Managing Innovation: A Social Benefit Analysis of Patents and Alternatives

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Synthetic biology and biomedical research raise many complex legal, ethical, and pragmatic issues related to how intellectual property law and practice influence innovation, impact technology, and ultimately alter society. After a review of relevant literature and our own experiences, we find that the current intellectual property-centric approach to innovation management has become destructive of its objectives, hampering innovation and systematically limiting access.

Given the rapid emergence of uniquely challenging new fields like synthetic biology that bear enormously on the public good, our innovation management process urgently demands fundamental renegotiation. Within our legal framework, there should at minimum be several new infringement exemptions, more careful distinctions between the patentability of completely novel and naturally derived "innovations," and stronger limitations on the ability of patent-holders to exclude others from exploiting a technology when they are not adequately developing the technology themselves, among other reforms, and the entire intellectual property regime should eventually be replaced with a reward system. Further, independent organizations like Openwetware and the Biobrick Foundation can do more to improve their impact on synthetic biology while serving as laboratories of innovation for testing new methods of promoting innovation that can be generalized to other fields.

I. Intellectual Property

In the United States, awarding intellectual property rights to innovators is the principal mechanism by which marketable innovation is incentivized. The form of intellectual property used to protect technological innovation is the patent, which operates by granting its owner the temporary right to exclude others from making, using, or selling the protected innovation.[1] While actual private property is naturally rivalrous and exclusive in that the right to exclude others from using one's private property is necessary to fully owning it, "intellectual property" is nonrivalrous and nonexclusive, and does not exist naturally, but is an artificial legal construct deployed to produce social benefits. This utilitarian incentives-based justification for intellectual property, not a natural rights conception, is consistent with the constitutional framers' intent: "The Congress shall have

[1] U.S.C.A. § 261

power . . . To promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries,"[2] which, for technological innovation, has been given its current legislative embodiment in the form of the patent.

Thomas Jefferson forcefully and eloquently rebutted the natural rights theory of patent when he wrote that "If nature has made any one thing less susceptible than all others of exclusive property, it is the action of the thinking power called an idea, which an individual may exclusively possess as long as he keeps it to himself; but the moment it is divulged, it forces itself into the possession of every one, and the receiver cannot dispossess himself of it. Its peculiar character, too, is that no one possesses the less, because every other possesses the whole of it. He who receives an idea from me, receives instruction himself without lessening mine; as he who lights his taper at mine, receives light without darkening me . . . Inventions then cannot, in nature, be a subject of property."[3]

From a social benefit standpoint, patents are only justified if they are the best way of producing societal benefit from innovation. A patent is essentially a bundle of rights including twenty years (up to twenty-five years for drugs, medical devices, and additives[4]) of monopoly privileges on using the invention with no obligation to exploit or develop it, providing a reasonable expectation of profit to the patent-holder when the technology is marketed under conditions of monopoly pricing.[5] Further, patents themselves can be bought and sold as property, thus allowing the transfer of their

[2] U.S. Constitution, Article I, Section 8, Clause 8
[3] Jefferson, Thomas. "To Isaac McPherson, August 13, 1813." *The Writings of Thomas Jefferson*. Vol. 13. Thomas Jefferson Memorial Association of the United States, 1903. 333-34.
[4] 35 U.S.C. § 156
[5] 35 U.S.C. § 154

exclusive rights after the innovation has already occurred.[6] It seems counter-intuitive that the optimal way to produce societal benefit from technologies would be to give inventors the right to prevent others from using them. As a legally defended monopoly privilege, every patent issued is functionally an *anti-right* for everyone else in the patent jurisdiction, regardless of independent creation or discovery. Further, the rights bundled in a patent do not intrinsically reward the inventor, only generating financial gain under certain conditions that are often unrelated to social value, allowing their exploitation for profit with minimal or negative social utility by whoever happens to own the patent, which is usually not the inventor.

Social benefit is the ultimate value consideration to be upheld when negotiating the limits of our contrived "intellectual property" abstractions. Properly conceived, institutions and incentive structures should be configured to maximize socially beneficial innovation and maximize access to that innovation, a means to the end of promoting creative progress. As with all other social institutions, when the patent system becomes destructive of the ends it was meant to serve, we need to alter or abolish it.

