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PATENT OFFICE AS BIOSECURITY GATEKEEPER: FOSTERING RESPONSIBLE SCIENCE AND BUILDING PUBLIC TRUST IN DIY SCIENCE

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ABSTRACT

When the fields of intellectual property law and biotechnology intersect, most analysis is driven by economic and ethical issues. This article examines these factors, but in relation to the emerging security threat posed by biohackers, or do-it-yourself ("DIY") scientists, who operate free from oversight and industry norms at the fringes of the biotechnology community. Public health risks are poised to grow as these citizen-scientists race for lucrative discoveries in the new frontier of synthetic biology. This article proposes that the existing paradigm adjust accordingly to leverage regulatory compliance from the most ambitious biohackers looking to benefit from patent protection. The U.S. government could bring aspiring entrepreneurial biohackers into the fold by making non-institutional patent applicants undergo Center for Disease Control biosafety training, personnel screening, and lab registration one year prior to receiving patent application eligibility in order to reduce some of the potential risk of these unmonitored labs present.

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INTRODUCTION

Much analysis at the intersection of intellectual property law and biotechnology is driven by economic and ethical issues.[1] These factors are considered within, but in relation to the emerging security threat posed by biohackers operating free from oversight and industry norms at the fringes of the biotechnology community.[2] Public health risks are poised to grow as citizen-scientists race for lucrative discoveries in the new frontier of synthetic biology.[3] Thus, it is recommended that the existing paradigm adjust accordingly to leverage regulatory compliance from the most ambitious biohackers looking to benefit from patent protection.[4] The U.S. government could bring aspiring entrepreneurial biohackers into the fold by making non-institutional patent applicants undergo Center for Disease Control ("CDC") biosafety training, personnel screening, and lab registration one year prior to receiving patent application eligibility. Requiring biosecurity compliance as a condition precedent to patent application eligibility could help reduce some of the potential risk of an unprecedented gold rush in garage labs.

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[1] *See* Christopher May, *On the Border: Biotechnology, the Scope of Intellectual Property and the Dissemination of Scientific Benefits*, *in* THE ROLE OF INTELLECTUAL PROPERTY RIGHTS IN BIOTECHNOLOGY INNOVATION 254 (David Castle ed., 2009).

[2] *See* Heidi Ledford, *Lifehackers: Amateur Hobbyists Are Creating Home-brew Molecular-Biology Labs, but Can They Ferment A Revolution?*, 467 NATURE 650, 650 (2010) (discussing those biohackers who work out of the public eye, with labs in closets, kitchens and garages).

[3] *See generally* Gaymon Gennett et al., *From Synthetic Biology to Biohacking: Are We Prepared?*, 27 NATURE BIOTECH. 1109, 1109–11 (2009) (discussing the need for a "rigorous, sustained, and mature approach" to prepare of risks associated with the growth of biotechnology).

[4] *See* May, *supra* note 1, at 258.

I. THE RISK OF DO-IT-YOURSELF SCIENCE[5]

"Biohackers," otherwise known as do-it-yourself ("DIY") scientists are a new phenomenon in the life sciences.[6] They are unique because they conduct research from their homes or other nontraditional venues[7] and range in training between complete amateurs and moonlighting Ph.Ds.[8] The DIY movement is underway as a result of the decreased cost of lab equipment and revolutionary advances in the life sciences combined with the promise of discovery and reward.[9] Unfortunately, this so called "democratization of science,"[10] which puts greater scientific power in the hands of a broader base of personnel actually raises challenging security and public health concerns.[11] Chief among these concerns is the proliferation of "dual use" science, which can be applied toward either civilian or criminal ends.[12]

The U.S. government has been grappling with the dual use dilemma with institutional researchers for several years.[13] The advent of the DIY scientist,

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[5] Special thanks to J. Corey Creek, J.D. candidate 2013, University of Maryland School of Law, for research assistance on this paper and the staff of the John Marshall Review of Intellectual Property Law for their invaluable editorial assistance.

[6] Ledford, *supra* note 2, at 650.

[7] *Id.*

> Would-be "biohackers" around the world are setting up labs in their garages, closets and kitchens—from professional scientists keeping a side project at home to individuals who have never used a pipette before. They buy used lab equipment online, convert webcams into US $10 microscopes and incubate tubes of genetically engineered Escherichia coli in their armpits.

Id.

[8] *Id.* (reporting that Rob Carlson, a physics Ph.D. student at Princeton University, took the advice of Dr. Sydney Brenner, head scientist of the Brenner's Molecular Sciences Institute in Berkeley, California, and set up a garage lab in 2005).

