

BIOFAB HUMAN PRACTICES REPORT 3.0*

**Open Technology Platforms:
(How) Should the BIOFAB
Give Things Away?**

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Summary Statement

The BIOFAB was framed in view of the proposition that basic biological parts should be non-proprietary, accessible, and freely available for use and reuse in an ongoing fashion (BIOFAB, 2010; SynBERC, 2011; Endy, 2005). There are a number of reasons for this framing, reasons which are detailed in this report. Most pronounced is the proposition that synthetic biology will not maximally contribute to health, wealth, and security unless and until such openness becomes characteristic of biotechnology (Baker, *et al.*, 2005).

Efforts to make the BIOFAB's work free and easily accessible center on the BIOFAB's *c.dog engineering projects*—projects designed to support forward engineering of biology's “central dogma” (<http://biofab.org/projects>). These efforts have been figured as the creation of an *open technology platform* for synthetic biology.

The term *open* is typically associated with software development. And indeed, analogies from open source and free software are often used to frame questions of openness and sharing in biotechnology. Many of these comparisons may be apt, and may facilitate re-conceptualization of possibilities in biotechnology. An *analogy*, however, is not an *identity* (Rabinow and Bennett, 2009). And open-source and free-to-use frameworks drawn from software development have their limits or simply do not apply in the BIOFAB's situation and in biotechnology more broadly.

One especially crucial limitation is that open-source frameworks in software development usually rely on copyright as the legal mechanism for defining the use of creative works. Copyright, however, is not currently recognized as a mechanism for intellectual property in biology. The principal mechanisms for constituting and circulating works in biotechnology are patents, and to a lesser extent, the public domain (Rabinow, 2006; Kelty, 2009; Torrance, 2010).

In this light, following precedents set by other public benefit initiatives in biology such as the Hap Map Project and the SNP Consortium, the BIOFAB has declared its intention to place all of its work in the public domain. Putting this intention into practice, however, has proven difficult.

There are actually multiple difficulties, several of which are discussed in this report. A principal difficulty concerns the fact that the BIOFAB is located in *mixed inventor* organizations—i.e. UC Berkeley, Lawrence Berkeley National Labs, and Stanford University. Mixed inventor organizations take as a core assumption that inventions developed by one researcher or team of researchers within that organization are likely to have proprietary connections to inventions (past and future) made by others in that same organization. As such, it is not clear how or whether to facilitate the declared intentions of a single researcher or research team to give work away (Endy, 2010).

This organizational difficulty consists of one part habit, one part disposition, and one part process. With regard to *habits*, technology transfer officers are accustomed to making one of two primary decisions in relation to ownership of inventions not subject to copyright protection: whether to patent that work or not. Placing work in the public domain is simply not customary (Torrance, 2010; Rai and Boyle, 2007).

With regard to *dispositions*, the decision not to patent is not the same as declaring an object to be in the public domain. Declaring an object to be in the public domain means foregoing proprietary benefits connected to that work, derivative works, or other inventions closely connected to it (Hope, 2008; Keltly, 2009). In the case of the institutions housing the BIOFAB there is not yet sufficient interest in risking either the loss of such proprietary gains in the face of the yet-to-be-proven benefits of open biotechnology or assuming possible liabilities associated with infringing on other patents.

With regard to *process*, the problem is straightforward: even where the institution is willing to place work in the public domain, it is not clear how this should be conducted. As discussed in the report, placing an object in the public domain assures neither that it will stay in the public domain, nor that *accessibility* will result in *facilitation*. That is to say, just because an object is declared free-to-use doesn't mean worthwhile uses will come of it.

The purpose of this report is to address these difficulties. Its approach is conceptual in form and pragmatic in orientation: to *better frame* the question of *how* the BIOFAB should distribute what it makes and *why* well-designed strategies of non-proprietary circulation are worth pursuing despite difficulties. The term *frame* here means to specify reasons, problems, blockages, strategies and hoped-for outcomes. *Better* means to do this in such a way as to establish parameters for a possible solution.

It has been proposed that the most expedient solution is the design new more appropriate legal mechanisms. Although such possible mechanisms might be worthwhile, it is not yet clear what they would consist in, if they would be accepted, and when they would be accepted for use. As such, new mechanisms, per se, are likely not a sufficient means of meeting the BIOFAB's stated aims.

This report thus situates the problem at a broader and more resolutely normative level. In response to existing encumbrances, and in the face of unknown and under-determined futures this report proposes candidate parameters for *determining* which legal mechanisms, institutional priorities, and strategic practices are consistent with the BIOFAB's defining goals. These parameters can be made to function as *directives* in that they indicate which mechanisms and practices should be cultivated and which refused.

Orientation: Report Components & Four Initial Clarifications

COMPONENTS OF THE REPORT

A methodological presumption of this report is that in order for *directive* work to be carried out successfully, sufficient *diagnostic* assessment of the current situation is required. Such diagnostics are fundamental to proceeding in a prudent, diligent, and responsible manner.

To this end, the report will consist of four principal components (note that these components are not always discretely separated in the report).

- (1) It will *recapitulate the key arguments* put forward in official BIOFAB statements concerning *why* and *how* the work of the BIOFAB should be given away.
- (2) It will *provide an overview of the primary difficulties* and encumbrances in meeting this aim.
- (3) In light of these arguments and difficulties it will provide a brief and schematic *analysis of exemplary frameworks* for open source biotechnology.
- (4) All of this will be sharply *oriented toward the formulation of parameters* for *strategic* and *ethical advancement*.

CLARIFICATION 1: TERMINOLOGY

In preparation for developing these components, a few initial clarifications are in order. The first concerns terminology. The aims of this report are pragmatic; hence its key concepts are intended to be concise and consistent, while being defined as part of the task and situation at hand. These key concepts include terms such as *analogy*, *open*, *intellectual property*, *frameworks*, and *directives*. Working definitions of these key concepts are provided in table 1 below. Readers are encouraged to make reference to these definitions as aides to following the report's conceptual trajectory.

CLARIFICATION 2: TECHNICAL AND LEGAL PRECEDENTS

A second clarification is a simple acknowledgement. No technology platform yet exists in a form that satisfies the goals and mandate of the BIOFAB, biotechnically or legally (BIOFAB, 2010). Several existing platforms provide points of reference. Technology platforms developed in relation to the notion of BioBrick assembly through iGEM, the MIT Registry, and the BioBricks Foundation, as well as the genome assembly protocols of the J. Craig Venter Institute, have been cited as exemplary and even defining for synthetic biology (Rabinow and Bennett, 2008; Torrance, 2010). These and other existent platforms, however, are currently insufficient to the technical goals of forward engineering and predictable genetic expression, or are not yet freely available and legally unencumbered.

CLARIFICATION 3: INSTITUTIONAL SETTING AND LONG-TERM AIM

The third clarification is less obvious than the second, but more important. The National Science Foundation funded the BIOFAB as part of the Synthetic Biology Engineering Research Center (SynBERC) (BIOFAB, 2010; SynBERC, 2011). The NSF's two-year investment was predicated on the expectation that the BIOFAB would serve as a key organizational component of SynBERC, helping to address operational gaps between its foundational and applied work. It was also expected, however, that the BIOFAB would extend and grow beyond this initial

purpose, and that the technologies and protocols it established as part of SynBERC would be made “freely available to both academic and commercial users” (BIOFAB, 2010).