II. Failures of Patent

Theoretically, the U.S. intellectual property system offers incentives for innovation by providing a temporary monopoly in the form of a patent to innovators. To understand a legal right to exclude as a functional incentive to innovate requires several assumptions about motivation, innovation, and society, including that an innovator is principally motivated by rationally self-interested profit-maximization, that the inventor benefits from the patent issued, that self-interest produces the most societally beneficial kinds of innovations, and that the best distribution model for the patentable technology is

[6] 35 U.S.C. § 261

under conditions of profit-motivated monopoly.

However, each of these foundational assumptions is demonstrably false in many important contexts. Innovators are not always rationally self-interested, many of the most impactful innovations arise from altruism or other forms of motivation, patents often become the property of the innovators' employer instead of the actual innovator or are otherwise transferred, many patented innovations are profitable despite negative social utility, and access to patented technologies is distributed along systematically unjust lines of market marginalization. Further, the nature of the innovation is substantially altered by the structure of incentives in which it is produced, as a pure profit-maximizing approach drives the creation of things that people are able and willing to pay for, not things people desperately need but cannot afford. Also, it creates enormous incentive to market "hot" technologies as rapidly and widely as possible at the temporarily guaranteed monopoly price before the full societal effects can be known, increasing the magnitude of risks associated with swift technological progress.

Further, many of the most pressing problems facing humanity do not have profitably marketable solutions. In the "neglected diseases" problem, therapies for diseases that affect primarily impoverished populations will be relatively under-developed and under-distributed by profit-motivated firms because doing so is not as profitable as marketing easier-to-develop drugs for people who can pay. For example, although tropical diseases account for 11.4% of the global disease burden in terms of morbidity and mortality, only 1.3% of new drugs in the past 30 years were developed to address them.[7] The needs of large numbers of people facing more urgent problems but

[7] "Diseases and Projects." Drugs for Neglected Diseases Initiative. Web. 27 Sept. 2011. <http://dndi.org/index.php/diseases.html?ids=2>.

who leverage "low market power" are systematically neglected in favor of smaller but more affluent markets. Within biomedical research, this results in a grotesque bias toward marketing drugs that solve much less impactful problems like male-pattern baldness and erectile dysfunction among a moneyed minority because the firms capable of producing these pharmaceuticals are governed by the dictates of the corporate charter to maximize profit for shareholders.

However, even when fully developed and marketed, profit maximization dictates that the patented product will always be under-produced and over-priced because it will be sold at monopoly output and price. This harm can only be avoided in a system in which monopoly rights are not granted.

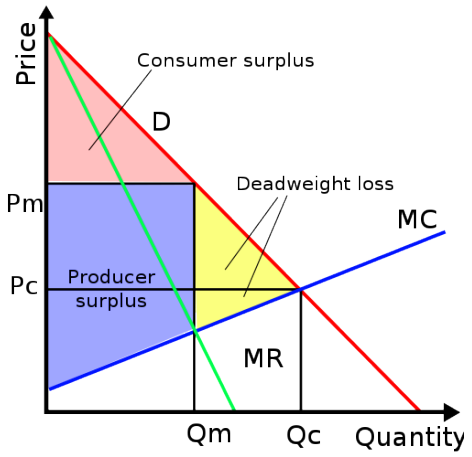

Figure 1: Deadweight loss due to monopoly[8]

Although using intellectual property rights to drive innovation admittedly functions as intended in many instances where the economic incentives offered by a temporary monopoly on commercializing an innovation align closely with societal benefit, it is often the case that patents' financial incentives and the production of socially beneficial innovation are mismatched. When those who profit most from patent rights are not the people responsible for the innovation (e.g. patent trolls, employees who've signed away their IP rights, and when patents are bought, sold, and controlled after the innovation has already occurred), when the profit gained is unrelated to substantive

[8] "File:Monopoly-surpluses.svg." *Wikipedia, the Free Encyclopedia*. Web. 27 Sept. 2011. <http://en.wikipedia.org/wiki/File:Monopoly-surpluses.svg>.

improvement (e.g. the patenting of naturally occurring regions of human genome, arguably the whole field of synthetic biology), or when market failure misrepresents the relative social utility represented by a set of problems (e.g. the neglected diseases problem), the patent system becomes a mechanism for profitable regulatory abuse.