[9] *See generally id.* (illustrating in the first diagram what little cost is associated with setting up a garage lab). For example, "[t]hey buy used lab equipment online, convert webcams into US $10 microscopes and incubate tubes of genetically engineered *Escherichia coli* in their armpits. (It's cheaper than shelling out $100 or more on a 37 °C incubator)." *Id.*

[10] *Id.*

> 'The era of garage biology is upon us,' he [Carlson] wrote in a 2005 article in the technology magazine *Wired*. 'Want to participate?' The democratization of science, he reasoned, would bring in new talent to build and improve scientific instrumentation, and maybe help to uncover new industrial applications for biotechnology.

Id.

[11] *E.g.*, *id.* (stating that, in response to the increase in DIY science, the FBI has adopted a "neighborhood watch" stance encouraging DIY scientist to monitor and report any threatening behavior).

[12] DANA A. SHEA, CONG. RESEARCH SERV., RL 33342, OVERSIGHT OF DUAL-USE BIOLOGICAL RESEARCH: THE NATIONAL SCIENCE ADVISORY BOARD FOR BIOSECURITY 1, n.1 (2007) (stating, "Dual-use biological research, in this context, is defined as "biological research with legitimate scientific purpose that may be misused to pose a biologic threat to public health and/or national security.").

[13] *See* NAT'L RESEARCH COUNCIL, BIOTECHNOLOGY RESEARCH IN AN AGE OF TERRORISM 18–19, 110 (2004).

> [The United States] . . . is only one of many pursuing biotechnology research at the highest level. The techniques, reagents, and information that could be used for offensive applications are readily available and accessible. And the expertise and know how to use or misuse them is distributed across the globe. Without

however, adds new dimensions to the dual use dilemma. In addition to the increased possibility of intentional misuse of dual use science there is greater cause for concern over accidents and errors with dual use science.[14] Specifically there are increased risks of laboratory error unique to amateurs, short cuts taken by moonlighting researchers competing for lucrative patents in their garages, and of course the intentional threat from terrorists or criminals seeking to exploit the improved access to lethal biotechnology in garages or community based hacker spaces.[15] Thus, the United States faces an ill-timed game changer with the growing interest in DIY science in garage labs.

II. THE DIY OVERSIGHT CHALLENGE

There is an interesting philosophical split in the scientific community between those for and against the use of patents in the life sciences.[16] The DIY movement is inspired in part by those clearly looking to reap great financial rewards from discoveries in their garages.[17] But the movement is also very much a part of proponents of the open science movement who likewise oppose the use of encumbering patents.[18] The divergent reactions to a change in the United States' position on gene patents speak to the rift.[19] The United States recently changed position and declared in court filings in October 2010 that genes should not be subject to patents, unlike manipulated DNA.[20] Thus, the key area of concern, synthetic biology, will most likely remain patentable subject matter. The oversight proposal discussed infra relies on the U.S. Patent Office as a linchpin to leverage compliance because the typical DIY scientist using dual use science for profit will probably seek patent protection if possible.

> international consensus and consistent guidelines for overseeing research in advanced biotechnology, limitations on certain types of research in the United States would only impede the progress of biomedical research here and undermine our own national interests.

Id.

[14] *See* NAT'L SCI. ADVISORY BD. FOR BIOSECURITY, U.S. DEPT. OF HEALTH & HUMAN SERVS., PROPOSED FRAMEWORK FOR THE OVERSIGHT OF DUAL USE LIFE SCIENCES RESEARCH: STRATEGIES FOR MINIMIZING THE POTENTIAL MISUSE OF RESEARCH INFORMATION 26 (2007).

[15] *See id.*

[16] Samuel Packer, *Biomedical Research and the Law—Embryonic Stem Cells, Clones, Andgenes: Science, Law, Politics, and Values: Article: Embryonic Stem Cells, Intellectual Property, and Patents: Ethical Concerns*, 37 HOFSTRA L. REV. 487, 487–88 (2008) (discussing how various philosophical schools would decide on whether stem cell research is ethical).

[17] Ledford, *supra* note 2, at 650; *see About BioCurious*, BIOCURIOUS?, http://www.biocurious.org/index.php?title=About_BioCurious (last modified Feb. 3, 2011).

[18] *See, e.g.*, *About the BioBricks Foundation*, THE BIOBRICKS FOUND., http://bbf.openwetware.org/Our_Goals.html (last visited Mar. 25, 2011) (seeking to ensure that BioBrick standard biological parts remain freely available to the public).

[19] *See generally* Andrew Pollack, *Gene Patent Ruling Raises Questions for Industry*, N.Y. TIMES, Nov. 1, 2010, at B1.

[20] Brief for the United States as Amicus Curiae Supporting Neither Party, Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, No. 2010–1406 (Fed. Cir. filed Oct. 20, 2010), *on appeal from* 702 F. Supp. 2d 181 (S.D.N.Y) (2010).