In this light the BIOFAB was proposed not only as a strategically and operationally important fix for a single institution. It was also proposed as “the first significant focused investment in the development of open technology platforms underlying and supporting the next generation of biotechnology” (BIOFAB, 2010).

The founding BIOFAB documents summarized this long-term aim in the following terms: “Our first objective is to develop and bring into existence a first example of a *public benefit production facility* supporting improvements to the process of engineering biology.” And although the notion of *public benefit* was not defined systematically, it was closely linked to the promise that the “BIOFAB will help to produce collections of *free-to-use* genetic components that will allow the next generation of biotechnology innovation and commercialization to take place more quickly and at reduced costs” (BIOFAB, 2010).

In short, although mandated to meet the needs of an existing community of practitioners, the BIOFAB has been designed and proposed, and is now in the process of being constructed and elaborated, as a *public benefit facility*. Which publics might actually benefit, *why* they might benefit, and *how* such benefits are linked to the proposal that the BIOFAB’s work will be freely given away are concerns which inform this report.

Table 1: Definition of Key Terms

Analogy	Discussions of “openness” and intellectual property in synthetic biology typically begin with analogies to developments in computer software as a means of explaining, justifying, or even orienting action. It is important to keep in mind, however, that an analogy is a comparison between two distinct things, e.g. “designing synthetic genomes <i>is like</i> designing operating systems for cells.” Analogies become misleading when the <i>similarity</i> implied in a comparison is confused with an <i>identity</i> , e.g. “our aim is to program DNA.” A key <i>conceptual challenge</i> thus consists in identifying the limits of analogies for meeting the <i>practical challenges</i> faced by the BIOFAB in establishing the terms of an open technology platform.
Open	The use and meanings of the adjective “open” and noun “openness” in technology settings can be strategic, heterogeneous, and contradictory. Minimally, it is clear that <i>open</i> is a term used to establish a contrast. “Open” is often contrasted to “closed,” suggesting that the key variable is <i>accessibility</i> . It is also contrasted to “proprietary,” suggesting that the key variable is not only accessibility per se, but also <i>ownership</i> . This latter contrast is particularly crucial for the design and sharing of the BIOFAB’s technology platform.
Intellectual Property	In familiar usage, intellectual property refers to a range of legal mechanisms for ensuring the proprietary rights of an individual or institution. Forms of intellectual property (e.g. patents, copyrights, etc.) and their strengths and limitations are often situated as a key problem in discussions of ownership, sharing and innovation in synthetic biology. This report concentrates on the ways in which notions of intellectual property affect and effect relationships. It focuses on how IP brings objects into the world in such a way that their movement and use can be partially regulated, and how it scales interactions predicated on those objects. Taken up in this way, the problem of <i>intellectual property</i> is defined by questions of <i>ontology</i> and <i>circulation</i> .
Ontology	Ontology is a term that designates <i>what things are</i> , i.e. how they come into existence, are named, sustained, distributed, and modified. The creation of new

	<p>objects is a primary goal of synthetic biology. These new objects include biological artifacts, such as <i>standardized parts</i>, <i>genetic architectures</i>, or <i>design software</i>. New objects also include distinctive ways of reasoning, forms of scientific organization, as well as an <i>ethos</i> of engineering. For some, including the BIOFAB, this new <i>ethos</i> is critically defined by efforts to ensure that new objects circulate in the world in an as open and legally unencumbered fashion as possible.</p>
Circulation	<p>The problem of circulation—how the movement of things in the world can and can't be regulated—is a longstanding and central problem of modern governance. Whether the spread of disease, the movement of traffic in and out of cities, or the economics of international trade, the problem of circulation has centered on how unavoidable as well as contingent variables can be combined and reworked in order to create different and more favorable circumstances and communities. In this sense, the question of whether and how the BIOFAB makes its work open and freely available is a question of how it is circulated.</p>
Technology Platform	<p>A key circulation challenge for the BIOFAB concerns the heterogeneous range of objects it is making, objects which need to be integrated not only technically, but also legally. Said differently, the BIOFAB is committed to making and circulating a <i>technology platform</i>. A technology platform is an ensemble of diverse techniques and technologies that have been integrated in such a way as to serve the <i>basis</i> for the production of <i>new technologies</i>. In the case of the BIOFAB, the principle technology platform is the <i>C.Dog project</i>. The C.Dog consists of designed genetic architectures (i.e. “expression operating units”); collections of standardized biological parts consistent with those architecture; characterization data; measurement and analysis protocols; reference objects; database and computer aided design software; and human practices analyses. In terms of intellectual property, technology platforms present particularly difficulties in that the range of technologies and uses which they support are under-determined by design.</p>
Public Domain	<p>One non-proprietary strategy for circulating the BIOFAB's technology platform is to declaratively place it in the public domain. The concept of the public domain has commonly been used to refer to informational works not covered by intellectual property law, such as works whose copyrights or patents have expired. Recent efforts to thematize notions of the public domain as a strategy for making technologies freely available emphasize (1) that public domains are the “outside” domains of exclusion in property law; (2) that they don't exist without being explicitly conceptualized and fostered; (3) that as such, they need some mechanism of animation; and (4) that such mechanisms open up space for experimentation and creativity. One possible mechanism for public domain biotechnology is the creation of a shared commons.</p>
Commons	<p>A commons refers to “provisions provided for a community in common, the common expense of such provisions; also the share to which each member of the company is entitled.” In technology settings a commons allows for mechanism of sharing in which common ownership can be coupled with disciplined regimes for governing the use of that commons, such as a give-and-get policy. Crucially, the term commons is suggestive of older notions of the common good or common-wealth. Originally, the term commonwealth literally referred to notions of “common well-being.” In common usage today, however, the term refers to a democratic state in which matters of common well-being have been putatively invested. Given the global and trans-institutional character of contemporary biotechnology, and given the ways in which biotechnology is ramifying across multiple domains, the BIOFAB should ask: who are the publics that are likely to experience open technology platforms as a matter of common good, and which are likely not to?</p>

Encumbrance	In intellectual property settings an encumbrance denotes proprietary restriction: the ability of a one property holding party to limit other parties proprietary uses of the intellectual property in question. Less formally, an encumbrance can be considered as a factor that complicates, impedes or restricts action. One of the crucial challenges that must be addressed in the BIOFAB is the fact that encumbrances to the development of open technology platforms, encumbrances to placing work in the public domain, are only partially a matter of designing new forms of intellectual property. It is also a matter of developing frameworks for assessing and addressing the habits, dispositions, inertia, and trained expectations of researchers and research institutions alike.
Framework	In policy settings a framework formalizes parameters for making judgments. More broadly defined, a framework is a way of describing a situation that facilitates diagnosis and justifies action. Frameworks, taken in this broader sense, consist of key claims about the character of a situation, the identification of crucial problems, the proposal of particular goods as a metric for determining which matters are most pressing, and, in light of these metrics, a set of parameters for taking appropriate actions. In this way, frameworks work to select specific events, actions, and relations and configure them as uniquely important.
Parameters	Given the unsettled and encumbered character of the current intellectual property situation in synthetic biology and in the BIOFAB in particular, a crucial next step is the formulation of a repertoire <i>parameters for discernment and direction</i> . When connected to key metrics (e.g. the amelioration of health, the fostering of scientific curiosity, contributions to human flourishing, etc.) parameters can provide points of orientation and indication, and therefore can serve as initial guides. In this sense, parameters should be <i>directive</i> in character, serving to equip individuals and institutions to face unknown futures in a manner that can be taken seriously scientifically, jurisdictionally and ethically.