Since financial incentives are strongest where the potential for profit-maximization is highest, patents amplify a systematic bias toward richer markets, maximal exploitation of monopoly privileges, and market-orientation of innovation. Whenever any of these criteria incompletely overlap with the public good, patent-based incentives produce suboptimal outcomes.

In short, patents often accelerate innovation in some areas only at the expense of compounding and exaggerating market failure in others.

Possibly the most extreme example of patents facilitating a mismatch of wealth extraction with social benefit is the non-practicing entity (NPE), more commonly known as the patent troll. Patent trolls are legal firms that purchase large numbers of patents and make profit by prosecuting unwitting infringers. While in the past they may have served some social value by enforcing patents, the social cost of their operations today is enormous in that they create an atmosphere of patent uncertainty, inflict tens of billions of dollars of financial damage to innovators, and ultimately raise the consumer cost of technologies.[9]

In addition to profiting from the losses of others who use certain technologies, the current implementation of intellectual property rights also gives rise to a number of

[9] Bessen, James, Jennifer Ford, and Michael J. Meurer. "The Private and Social Costs of Patent Trolls." Boston University School of Law, 19 Sept. 2011. Web. <http://www.bu.edu/law/faculty/scholarship/workingpapers/documents/BessenJFordJMeurerM091911.pdf>.

problems including patent encumbrance, a form of technological suppression in which a company will deliberately buy up patents for rival products to suppress or reduce competition. One example of this tactic stifling technological progress and causing social harm has been the practice of oil companies buying up patents for high efficiency electric vehicle batteries in an attempt to thwart the development of alternative energy transportation. In 2001, oil giant Chevron bought up and held for several years the patents to low-cost, high-performance NiMH vehicle batteries developed by Ovonics, refusing to license them or sell them in quantities car companies needed, thus influencing a shift toward lithium ion batteries which resulted higher cost and lower performance of battery electric and hybrid vehicles and delayed the large-scale adoption of alternative technologies that threatened their business model.[10] The social costs in terms of artificially prolonged infrastructural dependence on a finite resource, artificially inflated consumer energy costs, and direct environmental degradation are certainly substantial although impossible to estimate accurately.

Especially in synthetic biology and biomedical research, that patents should not enable private interests to hold the future of the fields hostage to their mercenary whims is crucial to preserving the public interest because the topics of research literally concern life-and-death. Although not always as intentionally sinister within the field of biomedical research, many competing claims to rights have the effect of over-excluding other researchers from using certain patentable innovations. Some critics claim this over-fragmentation of IP rights creates a "tragedy of the anticommons in biomedical research," where many firms and individuals exercise exclusive rights on patents that prevent the

[10] *Who Killed the Electric Car?* Dir. Chris Paine. Sony Pictures, 2006. DVD.

use of technologies and deter further innovation.[11] To the extent that the current patent system is directly responsible for hindering research of such critical importance, it has failed to achieve the objective of promoting technological progress.

Further, in synthetic biology, even the applicability of the concept of intellectual property is extremely tenuous because the ideas being patented are inherently simply discovered or slightly altered from genetic sequences that exist in nature. For example, nearly 20% of the human genome is already explicitly patented, and many critics believe that this "land grab" will make genetic diagnostics more expensive, hinder the development of new medicines, interfere with academic research, and discourage investment in downstream R&D.[12] In addition to it being simply unsettling that somehow a handful of companies have acquired exclusive legal rights to information that exists naturally within our bodies, there is a very real concern that this will impose high costs on future innovators, compounding into large social costs as useful subsequent innovations are delayed. Intellectual property law needs to recognize more consistently a distinction between naturally occurring organisms. In copyright law, for example, all discoveries and matters of fact are uncopyrightable, no matter how much work was required to discover them. In patent law, it was only after the controversial case of *Diamond v. Chakrabarty* that engineered living organisms became patentable, as long as "[the inventor's] discovery is not nature's handiwork, but [the inventor's] own." This is a problematic distinction because "synthetic biology" is almost always the slight

[11] Heller, Michael A., and Rebecca S. Eisenberg. "Can Patents Deter Innovation? The Anticommons in Biomedical Research." *Science* 280.5364 (1998): 698-701.

