Institutional Analysis of The Registry of Biological Parts, Cambridge, Massachusetts

December 7, 2015

1.0 Part I: System Structure - Collective Action

The Registry of Standard Biological Parts is maintained by the International Genetic Engineering Machine (iGEM) Foundation in Cambridge, Massachusetts. The Registry contains genetic information in the form of synthetically created deoxyribonucleic acid (DNA) sequences, protein, promoters, and other parts with various biological functions. The shared resources relevant to the commons dilemma faced by the community include the parts in the registry and their accessibility (common-pool). The action situation involves thousands of individuals from synthetic biology groups from around the world. There is a heterogeneous mix of natural and human-made infrastructures.

The case is an addition to the original Common-Pool Resource (CPR) database. David Gillum at Arizona State University entered this CPR report in 2015.

1.1 The Commons Dilemma

The iGEM Registry of Standard Biological Parts was founded in 2003 at the Massachusetts Institute of Technology (MIT). The registry was developed to be an open, publicly accessible library of synthetically nucleic acid sequences (i.e., parts) that can be mixed and matched to build novel biological devices and systems. The registry was spun off from MIT on January 1, 2012 to the International Genetically Engineered Machine (iGEM) Foundation. The iGEM Foundation is a non-profit organization located in Cambridge, Massachusetts that is "dedicated to education and competition, advancement of synthetic biology, and the development of open community and collaboration."[1]

The registry is the world's largest collection of open source DNA parts called BioBricks™. These parts all meet an established standard to ensure compatibility between parts, allowing them to be assembled together to build novel genetically engineered systems. The Registry contains over 20,000 specified genetic parts.

The DNA in the registry is currently accessible to participants of the iGEM Giant Jamboree, a synthetic biology competition held each year in Boston, Massachusetts. Participation in these competitions is limited primarily because of high costs to participate. Those individuals or teams with sufficient funds are able to participate.

The information in the registry is freely available to anyone with a computer, Internet connection, and knowledge and understanding of the materials in the library. However, only individuals with the expertise and equipment necessary to convert the genetic information into synthetic nucleic acid sequences will benefit from the library.

[1] PR Newswire. 2015. "Synthetic Biology Students Compete in iGEM 2015 Giant Jamboree." http://www.prnewswire.com/news-releases/synthetic-biology-students-compete-in-igem-2015-giant-jamboree-300123862.html

1.2 Biophysical Context (IAD)

As a resource, synthetic biology is variable and dynamic. Synthetic biology is developed from a combination of infrastructures—chemicals, gases, water, solar, and fossil energy make up the natural infrastructure. Vast amounts of soft-human infrastructure (knowledge, technical expertise, skills, etc.) are also required. In addition, the hard, human made infrastructure that is required to maintain the registry includes buildings, ultra-low temperature freezers, refrigerators, and other equipment commonly found in microbiology laboratories, as well as computers, internet networks, information systems, and other technologies required to enter, store, and access information. Further, manipulation, appropriation, and use of the resource also requires inputs of human hard and soft infrastructure such as public and private research laboratories and equipment, personnel, federal funding, venture capital, and so on.

One of the main driving forces for synthetic biology development is the potential for improving the quality of life for humanity. However, an even greater input driving synthetic biology is money. It is expensive to provision and appropriate the above combinations of infrastructure. According to the Wilson Center, between 2008 and 2014, the United States invested a total of $820 million dollars in synthetic biology research[2]. This investment does not include the billions of additional dollars going to transportation, information and communication, and satellite infrastructures that already enable synthetic biology research and development. The Registry of Standard Biological Parts also receives external funding through grants from the National Science Foundation, the Defense Advanced Research Projects Agency, and the National Institutes of Health.

1.3 Attributes of the Community (IAD)

The iGEM headquarters in Cambridge, Massachusetts, maintains the Registry of Standard Biological Parts. There are less than 20 full time people employed by iGEM. In 2015, over 4,600 participants on 280 teams registered to take part in the iGEM Giant Jamboree, a synthetic biology competition held each year in Boston, Massachusetts. Over 18,000 young scientists and engineers have participated in iGEM as students, instructors, or advisors since 2003. Participants in the iGEM competitions must raise the funds required to attend the event. This is often accomplished through a hybrid of public, government funding as well as private funding.