Context: Why it's Difficult to Give Things Away

The BIOFAB's proposal to make its work products free-to-use is strategically consistent with the long-standing stated aims of its host organization, SynBERC (SynBERC, 2006). The proposal is discordant, however, with the institutional and practical contexts within which both SynBERC and the BIOFAB are situated. Despite its stated aims, SynBERC has not actually made much progress on developing a framework for circulating open technologies. Many of the variables which have encumbered efforts in this direction are likely to affect the BIOFAB's efforts as well.

These variables consist, in part, of legal uncertainties: which legal mechanisms will ensure that biological data and materials that have been declaratively put in the public domain will prove beneficial to downstream proprietary and non-proprietary users alike (Rai and Boyle, 2007; Krikorian and Kapczynski, 2010)? What guarantees that industrial actor won't have to rework their business models, which they actively resist? And what assures non-proprietary actors that the objects they get or give from the public domain will actually remain in the public domain?

Uncertainties concerning legal mechanisms are regularly foregrounded as both a principle difficulty, and therefore as a warrant for inaction (Hope, 2008; Torrance, 2010). Such foregrounding often begins with comparisons to developments in free and open software. The

problem of how to give things away in these cases was dealt with, in part, by inventing copyright mechanisms which puts code into free circulation. Moreover, these copyright mechanisms became nuanced in such a way that some ensure that third parties couldn't take downstream developments out of free circulation, and some made code open and hence available, but protected the property rights of developers.

Even where such analogies prove helpful for making connections and comparisons, the invention of legal mechanisms for free software was only one part of a solution to a more basic set of institutional and practical set of difficulties (Kelty, 2009; Pottage, 2008). SynBERC and the BIOFAB will need to sort out similarly basic difficulties before any new legal mechanism—whether predicated on copyrights, patents, or the public domain—might be made to operate in a fashion considered to be worthwhile.

STATED AIMS

SynBERC has stated its commitment to something like a free-to-use approach for circulating the biological objects made in their funded projects. This approach is typically described as “open source.” The founding SynBERC documents state that it will offer its biological “parts, devices, and chassis as open source to other researchers and companies” (SynBERC, 2006).

The term *open* in open source might just mean “accessible” as opposed to “restricted.” Read in context, however, the use of the term open source by SynBERC describes scenarios in which SynBERC's work products would be free for other to use, with *free* meaning both not costing anything as well as available without legal encumbrance.

This difference between *accessible* and *free* is evident in the stated rationale for the inclusion of this aim. This rationale centers on matters of cost and the rationalization of *innovation* in bioengineering. In terms of costs, orienting SynBERC documents asserted that “many of the most effective biological parts (promoters, genes, plasmids, etc.) have been patented and are available only to those companies that can afford the royalty payments.” Such a situation, it is further asserted, will “increase the cost of drug development and hamper the development of new biological solutions to problems where the eventual monetary payoff is not significant” (SynBERC, 2006).

Contrastively, SynBERC has stated that “open-source biological parts, devices, and eventually whole cells will decrease the cost of engineering biological systems, make engineering more predictable with less guesswork, and encourage the development of novel biological solutions to some of our most challenging problems.” In this regard, SynBERC's core ambition to “lay the foundation for synthetic biology” through its strategy of establishing engineering standards was integrally and crucially linked to a vision for open source circulation of its methods, materials, and data.” It was promised that “all parts, devices, and chassis will be made available through the Registry of Standardized parts” (SynBERC, 2006).

The fact that SynBERC has failed to make much headway in its efforts to realize the stated aim of making its materials, data, and technologies free-to-use has actually had less to do with a lack of available legal mechanisms. It has much more to do with matters of *disposition*, *habit*, and current *norms of professional scientific life*. To the extent that principal actors involved do cite the matter of legal mechanisms as a key concern, the question is really whether or not there are mechanisms for making biotechnical work free-to-use which will ensure and

protect the extension and even reinforcement of *existing* disposition, habit, and current norms of professional scientific life (SynBERC, 2011).

The work of changing dispositions, habits, and norms would, of course, be partially facilitated by the invention of new and better legal mechanisms for free-to-use biotechnology. Such mechanisms alone, however, would fail to address a range of other current difficulties connected to ownership and sharing in synthetic biology. As the BIOFAB moves forward, these extra-legal difficulties will need to be formally raised and given strategic consideration.

INSTITUTIONAL DIFFICULTIES

Since 2006 SynBERC has continued to include the language of open source and notions of free use as part of its official materials and stated aims. Over this period tensions between these statements and the actual of practices of the Center's administrators and researchers has become increasingly evident.

The tensions are generated by a number of factors. A first concerns institutional setting (*see table two, row 1*). SynBERC consists of six member universities. Each of these six has distinct policies on intellectual property and technology transfer. And each university claims ownership of the work conducted by researchers at their institutions.

Differences across these institutions have not been reconciled, and SynBERC has not become a "one stop shop" for IP, as its industrial partners would want. The 2010-11 SynBERC report explains that "all IP developed through SynBERC-funded (and SynBERC associated) research by individual PIs (and their students and post-docs) remains the property of the PI's home institution." The report also stresses that "because of the relatively small amount of funds transferred to some of the schools, there is very little current incentive to share IP and licensing" (SynBERC, 2011).

The institutional situation is further complicated by the relative immaturity of open source and free-to-use legal schemes for biotechnology, and with the relative inexperience this inevitably implies (Torrance, 2010). Several of SynBERC institutions (MIT and UC Berkeley especially) have longstanding and routinized processes for licensing and distributing software developed by university researchers as both free and open-source. To this extent, the technology transfer offices of these universities would not seem to have an *a priori* objection to the prospect and proposal of open source in biotechnology.

In actual practice, however, TTOs have not yet taken steps to facilitate such a prospect (SynBERC, 2011). Hesitation to do so begins with the simple fact that biotechnology is not customarily licensed under copyright, the legal mechanisms that facilitates free-to-use schemas for software, which universities have developed (Rabinow, 1996; Hope, 2008; Torrance, 2010). In this light, giving away biotechnological work would require legal invention and experimentation. Invention and experimentation the TTOs at SynBERC institutions have not been willing to undertake.

In the case of the BIOFAB and its relation to its primary host institution, UC Berkeley, this reluctance to experiment with developing free-to-use frameworks for biotechnology shows itself in a simple reluctance reconstitute existing habits (Endy, 2010). As described in the summary statement, technology transfer officers are accustomed to making one of two primary decisions in relation to ownership and biotechnology: patent or don't patent. Making work freely

available, by placing it in the public domain, or by some other commons mechanisms, is simply not customary.

If a question of habits, it is also a question of disposition. The decision not to patent is not the same as declaring an object to be in the public domain (Rai and Boyle, 2007; SynBERC, 2011). Declaring an object to be in the public domain is a formal action that entails foregoing proprietary benefits connected to the work in question, derivative works, or other closely connected inventions (Krikorian and Kapczynski, 2010). In the case of the institutions housing the BIOFAB there is not yet sufficient interest in risking either the loss of possible proprietary gains in favor of the distributed benefits of open biotechnology, or in assuming possible liabilities associated with infringing on other patents (Endy, 2010).

In this regard, hopes for free-to-use biotechnology would seem to suffer from the intense institutional pressure TTOs are under to secure as much proprietary advantage for research institutions as possible (Shapin, 2008). Such pressures fortify reticence to experiment with giving technologies away, with all the risks such experimentation might entail.