[12] Jensen, Kyle, and Fiona Murray. "Intellectual Property Landscape of the Human Genome." *Science* 310.5746 (2005): 239-40. Web.

modification of "nature's handiwork," merely changing or adding a genetic sequence in an otherwise natural and inordinately complex biological system. Even the most radically re-inventive synthetic biology projects, such as J. Craig Venter's "synthetic life," cannot be properly understood as the "the inventor's own handiwork" since this was still a sequence written that requires a naturally derived cell to actually construct it. Patent law as currently formulated does not adequately address the unique challenges presented by synthetic biology.

III. A Conceptual Framework for Evaluating Innovation Incentives

Sensible innovation policy should begin with the end result of social benefit in mind and recognize that not all technological innovations are created equal. While some innovations are the calculated products of a firm's self-interest, some spring from genuine altruism or pure curiosity. Some concern matters vital to the public interest while others have more frivolous applications. While some patents carve out entirely new technological fields, some are trivial. The ultimate goal of any innovation management scheme should be to maximize the development of socially beneficial technology.

Ethically, there should be a distinction between patents on innovations that hold enormous relevance to the public good and those that do not. Since a patent is by definition the right to exclude others from using a useful invention, it is theoretically possible for enormous public harm to be inflicted when patent-holders under-produce the protected innovation. Not only is this the core business model of patent trolls, but it is also used by companies to suppress superior technology that threatens to make their product obsolete, causing enormous public expense.

Given that technological innovations span an enormous range of originating

motivations, public relevance, inventive magnitude, and subject areas, the current incentive scheme is suboptimal. The only categories of patents currently recognized are utility patents, design patents, plant patents. Synthetic biology occupies a unique niche within these criteria: every synthetic biology experiment has the potential to alter the biosphere unpredictably, fundamentally, and indelibly because the products are self-replicating and interact in new and unforeseeably complex ways with the ecosystem; even the most radically synthetic organisms to date cannot be properly understood as "the inventor's own handiwork;" and motivations for research in it span from altruism to pure curiosity. Intellectual property practice (like our current patent practice) that is indifferent to the implications and nature of the discovery while assuming self-interest and the same brand of inventiveness will not promote synthetic biology in a socially optimal manner.

Many institutions attempt to fill the gaps in the market-based free-enterprise approach to innovation. Non-profit organizations distribute generic pharmaceuticals in areas the market has neglected as unprofitable, governmental organizations fund basic research in areas that are not immediately profitable, and creative commons organizations like the BioBricks Foundation help promote an open interchange of ideas in a research area often riddled by trade secrecy and patent thickets. This sort of vigilante approach plays a vital role in enhancing openness, but is inherently patchy in its coverage, is often less effective at producing wide-scale distribution, and is crowded out by better-coordinated and more heavily funded private enterprise. Further, the innovations produced by public-interest researchers and inventors are often gobbled up and appropriated for profit by self-interested firms that then restrict access to those innovations, creating a worst-case scenario incentive-to-innovation matching.

IV. Relation to Our Research Experience

Our project involved designing and synthesizing a novel genetic sequence for expression in yeast at wound-sites with the aim of accelerating wound healing in humans. A crucial genetic part used in our project was a bi-directional promoter in a patented sequence.[13] Although we were able to obtain permission to use the sequence from the patent-holders after personally contacting them, we are prohibited from sharing the sequence of that part on the registry or in our paper by Openwetware rules, changing our construct design to a different, naturally occurring bi-directional promoter instead. Patent-holders do not have to give the permissions we received, and have the legal right to sue anyone who uses their protected inventions without permission for anything beyond the "very narrow and strictly limited experimental use defense" for "amusement, to satisfy idle curiosity, or for strictly philosophical inquiry."[14]

Further, the real-world impact of our synthetic biology project depends on its relation to the external world of intellectual property. By submitting genetic parts to the BioBrick registry, we have entered our work into the public domain, which effects later patentability of related innovations. Because pharmaceutical corporations are obligated to maximize profit, and because the inordinate cost of developing new pharmaceuticals and having them approved prevents them from developing drugs that don't have a high likelihood of profitability which can only be sufficiently protected by patent, companies will not develop drugs deemed insufficiently patent-protectable.[15] In order to qualify for a patent, an invention must meet the requirements of non-obviousness, novelty, and

[13] US Patent 7,285,414
[14] *Madey v. Duke University*
[15] 87 Tex. L. Rev. 504 (2008-2009) Unpatentable Drugs and the Standards of Patentability; Roin, Benjamin N.

usefulness, which often has no relation to its public benefit. One standard that can render a drug unpatentable is if it has been disclosed to the public, regardless of whether it has been developed and FDA approved or not.