1.4 Rules in Use (IAD)

The Bayh-Dole Act stipulates that patents from federally financed research may be transferred from the federal government to individuals, research groups, and business university technology (information and payoff rules). The absence of a feedback (for example a revised scope rule) linking technology transfer to applications with high potential social gain may perpetuate the mismatch in which public funds are provisioned for general research but benefits accrue to small groups of individuals or firms.

The 1986 Coordinated Framework for Regulation of Biotechnology directed the Environmental Protection Agency (EPA), Food and Drug Administration (FDA), and the Department of Agriculture (USDA) to work together and use existing regulatory frameworks to govern biotechnology. According to the Woodrow Wilson Center, the core premise was that the legal authorities (which remain largely unchanged today) "provide federal regulators sufficient authority to manage any health or environmental risk the products of biotechnology may pose."[3]

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[2] Wilson Center. 2015a. "Synthetic Biology Project. U.S. Trends in Synthetic Biology Research Spending." Web. http://www.synbioproject.org/site/assets/files/1386/final_web_print_sept2015.pdf.

[3] Wilson Center. 2015b. "The DNA of the U.S. Regulatory System: Are We Getting It Right for Synthetic Biology?" Web. http://www.synbioproject.org/site/assets/files/1388/synbio_reg_report_final.pdf

1. **Position Rules:**

    - iGEM headquarters has supervisory authority over the Registry of Standard Biological Parts, including the physical DNA and sequence information in databases held in the registry.
    - *Approved individuals* are permitted to have access to the DNA in the registry.
    - The information in the library is freely available to anyone with a computer, Internet connection, and knowledge and understanding of the materials in the library.

2. **Boundary Rules:**

    - Individuals that would like access to the Registry of Standard Biological Parts must adhere to the Biobrick™ Public Agreement. The BioBrick™ Public Agreement was developed for sharing the uses of standardized genetically encoded functions (e.g., BioBrick™ parts).

3. **Choice Rules:**

    - Individuals that have access to the Registry of Standard Biological Parts may choose to use the parts to develop new biological parts, devices, and systems.

4. **Aggregation Rules:**

    - The aggregation rules are not clear at this time.

5. **Payoff Rules:**

    - Allowances for technology transfer may be part of what makes synthetic biology research commercially viable.

6. **Scope Rules:**

    In the United States, under the Coordinated Framework of 1986:

    - The Animal and Plant Health Inspection Service (APHIS) regulates field trials of genetically engineered crops and plants under general authority to regulate plant pests. APHIS also reviews requests to "deregulate" the crop or plant in order for it to be grown without a permit at a commercial scale.
    - The Environmental Protection Agency regulates genetically engineered microbes as "new chemical substances" under the Toxic Substances Control Act (TSCA). EPA also regulates genetically engineered pesticides (including biopesticides and pesticides incorporated into plants) under its authority to regulate pesticides.
    - Lastly, the Food and Drug Administration regulates food, food additives, human and animal drugs, and certain other products, including those that have been produced through genetic engineering.

7. **Information Rules:**

    - The information rules are not clear at this time.

1.5 Summary

The iGEM Registry of Standard Biological Parts is the world's largest collection of open source, publicly available, synthetically created standard biological parts. The resource consists of both DNA and biological information in databases. It is available participants of the iGEM Giant Jamboree and approved academic laboratories at an accredited university. The regulatory framework governing the parts included in the library is not entirely clear. However, attempts have been made to formalize the openness and accessibility of the parts by have people using and submitting new parts to sign a contract, called the Biobricks™ Public Agreement.

Part II. Robustness

2.0 Robustness Summary

In summary, the future of the Registry of Standard Biological Parts is not clear. The quality of the synthetic parts currently in the library, as well as the new materials added, have not been fully verified. The registry is also vulnerable to the closing of iGEM headquarters, which is a non-profit organization that relies on federal grants, private donations, and participant fees for the iGEM Giant Jamboree. There is also fierce competition in the realm of synthetic biology, with most new ventures trying to make money off the technology. There is currently no other synthetic biology commons like the iGEM Registry of Standard Biological Parts. Therefore, steps should be taken to help preserve its long-term viability for current populations and future generations.