CAREERS, TIMING, AND REUSE

A second source of discordance centers on questions of concerning the timing of the release of data and analyses, scientific credit, and the realities of career development (*see table 2, row 2*). Few SynBERC PIs or industrial partners have openly criticized the stated commitment to making work freely available. Of course, as one analyst puts it: “everyone agrees that being open is the obvious thing to do” (Kelty, 2009). What is meant by this, and what being open actually requires in terms of changes in practice, and what such changes might entail in terms of career rewards or costs, remains unresolved. As such few PIs and even fewer industrial partners have actively worked toward solutions.

The easy criticism is that PIs simply do not want to forego the possible proprietary advantages of their work. After all, the last two years have seen a significant increase in capital investments in synthetic biology. Such a criticism is warranted in some cases. But the reluctance to actively pursue free-to-use strategies for circulating work is more plausibly explained as a trained reluctance to risk other sorts of losses (Rabinow, 1996; Rabinow and Bennett, 2009; Shapin, 2008).

Early in SynBERC’s development, PIs and administrators alike asked the curators of the MIT Registry of Biological Parts to create a non-open database into which biological components could be placed until they either appeared in publication or were otherwise accounted for in terms of scientific credit. The impulse is consistent with the common expectation of receiving professional recognition for work which is often painstaking, inventive, or costly.

The requests were refused as being contrary to the registry’s effort to foster a get-and-give community of practitioners. The refusal and the subsequent unwillingness of some SynBERC PIs to place their lab’s data in the registry, reflect trained expectations about how to secure credit, authority, and career development in the academic biosciences today (Rabinow, 1996; Rabinow and Bennett, 2009; Shapin, 2008). Such expectations have contributed to reluctance on the part of junior and senior participants alike. Junior participants, of course, understand that career advancement turns more on first-author publication than on public contributions. And senior participants, many of whom have actively engaged in building

synthetic biology institutions, have resisted taking actions that might compromise strategic advantage.

It is worth noting that discussions of open source business strategies in software development frequently emphasize that there is no in-principle trade-off between given things away and making money. It is pointed out that many for-profit companies both develop and use open source software (Hope, 2008; SynBERC, 2011). The difficulty and limit of such comparisons as guides for efforts in biotechnology is that under the current system for securing scientific credit and professional advancement, the risks of such give-aways are likely to be felt most by young researchers.

THE SUFFICIENCY OR INEVITABILITY OF THE STATUS QUO

A briefer note should be made about SynBERC PIs and industrial partners who do, in fact, express opposition to the proposal that SynBERC and the BIOFAB should proceed in an open source or free-to-use manner.

Such opposition has been predicated on several claims. First is that current licensing regimes and practices of sharing, whatever their limitations, nonetheless provide a setting within which the significant capital investment needed to pursue biotechnological innovation, can be assured some hope of direct remuneration. Second is the claim that non-proprietary circulation will therefore scare away potential industrial investment in synthetic biology. Taken together: there is an expressed resignation to the incommensurability of commitments to free distribution and existing commercial practices.

One counter to these claims in SynBERC's official statements has been to point out that their industrial advisory board has expressed a willingness to participate in discussing open source licensing strategies (SynBERC, 2011). And members of the SynBERC IAB have indeed participated in animating initial discussions with SynBERC and BIOFAB researchers. Such a counter, however, risks overstating the practical outcomes such discussions are likely to generate. As one member of the SynBERC IAB publicly put it: "I'm personally in favor of open source. But my company can't be expected to accept it unless you show how it is consistent with our business model." The IAB will support an open or free-to-use approach if it fits with their current plans.

Another response, discussed further in the section on frameworks below, has been to simply refuse the sufficiency of current regimes in terms of their costs and negative ramifications (BIOFAB, 2010; Endy, 2010). This response stresses that current regimes and practices, however seemingly inevitable, nonetheless require researchers to pay too high a price, monetarily and scientifically, a price which is unsustainable over time. The question is whether the *transaction costs* associated with current licensing practices in biotechnology, and the barriers to entry associated with such costs, are actually generating an overall *opportunity cost* in terms of innovation and the advance of technology. Questions of equity and the cultivation of scientific curiosity should be raised as well.

THE NSF ENGINEERING RESEARCH CENTER GOALS

In its 2010 annual National Science Foundation review, SynBERC was called to task for the now-apparent tensions between its stated commitment to a center-wide non-proprietary distribution of its work products and the fact of its institution-specific (hence fragmented) and proprietary approach to managing intellectual property (SynBERC, 2010). The NSF's principle

concern was that industrial actors were unlikely to actively support either SynBERC or synthetic biology until approaches to IP were clarified and made consistent.

The directors of the ERC program informed SynBERC administrators that the Center either needed to provide empirical demonstration of the commercial salience of open source or free-to-use approaches or remove the stated aim from future official materials. This demand applied to the BIOFAB's work as well (SynBERC, 2010).

The ERC's demand did not come as a surprise. The ERC Program, after all, was designed explicitly to support the needs of industry through Federal investment in the development of platform technologies at US universities. Indeed, its long-term strategic aims include cultivating an ethos of commercial application throughout US academic communities. In the case of SynBERC and the BIOFAB, it appears that the ERC directorate accepted the claim that open source licensing and commercial advantage are not, *a priori*, in tension. The directorate, nonetheless, has become impatient for real-world evidence of such advantage in practice.

C.DOG: POLYVALENCE AND TECHNOLOGY PLATFORMS

In the near term, these matters of habit and disposition are likely to continue to be principal encumbrances to the BIOFAB's ability to give things away. In addition to these, however, the BIOFAB is also likely to face difficulties connected to the character of the objects it proposes to put into circulation.

The BIOFAB's *c.dog engineering projects*—efforts for the forward engineering of biology's “central dogma”—constitute the main object of its efforts to foster free-to-use circulation strategies (<http://biofab.org/projects>). Strictly speaking, the *c.dog* projects constitute *technology platforms*. Technology platforms are ensemble of diverse techniques and technologies that have been integrated in such a way as to serve the *basis* for the production of new technologies. Specifically, the *c.dog* projects consist of designed genetic architectures (i.e. “expression operating units”); collections of standardized biological parts consistent with those architecture; characterization data; measurement and analysis protocols; reference objects; database and computer aided design software; and human practices analyses.

A number of factors make *c.dog* platforms especially difficult to give away. First is that although functionally integrated as a *single ensemble*, they are made of discrete and heterogeneous elements. This is a difficulty only insofar as different elements customarily fall under the purview of different property right laws.

Second is the fact that the core elements of the *c.dog* project are collections of parts. These parts do not yet have consistent defining features (e.g. there is not a materially consistent definition of what makes a promoter a promoter and a terminator a terminator). Moreover, the function of each of these parts varies in context—albeit a variability that the BIOFAB is striving to overcome to the extent possible. In any event, this biological under-determination means that the parts in the *c.dog* collections are likely to suffer from the same legal under-determinations that have been faced in gene patents.