Since our project involves submitting the key parts of our design into a public domain commons, the current intellectual property environment means that our actions may have been counter-productive, reducing the likelihood that our ideas will ever be translated into reality. In a sense, documenting ideas for prospective therapies in public domain commons such as this makes it highly unlikely that they will be commercialized.

In a system of innovation in which the development of the drug could be effectively funded and pursued without the expectation of profit, for example by subsidizing the FDA New Drug Approval process for suitably promising therapy, this Catch-22 disincentive to discover would not arise.

V. Alternative Models of Innovation Management

The challenge today is to produce institutions that harness alternative innovation paradigms in ways that fully address the new complexity of our current innovative landscape and effectively promote the ethical development and distribution of socially beneficial technologies. This requires a more thorough appreciation for the motivations underlying innovation, consideration of the conditions in which the affected technology will be used and distributed, and considerable creativity in forging innovative forms.

Patent Reform

One strategy is to make small changes to the existing patent system with the purpose of enhancing its original function. In biomedical research specifically, this would entail a number of specific policy adjustments including the promotion of increased

communication between the Food and Drug Administration (FDA) and Patent and Trademark Office (PTO) to curb the extended monopolistic effects of drug reformulation, the creation of new infringement exemptions, and a mechanism by which NPE's can be prosecuted.

The gap between PTO and FDA approval has constituted an extremely lucrative opportunity for regulatory abuse through drug reformulation. When patents on exclusive "blockbuster" drugs expire and cheaper generic versions arise, pharmaceutical companies lose enormous amounts of revenue, generating a substantial incentive to forestall as long as possible the marketing of generic substitutes. They do so primarily through "reformulation" in which a drug is altered in just enough non-substantive ways to technically qualify for a new patent from the PTO while remaining so obviously identical bioactively that previous clinical testing results can be used to obtain FDA approval. Although this practice raises antitrust concerns because the patent process is being abused to improperly extend a drug's market exclusivity, the information gap between the PTO and FDA makes abuse inevitable. PTO has no authority to consult with the FDA before approving a patent, and the FDA does not conduct any analysis of the patent itself, allowing the patent holder to unilaterally certify its legal right to list the patent. Better interaction between the FDA and PTO would make it more difficult for pharmaceutical companies to take inconsistent positions before the PTO and FDA, and protect consumers' interest in access to affordable versions of the discontinued product.[16]

At minimum, there should also be a new set of infringement exemptions for research. Similar to fair use exemptions in copyright law, which allow for a wide range of

[16] Yoshitani, Rebecca S., and Ellen S. Cooper. "Pharmaceutical Reformulation: The Growth of Life Cycle Management." *Houston Journal of Health Law and Policy* 7 (2007): 379-410. Web.

reproductions and circulations of copyrighted works as long as the infringement meets a set of standards of educational value, there should be a more substantial fair use exemption in patent law, especially in bioinformatics for use in education and basic research or when the use being excluded is likely to produce large societal benefit. Although there is technically already a research exemption, in cases such as *Madey v. Duke University* (2002) the courts have drastically limited the research exemption to the "very narrow and strictly limited experimental use defense" for "amusement, to satisfy idle curiosity, or for strictly philosophical inquiry."

The narrow confines of these legal standards at once stifle an untold amount of potentially groundbreaking research while making more lucrative the position of the patent troll who buys up large numbers of patents with or without the intention not of using them but suing those who unknowingly use the patented technology.

There should also, at minimum, be effective legal mechanisms by which non-practicing entities (NPEs) and those who suppress socially beneficial technologies through patent encumbrance can be prosecuted, to prevent abuse of the patent system for ends antithetical to its design.

Direct Research Funding

An alternative model already in practice is that of directly funding research without expectation of profit from the exercise of intellectual property. Government agencies, nongovernmental organizations, universities, and corporations invest resources in basic research for purposes related to enhancing public image, promoting research in the public interest, and a plethora of other splintered research objectives.

