_

<http://hdl.handle.net/1721.1/49434>

# Mapping the Paths of BioBrick Parts



# *How is this going to help me?*



- 1. Over time, but on a timescale much faster than patent terms, sets of genetic parts should become available for commercial use.***
- 2. Expansion of existing biotechnology communities and many new service opportunities.***
- 3. Reduction of capital costs for new R&D projects and startups.***

# *How will this not hurt me?*



[http://aunz.siemens.com/Safety/PublishingImages/CC\\_2095\\_safety.jpg](http://aunz.siemens.com/Safety/PublishingImages/CC_2095_safety.jpg)

**1. *Opt-in.* Individuals and corporations can choose to participate as Contributors or Users as appropriate.**

**2. *Mixed-use.* Heterogeneous systems can be protected by patents, if needed.**

**3. *Liability management.* Transparent disclosure, direct disclaimer, & compartmental.**

**4. *Strategic awareness & leadership.* The world of biotechnology is changing. Ignoring new ideas and approaches can be a greater risk.**

# Frequently Asked Questions

## **1. How will this work practically? Will it be like iTunes?**

Contributors will contribute materials via the BioBrick Contributor Agreement. The BioBricks Foundation (BBF) will provide this service for free via the web. Third parties could (theoretically) also provide such service. The Contributor Agreements themselves will be made publicly available for use and redistribution. Users will agree to the BioBrick User Agreement via a “clickthrough” form that will be freely available via the web (c/o the BBF). The BBF will not maintain records of User Agreements, but will provide a free service to validate User Agreements as needed.

## **2. What is being contributed?**

An irrevocable promise not to assert any property rights held by the Contributor over Users of the contributed Materials.

## **3. Will all existing BioBrick parts be covered by the BPA?**

The BioBrick Public Agreement will not apply retroactively to all BioBrick standard biological parts. Existing or new parts must be contributed under the BPA to be covered.

## **4. Can only BioBrick parts be covered by the BPA?**

The BPA is optimized for use with, and best supports, contributions of use for genetic material that has been refined and standardized in accordance with one or more open BioBrick Standards.

## **5. Is institutional sign-off required?**

Sometimes, for example, if your terms of employment would require such sign-off.

## **6. When would this impact me?**

It depends. For example, if you are a researcher who would like to contribute something, sign up now as one of the lead BPA launch teams. A bioproducts company? Build awareness now so that as parts become available R&D, business, and legal teams are knowledgeable. A tools company? Develop strategy now. A next generation synthetic biology startup? Integrate thinking into soul of company strategy and structure.

# More Questions

## **7. Is the BPA “viral”?**

No, not as currently drafted. Users of BPA-contributed parts are not required to “give back” any other genetic components that they might combine with BPA-contributed parts.

## **8. Can I patent something that uses BPA-contributed parts?**

Yes, as currently drafted. Novel materials and applications produced using BPA-contributed parts may be considered for protection via conventional property rights.

## **9. Why won't a patent “troll” file patents on all possible novel uses of BPA-contributed parts.**

In theory, nothing. In practice, many things. As one example, the costs of such filings would be formidable. As a second example, contributors and others can readily disclose at the time of contribution known and imaginable uses of so-contributed parts, making obvious many future uses. As a third example, the community of BioBrick parts users continues to grow (e.g., a highschool student could make and contribute a new part) and professionally-staffed public-benefit production facilities for making and contributing high-quality free-to-use parts are getting started.

## **10. Will the BioBricks Foundation own the parts that I contribute?**

No. You decide who owns or can use your parts. By contributing a part under the BPA you are enabling others who agree to the BPA User Agreement to freely use the parts that you contribute.

## **11. Why does the BioBricks Foundation use a trademark right?**

The BBF hold trademark on uses of the word “biobrick” in order to protect its free-to-use and open technical standards and legal framework. As a government recognized not-for-profit organization the BBF has no intention of profiting from these public benefit services.

## **12. What if I have a different question?**

Please contact us by email via the addresses on the next slide.

# *How To Participate!*

***We are looking for very strong feedback and participation.***

***Please send us your comments, questions, or concerns.***

***Contacts: Drew Endy via [endy@biobricks.org](mailto:endy@biobricks.org)***  
***David Grewal via [grewal@biobricks.org](mailto:grewal@biobricks.org)***