Table 2: Encumbrances to Developing an Open Technology Platform

	Key Variables	Challenge	Status
1. Institutional Situation	<i>Few precedents</i> for giving away materials not licensed under copyright;	Designing or adopting mechanisms for <i>non-proprietary licensing</i> ;	University tech transfer offices have established precedents for freely giving

	discordant regimes across multiple institutions; little incentive for mixed-inventor organization to assume possible liabilities	adjusting habituated practices of protecting downstream proprietary opportunities	away software; these precedents suggest that the situation, if encumbered , is not blocked .
2. Timing and Use	Institutional means of establishing the trust needed to conduct research in the face of career pressures have consisted in researcher controlled release and use of data and materials	Whether or not the open source practices of “ releasing early and often ,” which have been a crucial variable in open development strategies, are too risky for young researchers and too at odds with the habits of established researchers	If practices of free and open sharing are to become normal in biotechnology, mechanisms need to be established for assuring forms of scientific credit needed for career advancement; this will be particularly difficult in the BIOFAB where emphasis is on productivity not research.
3. Status Quo	Despite high capital costs advances are being made in biotechnology; moreover, given these costs industry actors are unlikely to invest without negotiated IP; moreover informal research exemptions are the norm	Two challenges: to demonstrate that overall opportunity costs associated with existing IP regimes outweigh proprietary benefits ; to overcome institutional inertia in accepting these demonstrations and changing habits	Arguments-by-analogy to open source developments in software might be plausible, there are not yet persuasive enough to get individual actors to be the first to try them ; in this light consortia of competitors need to be positioned to take risks together
4. NSF ERCs	The NSF ERC program is explicitly designed to support the needs of industry ; beyond analogies, it is not yet obvious to them that an open source approach is feasible and will allow industry to thrive	Shift from case studies of open source in software domains, in which open copyright regimes are robust and engineering at scale allows for multiple proprietary strategies to reports on empirical experiments in biotechnology	The ERC program officers are likely to support open source strategies if industrial partners advocate and help design these strategies; such an approach, however, runs the risk of favoring the status quo needs of current industry rather than the imagined future possibilities
5. Polyvalence	Technology platforms are characterized by the integration of a heterogeneous range of technology types ; moreover various jurisdictional domains and situations treat these technology types as different kinds of legal entities	A key challenge for parts-based bioengineering is to ensure that physically defined boundaries are commensurate with functionally defined characterization . If such bounded characterization is not possible than ontological polyvalence will continue to be a breaking point in IP	Norms of characterization in synthetic biology are already a key technological challenge ; this challenge can be dealt with incrementally . It is not clear if such an incremental approach will be legally salient .

Framing Open Technologies: How the BIOFAB Justifies Its Aims

From the outset, and despite these difficulties, the BIOFAB directors have stressed a desire to make work products accessible and free to use (BIOFAB, 2010). This emphasis has been foregrounded as defining for the BIOFAB's status as a public benefit facility. The emphasis remains a desire, however, and not yet an actual practice. And the demand that the desire be justified continues to be repeated by the BIOFAB's institutional sponsors (SynBERC, 2011).

In justifying its commitments, the directors have framed the need for open technology platforms in terms of the need for rapid distribution and unrestricted reuse (BIOFAB, 2010). Such speed and openness, in turn are figured as a questions of *innovation*, *confidence*, and the development of a *community of practitioners* (see table 3, row 1).

TRANSACTION COSTS FRAMED AS OPPORTUNITY COSTS

Formal statements made by the BIOFAB take as self-evident a strong connection between *transaction costs* and *opportunity costs* in biotechnology today (BIOFAB, 2010; SynBERC, 2011). Transaction costs consist of the time, money, talent, creativity and other resources that must be paid in order to: (a) determine the property status of a given set of materials or data, (b) negotiate for the use of those materials or data once property right holders have been determined and contacted, and (c) contend with the range of uncertainties and vulnerabilities associated with such efforts. Opportunity costs typically refer to a presumed loss of innovations resulting from attendant slowdowns, exclusions and fragmentations.

The specific strategy used for linking transaction and opportunity costs has been to focus on operational dimensions of the current situation in biotechnology and intellectual property: *freedom to operate*, *patents*, *pacing*, and *clarity*, and *foundational blockages*.

FREEDOM TO OPERATE

A first aspect of the current situation concerns the high capital costs associated with engineering biology. These capital costs obviously include the purchasing of tools and equipment and the support of researchers and developers. They also include costs associated with determining *freedom to operate* (i.e. the property status of the materials or systems one wants to work on), as well as potential royalty fees (SynBERC, 2011).

In stating their case to the NSF in support of an open technology platform, the BIOFAB directors have made a strong and central assertion: "The high capital costs associated with engineering biology create a high barrier to entry for new companies and products." This assertion is connected to a second, equally pivotal: "Open source Parts will relieve the burden of FTO searches for all SynBERC members...and allow more products to reach the marketplace in a timely fashion." Such relief will be good for established and new developers alike: "companies DowAgroSciences, Life Technologies, Amyris, Codexis, and others," as well as "spin out companies, Ginkgo Bioworks, Refactored Materials, and Lygos." A subtext to such assertions is that a primary reason not to pursue an open technology platform is that companies may not support it, i.e. its industry that must be convinced (SynBERC, 2011).

PATENTS, PACING, AND UNCERTAINTY

A second aspect of the current situation, which is highlighted by the BIOFAB directors, concerns the cumbersome and uncertain character of current proprietary regimes (especially patenting) for biotechnology (Hope, 2008; Torrance, 2010). Although acknowledging that "over the last 30 years, patents have been used to define important property rights underlying the terms

and conditions by which biological components can be shared and reused,” the official BIOFAB proposal argued that “the rapid growth of collections of standard biological parts,” is likely to outstrip “the capacity of existing patent-based frameworks to recognize and protect each part” (BIOFAB, 2010).

As an example they cite the growth of the iGEM competition. In 2008, 1,500 new BioBrick parts were contributed to the MIT Registry: “Protecting and sharing these parts using patents would have cost ~\$35,000,000, which is roughly 10-fold greater than the total worldwide iGEM budget.” In this regard, establishing patent protections for newly developed genetic elements are likely to be as costly, slow and uncertain as clearing FTO on existing materials (SynBERC, 2011).

Add to this that property rights on functional genetic elements can often be over-determined in their underlying ontological implications (*see table 2, row 5*) (Pottage, 2006). The function and value of a given genetic element depends on a range of contextual variables. Such variability raises a host of questions. What is it, exactly, that a patent on a given sequence protects? Does a given patent pertain to the sequence per se or to the function or functions associated with that sequence? Can the relation of sequence and function be distinguished well enough to protect the latter, while leaving the former free of encumbrance to other researchers? Is the value and proprietary distinctiveness of functions associated with a sequence actually dependent on a more complicated ensemble of activities such that patents shouldn’t be grounded on sequence per se? Do patents apply to a material instance of a genetic function? To data? To use? It is not surprising that, the range and legitimacy of patents on raw genetic data has been questioned for more than two decades.

Recent court decisions undoing gene-specific patents increase the lack of clarity. Add the fact that various jurisdictional frameworks define the limits and applicability of gene-patents in relation to a varying range of interests and the scope of legal uncertainty widens further (Pottage, 2006; Rai and Boyle, 2007). Given the fact that definitions of what counts as a standardized part remain unsettled, and the question of whether specific physical boundaries at the level of sequence are adequate to circumscribing functional activity at the level of expression, the objects made by the BIOFAB are likely to suffer these same uncertainties.

FOUNDATIONAL BLOCKAGES

A third and related aspect follows. Although addressed less directly in formal BIOFAB documents and statements, this third aspect has been crucial to notions of openness and parts-based synthetic biology in other settings (e.g. the BioBricks Foundation; iGEM). A parts-based approach to bioengineering, such as the one pursued by the BIOFAB, is predicated on the notion that sets of standardized parts can provide the basic units of composition for genetic engineering (Endy, 2005; Baker *et al.*, 2005). The construction of such sets is thus oriented toward establishing a foundational capability: being able to functionally compose individual parts in an *additive fashion* to the end of *rationally engineering* higher levels of functional complexity, even *genome-scale functionality* (SynBERC, 2011).