One of the core values of a university research experience is that it enables

researchers to pursue lines of inquiry without the consideration of profitability. In the long-run, it usually turns out that the most revolutionary, beneficial, and incidentally profitable technologies were originally developed by people free from the profit motive *and then* deployed and marketed (such as the Internet, whose groundwork was originally laid by public researchers and is now an integral pillar of modern market society, Einstein's theories of relativity which were originally expounded as pure physics but later became enabling principles of the nuclear age, and many modern pharmaceuticals including the majority of AIDS and cancer therapies, which were developed by genuinely altruistic public researchers at public institutions using public funds and later bought up, patented, and sold by pharmaceutical corporations who artificially restrict supply to maximize profits, and so on). The point is that absolute freedom from market pressures when developing original ideas often produces what we in hindsight realize were the most revolutionary, most practical, or even selfishly profitable technological innovations, while starting with the explicit goal of profitability more often than not results in the propagation of more frivolous products.

However, a limitation of this approach is that few organizations have the financial ability to make such long-term and risky investments, and those that do often see their budgets slashed, making research dependent on whether securing funding is politically expedient. Further, without a profit motive, the further development and distribution of an invention into a distributable product is not incentivized. Within a market-based society, this is often the only channel by which the public can access the benefits of a new technology, so publicly developed innovations will often have to be enclosed into private intellectual property to reach the public and serve any social function. This

introduces yet another example of how the patent system is used to produce private profit at public expense.

Reward System

Another approach is to replace patents' financial incentives with direct monetary rewards. Instead of the government granting and enforcing monopoly rights for new inventions, the government directly rewards inventors either up-front or on the basis of sales for their inventions, never granting exclusive production rights. Such a system would retain a profit incentive for inventors while avoiding the many social harms of court-mediated technological exclusion including deadweight loss by monopoly pricing, the massive social burden of intellectual property litigation, and hampered subsequent innovation. Shavell and Ypersele (2001)[17] describe an optional rewards model in which inventors can choose between receiving a reward from the government for passing the innovation into the public domain, or intellectual property rights, proving that such a system is objectively more efficient than an intellectual property model, capturing most of the benefits of intellectual property while avoiding the harms of monopoly pricing.

A variant of this system could be very fruitfully applied to the pharmaceutical industry. The immense cost of sponsoring a drug through the FDA's rigorous clinical trials (on average, 10-15 years and $800 million to get FDA approval) virtually prohibits all but the most surely profitable drugs from reaching distribution (as only 1 in 10,000 potential medicines make it all the way to patient use). Providing rewards for the inventors and marketers of socially beneficial drugs would ideally start a race to the top in which pharmaceutical companies' profit motive would be aligned with expert analysis

[17] Shavell, Steven, and Tanguy Van Ypersele. "Rewards versus Intellectual Property Rights." Journal of Law and Economics XLIV (2001): 525-47. Web. 23 Sept. 2011. <http://www.law.harvard.edu/faculty/shavell/pdf/44_J_Law_Econ_525.pdf>.

of social benefit, not just marketability.

The details of implementation present a number of challenges, mostly revolving around the fallibility of government information regarding the social value of the innovation. Making compensation at least partially proportional to sales can help mitigate this drawback. However, this reintroduces the problem of compounded market failure and imbalanced incentives toward affluent markets.

Commons-Based Peer Production

Along similar veins to open source projects in other fields including GNU/Linux and Wikipedia, projects like Openwetware, iGEM, and the Biobrick Foundation exemplify methods of promoting synthetic biology innovation that don't involve policy. These empirical examples are useful for evaluating the results we can expect from larger-scale adoption of the principles of commons-based peer production in synthetic biology. As in other implementations of the model, there is little to no financial incentive for the individual researchers to produce anything new or of value, yet hundreds of teams from all over the world devote an enormous amount of time, energy, and resources to developing new and creative applications of synthetic biology.

Despite its many successes, the OpenWetWare project and iGEM need to address several gateway issues before they can fully realize their potential. First, simple ease-of-use improvements in the standard registry of biological parts would likely go a long way toward expanding the user-base and promoting up-keep. Although iGEM does award a special medal for documenting existing parts, reliably well-characterized parts are still the minority, limiting the utility of the registry.