Such a proposal is implied in the use of abstraction hierarchies such as the SynBERC “parts,” “devices,” “chassis.” More to the point, it is the core assumption of the BIOFAB’s work (<http://biofab.org/projects>). The BIOFAB is not only working to produce sets of standardized parts; it is working to refine those sets in such a way that they function as the basis for operations, which are imagined on the metaphor of cellular operating systems.

The biological feasibility of such an operating system remains an open question (Purnick and Weiss, 2009). In the meanwhile, the effort to license and circulate such putatively basic sets of parts continues apace. The BIOFAB directors emphasize the foundational position of such sets within bottom-up composition schemas when arguing the need to *maximize* and possibly even *ensure* the c.dog projects' open circulation.

The worth of the parts-based approach, in the end, will of course be judged worthwhile or not worthwhile to the extent that it facilitates the design of biological systems capable of contributing to the resolution of real world problems. How such a technology platform, if actualized, is made available will contribute to determining whether and to what extent such an imagined future is becomes possible.

THE PUBLIC DOMAIN: FACILITATING COMMUNITIES OF PRACTITIONERS?

The translation costs of clearing FTOs, the cumbersome and over-determined character of current practices in patenting, and the foundational character of standardized parts in relation to engineering complex systems: these three have been cast by the BIOFAB as converging to bring about a significant *opportunity cost* in terms of lost innovation (Endy, 2010; SynBERC, 2011).

Lost opportunities for innovation, in turn, are connected to lost opportunities to ameliorate health and security as well as failure to realize opportunities for commercial prosperity. Encumbrances to speed and breadth of circulation, in short, are cast as encumbrances to health, wealth, and security (BIOFAB, 2010; SynBERC, 2011).

Non-proprietary mechanisms for licensing and circulating the BIOFAB's parts, data, and software are asserted as a crucial step to decreasing such opportunity costs and thereby indirectly increasing innovation (BIOFAB, 2010). This assertion echoes advocates of open source regimes in software development who typically foreground the *advantages to development* facilitated by unrestricted or under-restrictive access to source code (Hope, 2008; Kelty, 2009).

The key idea is that open source development allows for a *broadly distributed and self-selected community* of user-developers whose creativity and energy can be *focused*, even if not directly managed. A crucial aspect of these open development strategies—an aspect that tends to be underplayed by advocates—is that they are effective in large part because of the disciplined processes by way of which innovative contributions are re-integrated into the original platform. That is to say, open source as a strategy for development actually requires a disciplined combination of open and closed practices (Kelty, 2009).

The notion and prospect of an *open* technology platform for the BIOFAB is ultimately oriented to notion and prospect of such a community of user-developers for biotechnology (Endy, 2010). Indeed, the effort to generate the necessary formal conditions for such a community (“lowering the bar to entry”) has arguably been a central aim of a parts-based synthetic biology from the outset and of the BIOFAB's approach in particular (Endy, 2005; Baker *et al.* 2005). In this sense there is a mutually reinforcing relation between the proposal that a parts-based approach will make bioengineering more predictable, less costly, and thereby more accessible to a wider range of designers. Working to actualize the technical possibility of such a lowered bar was central to justifying the BIOFAB in the first place.

The goal of circulating such technologies in an open fashion—however such circulation is ultimately legally and institutionally accomplished—would thus seem to follow. How to do this in a way that assures parts can be used in common and that removes uncertainty about

proprietary status is thus a primary question. And whether or not such open circulation can be governed in a way that facilitates disciplined and responsible engagement a yet again more difficult one (Foucault, 2008; Nowotny *et al.*, 2001).

One interim strategy might be to retain the use of patents, but to design a “viral clause” on biological parts that reproduces the viral clauses that have been crucial to the development of open source copyright schemas in software development. These clauses require that anyone is free to use the materials made available, but must not restrict others from downstream reuse of those same materials. Early attempts to reproduce the viral clause in biotechnology, however, have only intensified the uncertainty and thereby the costs associated with freedom to operate (Endy, 2010).

Another strategy is to declare materials and data into the public domain, i.e. make them available in a more-or-less unrestricted fashion—to create a commons. Such an approach follows the precedents set by the EST (expression sequence tag) and SNP (single-nucleotide polymorphism) consortia (e.g. <http://hapmap.ncbi.nlm.nih.gov/cgi-perl/registration>). In both cases, commercially and publically funded researchers chose to declare their work to be in the public domain given how foundational that work seemed to be to downstream discoveries and applications. In both cases use of the commons which was created, was disciplined by a licensing agreement. Such licensing agreements entailed such requirements as “get and give” provisions. The aim was to assure that researchers using the publicly accessible data could not keep others from using it as well.

The advantage of placing materials and data in the public domain is that it makes them quickly and readily available to a wide community of potential users. The disadvantages include the fact that there is no assurance that materials and data will remain in the public domain (Rai and Boyle, 2007). Researchers can use materials in the public domain to develop derivative proprietary functions, technologies, objects, and processes. Such proprietary developments might result in effectively taking those materials and data out of circulation. Said differently, placing work in the public domain, especially by way of licensing agreements that demand a certain measure of mutuality or reusability does not assure that such work will remain non-proprietary and widely available.

In founding a BIOFAB the hope was that new, more refined, materials and data could form the substance of such a commons through rapid, regularized and ongoing contributions (BIOFAB, 2010). This regularization would be designed to have two effects. The first is a flooding effect whereby a sufficiently renewed repository of materials and data remain in place to sustain the growth of a user community, even if select elements are taken out of circulation by other actors. The second is that the practices of sharing and circulation animated and exemplified by the BIOFAB would stabilize as common practice as the community itself stabilized.

All of which has lead the BIOFAB directors to officially declare that the facility “will not assert ownership of the parts (and information) it contains.” The language of the declaration is worth attending to. The BIOFAB might not declare ownership; but the institutions that sponsor and partner with the BIOFAB just might. And even if these institutions agree to a non-proprietary approach, a failure to claim ownership is not the same thing as legally ensuring a legacy wherein the BIOFAB parts continue to be used, refined, reused, and re-circulated in an unencumbered fashion. To quote the BIOFAB directors: “Non-assertion of ownership does not

imply the user of the part will have freedom to operate. FTO will have to be determined by the Part user until all matters relating to gene patents have been resolved legally” (SynBERC, 2011).

Table 3: Comparative Table of Open Technology Frameworks

The BIOFAB’s framework of justifications for developing an open technology platforms can usefully be compared to other existing open technology frameworks. Two prominent and closely related frameworks are those that justify the pursuit of open technologies in the name of *innovation* and those that emphasize matters of *access*. The innovation framework figures openness and sharing as a solution to a problem of innovation lock-down connected to industrial monopoly and irreducible uncertainty connected to stultified property regimes. It is deliberately cast as non-political in its diagnoses and reasoning. Such casting is, of course, strategic and relies on a conflation of politics and ideology. This conflation constitutes a key limitation of the arguments developed within this framework. The access framework figures openness and sharing as a solution to problems created by the pervasiveness of intellectual property in contemporary life, and the exploitative and domineering exercise of power resulting from asymmetries between those who use and those who own the intellectual property. This framework can be cast as an access framework in that its exemplary articulations have been connected to the so-called A2K (access to knowledge) movement.