Another dimension of complexity in open-access creative commons is the

immense degree of trust of everyone in the world to put the knowledge only to benign or socially beneficial uses. Putting the results of all of our research in an indexed, searchable, online database that makes genetic parts standardized and easy to use has the potential to enable a great deal of new and innovative research, but it may also have the effect of enabling virtually anyone with internet access and a few thousand dollars to engineer profoundly new organisms, perhaps incompetently or with nefarious intentions. This introduces an immense degree of uncertainty into predictions regarding the nature, probability, and magnitude of the probable impacts of enabled projects, since any synthetic organism can, at least in theory, cause incalculable impacts on the biosphere. This uncertainty makes it difficult to evaluate whether such radical openness and transparency is truly in society's best interest when applied to synthetic biology.

Further, several aspects of the iGEM competition structure may have counter-productive effects on bright and altruistic young people interested in pursuing synthetic biology. Most notably, the short competition time can create unrealistic and discouraging impressions of the time-scale, pace, and likely success of future synthetic biology research projects among participants, particularly in smaller or under-funded teams.

Further De-privatization of Biomedical Research

Another approach is to replace the patent system for biomedical research with direct funding. Considering that nearly half of all biomedical research and development funding in the United States already comes from public coffers, total socialization would not be too radical an increase in public involvement directly, and would allow a massive scale-back of governmental involvement in the enforcement of patent monopolies and their related legal battles.

Although it runs counter to entrenched notions of the sanctity and superiority of private enterprise, socializing biomedical research along with other fields that bear especially strongly upon the public interest could potentially be less socially costly and better provide for the public good than our notoriously litigious system of patents and their enforcement. The financial costs inflicted by patent trolls alone on innovators amounts to over a half a trillion dollars in lost wealth from 1990 to 2010,[18] not to mention the public costs of the court cases and incalculable social harm realized when this uncertain and hostile intellectual property climate hampers other potential innovators.

All of these social costs are endured with the result of stimulating roughly $55 billion per year in private biomedical research and development spending.[19] Considering that the public already funds about $40 billion per year in biomedical R&D, it may be a better use of public resources to directly fund all biomedical research instead of going through such a roundabout and socially costly way of enticing private actors to do so.

Although doing away with the whole system of competing monopolies and their costly and intimidating enforcement would free up enormous public resources to promote biomedical research, the success of such a system would rely more heavily on alignment of the judgment and research interests of the researchers and their funders with subjects of social value in the absence of the profit-motive.

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[18] Bessen, James, Jennifer Ford, and Michael J. Meurer. "The Private and Social Costs of Patent Trolls." Boston University School of Law, 19 Sept. 2011. Web. <http://www.bu.edu/law/faculty/scholarship/workingpapers/documents/BessenJFordJMeurerM091911.pdf>.

[19] Osterweil, Neil. "Medical News: Medical Research Spending Doubled Over Past Decade - in Public Health & Policy, Health Policy from MedPage Today." *Medical News and Free CME from MedPage Today*. Everyday Health Inc., 20 Sept. 2005. Web. 27 Sept. 2011. <http://www.medpagetoday.com/PublicHealthPolicy/HealthPolicy/1767>.

VI. Conclusions

The US patent system has many shortcomings resulting from the function of the monopolistic rights it grants, the systematic misalignment of financial incentives and social benefit, and failures of interagency communication. The impacts of these failures on synthetic biology and biomedical research are a matter of enormous public interest because of the unique nature of the technology. A number of public policy proposals and private organizational forms can address different facets of the problem. The most promising policy adjustment considered here is to replace the system of competing patents with a reward system that provides direct incentives to inventors without implementing monopolistic access restrictions on their innovations, but instead putting them into the public domain. This results in a closer alignment of incentives and socially beneficial innovation by closing several loopholes by which patents can be exploited for financial gain without returning innovation, drastically improving access by entering all rewarded innovations into the public domain, and reducing system-wide social cost of obtaining these technologies, among other benefits.

When evaluating or crafting other changes or alternatives to the patent system, we defend a utilitarian ethical framework that avoids the pitfalls of treating intellectual property rights as absolute, bearing in mind that for social benefit to be realized, several factors including the nature of innovation, the distribution of access to that innovation, and other structural factors ultimately produce societal impact. We should be wary of letting a misplaced sense of fidelity to the sanctity of private enterprise or intellectual property blind us to the ultimate goal of any technology regulatory system, which is to maximize the social benefit of science and technology.