	Key Diagnostic Claim	Problem	Parameters	Externality/ Limitation
BIOFAB	Transactional dynamics of work with genetic materials are often costly, slow, and uncertain.	Such dynamics are generating opportunity costs by raising the entrance bar, restricting the growth of a community and thereby slowing innovation .	Ownership and sharing regimes are needed that provide confidence that materials are freely available, and can be used, re-used, and re-circulated without fear.	Does not foreground the advantages and successes of current regimes . It has not yet determined whether openness needs to be moderated and even off-set.
Innovation	Two claims: given high capital costs, large biotech companies hold a near monopoly on crucial IP; IP in biology is fragmented and over-determined.	Large biotech companies have an incentive to stifle innovation through protectionism ; fragmentation in IP generates multiple levels of uncertainty .	Metrics shift between an idealization of non-proprietary , problem-driven research and the development dynamics of open source .	Externalizing advantages of current IP regimes , this framework tends toward a “politics of purity” in which open source is not only advantageous but good, its critics unreasonable and malicious .
Access	The contemporary world has become an “ information culture ” saturating bodily life; meanwhile IP has been intensified and consolidated .	Questions of IP are considered questions of power and control of IP and access to the goods of information questions of freedom and empowerment .	Given the strategic importance of IP, access to information is cast in terms of rights and denial of access in terms of injustice .	Epochal claims about the significance of IP for “life today” externalize the heterogeneous character of actual practices of sharing and ownership; this reinforces a strong politics of purity and malice

Strategic Guidelines: Tensions, Directives and Parameters

Despite the BIOFAB's formulation of a framework for justifying the development of its open technology platform, several points of tension remain. These points of tension concern persistent use of analogies, the under-determined character of its relation to partner institutions, and a lack of specificity with regard to questions of responsibility. The BIOFAB will need to forthrightly address these tensions if it is to establish and follow strategic guidelines for circulation, guidelines that can be judged worthwhile not only legally, but scientifically and ethically as well.

THE BIOFAB AND THE LIMITS OF ANALOGY

The first point of tension concerns a tendency to rely on comparisons to open source practices in software development as a means of explaining and orienting the BIOFAB's position.

One of the key lessons learned in the first year of the BIOFAB's operations is that in practice such analogies simply do not apply. They do not apply in the first place because licensing and circulation strategies for open source and free software can be licensed and circulated rely on the use of copyrights. As previously noted, copyrights are not currently used to protect the biological data and materials.

The analogies do not apply in the second place because these licensing and circulation strategies were animated and refined in relation to technology platforms that were mature enough to work as designed. Advancing the rudiments of such maturity for parts-based bioengineering is principal goal of the BIOFAB and cannot yet be taken for granted.

Despite this, in its official statements, the BIOFAB continues to cite examples of open source developments in computer engineering as warrant and orientation. Such examples are evocative and allow for the BIOFAB directors to argue that open source strategies are not, *a priori*, antithetical to proprietary strategies. In the 2011 annual report, for example, the BIOFAB directors wrote that "Google uses open source server software to backend its profitable advertising network, Verizon uses the open source Android operating systems to sell mobile phones, and IBM uses open source server software to sell server hardware" (SynBERC, 2011).

Such facts are no doubt true. Their introduction, however, covers over an important lesson: that analogies have their limits, and that in order to move forward effectively and responsibly the BIOFAB may need to leave such analogies behind.

THE BIOFAB AND ITS STRATEGIC PARTNERS

If the first defining parameter of the BIOFAB's self-definition as a public benefit facility is that it will make its work freely available, a second is that it will "serve as a worldwide examples for how partnerships and sharing" can thrive between and among other research institutions as well as biotechnology companies (BIOFAB, 2010).

In its 2011 report the BIOFAB describes this second parameter in terms of "BIOFAB network projects" (SynBERC, 2011). Such projects, the report explains, seek to "promulgate a public private partnership model wherein many otherwise competing organizations can work together to advance synthetic biology to benefit all people and the planet." Cited examples of these otherwise-competing-organizations include industrial partners such as DSM Delft, other university partners such as Imperial College London, and state-sponsored laboratories such as the Beijing Genomics Institute.

The notion that the BIOFAB can model partnerships that overcome differences between otherwise competing organizations is predicated in part on the notion that the technology platform which the BIOFAB is producing will be good for everyone (SynBERC, 2011). As such, competing organizations can put aside other differences or sources of tension and contribute commonly to the BIOFAB's advance.

A key assumption of such advance, of course, is the expectation and possibility of being able to make the work of the BIOFAB freely available to commercial and research-oriented partners alike (BIOFAB, 2010). To this end, the BIOFAB has included the participation of the BioBricks Foundation as a key organizing partner. Indeed, the BioBricks Foundation has taken over the organization of the BIOFAB's institutional partnerships and the coordination of its fundraising activities.

A crucial aspect of the BIOFAB's relation to the BioBricks Foundation is the Foundation's longstanding work on developing "a framework by which collections of standard biological parts can be openly developed, and the resulting parts freely shared and distributed with full recognition of the law," the BioBricks Public Agreement or BPA (BIOFAB, 2010).

The BPA presents a first experimental attempt to design formal mechanisms for declaring engineered biological parts to be part of the public domain. An important proviso of the BPA, which the BIOFAB has emphasized in describing its relation not the BioBricks Foundation, is that it is an "opt-in framework." That is to say, "BPA does not require users to "giveback" derivative works, so that novel inventions based on BPA-protected parts can be patented if needed. Instead, the BPA-covered parts collection will grow over time as the community grows, and as government and industry sponsored facilities such as the BioFab contribute new free-to-use parts" (BIOFAB, 2010).

The fact that the BPA is opt-in is taken to be strategically worthwhile for two reasons. The first is that such an opt-in framework is likely to "ensure its compatibility with the existing patent-based system used in biotechnology today." The second is that such a framework is likely to "support contributions of patented and otherwise not-yet-protected uses of biological materials" (BIOFAB, 2010).

The BPA, in this regard, provides a means of facilitating contributions to the public domain while still maintaining "a neutral posture with respect to intellectual property rights." The BIOFAB, in other words, is willing and able "to support many additional partnerships with additional academic and commercial entities, some of whom might hope to work with the BIOFAB in developing both improved open access and propriety parts" (BIOFAB, 2010).

One year in, it is not at all clear whether the principal sponsoring organizations (i.e. UC Berkeley, LBNL, and Stanford) will allow the BIOFAB to use the BPA or an equivalent declaration to place its work in the public domain (Endy, 2010). Even in the event they did, it is also not clear whether or not the mechanism would provide favorable results. The reason is that it remains an open question whether an opt-in commitment to open access and free-to-use distribution will provide the level of consistency and clarity needed to move forward in a collaborative fashion with those institutions who choose to opt-out.

Said differently: an opt-in framework risks introducing contradictions into operational heart of the BIOFAB's efforts to create a community of users characterized by practices of openness and sharing. And given that the BIOFAB's relations with many in its proposed network

of partners remain under-defined and not yet settled, it cannot be determined in advance whether or not such a risk is worth taking.

As explained above, for the NSF ERC program, time is running short on resolving the question of whether and how the BIOFAB will be able to make its work freely available. For the ERC, the needs and interests of the biotechnology industry are paramount. And if a “roadmap” for openness and sharing cannot be developed which will be adopted by SynBERC’s and the BIOFAB’s industrial partners, the NSF will insist that the BIOFAB drop statements about commitment to open.

The demand may prove moot; NSF funding may simply expire before such a roadmap could be developed, were the design of such a roadmap even to be attempted. It is worth asking, despite this short funding timeline, whether or not the BIOFAB directors should be putting the terms of the situation the other way round. Rather than dropping a commitment to openness and sharing, the BIOFAB might consider dropping funders and other partners who do not choose to support the development of open technology platforms. Such a firm line, however, might prove to be at odds with the opt-in ethos the BIOFAB has previously endorsed.

THE BIOFAB, OPEN SOURCE, AND RESPONSIBILITY

The proposal that synthetic biology should be predicated on a commitment to openness and sharing was articulated early on by the organizers of the MIT Registry of Standard Biological Parts, the BioBricks Foundation and the iGEM competition. It was subsequently reiterated and advanced as a defining aim by SynBERC and the BIOFAB.

This informs SynBERC’s stated commitment to making materials, data, and know-how widely and freely available. Such a commitment is put forward as both an organizing norm and as a key virtue (SynBERC, 2006). It has also been cited as synthetic biology’s principal danger, however (Bennett *et al.*, 2009). Indeed, concern for biosecurity and biosafety was a key part of the NSF deciding to require the inclusion of anthropology and ethics as a formal and integrated part of SynBERC research structure.

In light of this apparent tension between making work products and know-how freely available and the problem of biosecurity, organizations such as the BioBricks Foundation have stated their intention to cultivate “responsible use of technologies” based on standard biological parts. That responsibility is important would seem to go without saying. What it might consist in is far from settled.

The term responsibility has had two primary meanings. The first centers on imputation of cause or consequence—the question “who is responsible for this?” The second centers on taking accountability—the question “who intends to take responsibility?” (McKeon, 1957; Ricoeur, 2000). In light of this two-fold meaning, a question that needs to be answered as the BIOFAB proceeds to make its data freely available (and the BIOFAB is proceeding) is: what responsibility does the BIOFAB have for the possible negative ramifications of its work?

The BioBricks Foundation website stresses that: “Any individual or organization is welcome to design, improve, and contribute BioBrick™ standard biological parts to the Registry.” The BIOFAB website lacks a similarly explicit invitation. But its data access client makes it implicitly clear that the BIOFAB is equally prepared to make its work products available to anyone interested in and capable of downloading, analyzing, and using them.

FROM RESPONSIBILITY TO PARAMETERS

The tensions involved in the BIOFAB's defining commitment to openness and accessibility is generating the now-familiar uncertainties connected to the development of new technological capabilities (Luhmann, 2005).

One unanticipated site of that uncertainty is the relation of the BIOFAB experimental team to their own work. Because the BIOFAB's policy on circulation has not been settled either in-house or in relation to its primary collaborative partners, BIOFAB research cannot be confident that they will be allotted the first opportunity to analyze data and propose models and improvements. In this way they cannot be confident that they will be able to secure sufficient scientific credit for work done.

That such uncertainty is already being felt within the BIOFAB only underscores the central importance of taking decisive steps to act responsibly. As a number of social scientists have shown, such steps are unlikely to produce the means for eliminating or even governing such uncertainties. They might, however, provide a means of establishing a directed and determined course of action in the face of such uncertainty.

I close this report by offering a table of parameters as initial guidelines that the BIOFAB might consider as it moves forward in the development of such directive plans for the release and circulation of its work. To this end, these parameters are formulated in a directive and declarative tone. They should be read as points of orientation, indications of how responsible action might be more adequately realized in face of unknown futures (cf. <http://anthropos-lab.net/arcstudio/>).

Table 4: Candidate Parameters for BIOFAB Distribution

Parameter 1. Facilitate Restless Experimentation	The BIOFAB should not be satisfied with declaring its work to be in the public domain. From the outset, work should be designed and distributed in such a way as to <i>facilitate restless experimentation</i> . All three terms are crucial. To <i>facilitate</i> means both to make easier and to assist or aid. Meeting a criterion of facilitation thus requires producing a technology platform of a certain quality: one that simplifies work and makes it better. The term <i>restlessness</i> means both continual motion and active discontent. Taken as a virtue-term restlessness is a counterweight to both perfectionism and easy satisfaction. The BIOFAB should release its work in an ongoing fashion and should quickly move to improve upon it. Experimentation is a matter of engaged production, clarification and rectification. In an unsettled situation, experimentation proceeds through recursive efforts of diagnosis, inquiry, testing, and determination. Creating mechanisms to aid in such efforts must be made a priority.
Parameter 2. Cultivate Disciplined Curiosity	The free and open source software projects cited as exemplary by advocates of open biotechnology are marked by the fact that freedom and openness were always means as well as ends. Said differently, exemplary projects not involved open, self-selective, and participatory communities of users and developers; they also involved disciplined and often closed practices for designing mechanisms of distribution and vetting of reworked elements. Such disciplined cycles of openness and closure allow for (though don't guarantee) several worthwhile outcomes. They allow participation while also protecting against the dissipation effects of treating all participants as though they were equally capable of meaningful contribution. They invite contributions, while creating minimal quality thresholds, thresholds which require participants to exercise a measure of labor and capacity-building. Most importantly, they prevent univocal commitment to <i>access</i> from washing out spaces of <i>disciplined curiosity</i> crucial for scientific advance.

<p>Parameter 3. <i>Prioritize Mutuality</i></p>	<p>If the BIOFAB is to contribute to fostering a community of practitioners worthy of the name, it will need to conduct its work in a fashion that makes <i>mutuality</i> a <i>priority</i> both internally and in relation to external partners. In the context of new experimental undertakings such as synthetic biology the term <i>mutuality</i> carries two meanings. The first involves exposure to risk and is often discussed in connection with ownership and sharing; the second involves reciprocity of responsibilities and privileges is often overlooked. The first meaning of mutuality concerns the fact of sharing or holding something in common between two or more parties. Mutuality, understood in this sense, is can simply refer to contracted arrangements: a formal assurance shared responsibility or fair-play. It is a formal assurance that vulnerability (an enemy of commitment and excellence) will be minimized to the extent possible. The second meaning concerns matters of virtue. When referring to an affect, action, or undertaking involving two or more persons <i>mutuality</i> means <i>reciprocity</i>. Taken in this sense, we can say that the BIOFAB should produce and circulate its work in a way that ensures a symmetrical exchange of goods, services, obligations, privileges, and respect.</p>
<p>Parameter 4. <i>Guard Against Exploitation and Futility</i></p>	<p>Producing and circulating work in a fashion that prioritizes mutuality requires actively guarding against <i>exploitation</i> and <i>futility</i>. Exploitation concerns the exercise of power in a situation where there is an asymmetrical relationship. Given the relative immaturity of practices of openness, sharing, and mutuality in biotechnology, junior participants (institutions as well as individuals) are more likely to be at risk of exploitation. Exploitation could mean the loss of opportunity for financial gain, the loss of scientific credit, or simply a situation in which contributions are made and rewarded disproportionately. Situations in which exploitation is likely or even possible generate the sense that one's efforts will ultimately prove useless or ineffective relative to a specified set of expectations. Among such a set are the expectation that the goods produced by a situation will be enjoyed in a fair or even generous manner. The BIOFAB must actively work to counter the sense that hoped-for outcomes may be futile. Among such hoped-for outcomes are those already articulated here: that experimentation will be facilitated, that disciplined curiosity will be cultivated and that mutuality will be prioritized.</p>

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