Unfortunately, DIY labs lack competent peer support and institutional oversight, which are emerging as cornerstones in policy deliberations on dual use science and security.[21] Academic and industry labs are governed by professional norms and regulations that are simply not commensurate in the DIY community despite efforts by DIY advocates to mimic these institutional attributes through communal oversight of hacker spaces.[22] These attempts are clearly inadequate standing alone, but are an important step nonetheless.[23] The popularity of synthetic biology in the ranks of DIY researchers heightens concern over the lack of oversight.[24]

Synthetic biology is,

> the use of advanced science and engineering to make or redesign living organisms, such as bacteria, so that they can carry out specific functions. Synthetic biology involves making new genetic code, also known as DNA, that does not already exist in nature.[25]

These security issues are compounded by the fact that the United States is grappling with security and oversight issues for life science research activities in institutional settings.[26] Rapidly unfolding developments in the life sciences create a need to evaluate biosecurity risks at all levels because specialized know-how is more widely available and the costs of conducting specialized research is decreasing.[27]

On one hand, these factors lead to risk from malefactors seeking to exploit newly accessible science in pursuit of bioterrorism.[28] A vibrant DIY science community

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[21] *See* NAT'L SCI. ADVISORY BD. FOR BIOSECURITY, *supra* note 14 (stating "[t]he foundation of oversight of dual use research includes investigator awareness, peer review, and local institutional responsibility.").

[22] Ledford, *supra* note 2, at 652 ("The FBI seems to have taken the message on board, and has adopted what some call a 'neighborhood watch' stance. The approach relies on biohackers monitoring their own community and reporting behaviour they find threatening, says Edward You, a special agent in the FBI's bioterrorism unit.").

[23] *See* NAT'L RESEARCH COUNCIL, *supra* note 13, at 110–11.

[24] Ledford, *supra* note 2, at 651.

> Many biohackers are keen to tackle projects that involve engineering cells by piecing together new genetic circuits, an approach called "synthetic biology". DIYbio has picked up both momentum and stigma from this field, which has been alternatively hyped and decried as the solution to society's ills or the nursery for a bioterrorist scourge.

Id.

[25] HART RESEARCH ASSOC., AWARENESS AND IMPRESSIONS OF SYNTHETIC BIOLOGY: A REPORT OF FINDINGS BASED ON A SURVEY AMONG ADULTS 7 (2010), http://bio.org/ind/syntheticbiology/hart2010report_final.pdf.

[26] *See, e.g.*, Martin Matishak, *Biosecurity Panel Findings Sent to U.S. Cabinet Officials for Approval*, GLOBAL SECURITY NEWSWIRE, Nov. 19, 2010 ("[T]he findings of a presidentially mandated panel assigned to identify the most dangerous disease agents and offer strategies to boost safeguards at research facilities that house them have been presented to senior administration officials.").

[27] *Id.*

[28] Eric Lipton, *U.S. Lists Possible Terror Attacks and Likely Toll*, N.Y. TIMES, Mar. 16, 2005, at A1 (stating that the Department of Homeland Security identified and estimated the effect of a

may inadvertently accelerate the progress of would be bioterrorists by giving them a free ride through the benefits shared within the community and even cover for illicit activities if garage labs become commonplace.[29] On the other hand, well-intentioned biohackers run the risk of making amateur errors in garage labs operating beyond the professional norms and institutional oversight found in traditional labs.[30] Human errors in unconventional labs conducting sophisticated research are of particular concern.[31] If accidents can happen at respected university and industry labs, it is reasonable to expect that amateur garage labs would incur an even higher rate of error.[32]

III. DIY GROWTH BY GOLD RUSH AND BIOBRICK

Thus, the critical question begged from a security perspective regarding DIY biotechnology is whether there will be a biotech-bubble reminiscent to the dot-com bubble of the 1990's. A biotech gold rush or bubble involving DIY scientists could be disastrous for public health and national security before appropriate oversight mechanisms are put in place.[33] The prospect of a biotech bubble has recently become the topic of conversation on investment blogs.[34] The following post was made in January 2011:

> I think there is a potential for another bubble over the next decade. . . . there is one I am particularly interested in and that is biotech . . . . I think we are on the cusp of a decade of remarkable breakthroughs which will change the way we do medicine. . . . breakthroughs will come via large firms, others will be in smaller companies. . . . The list of potential

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number of terror threats, which included anthrax, pneumonic plague, food contamination, and the intentional spread of foot-and-mouth disease).

[29] *See* Howard Wolinsky, *Kitchen Biology: The Rise of Do-It-Yourself Biology Democratizes Science, but Is It Dangerous to Public Health and the Environment?*, 10 EUR. MOLECULAR BIOLOGY ORG. 683, 684 (2009) (stating that DIY science is a "double-edged" sword that could be used for malicious purposes as well as benefitting society).

[30] *See id.* at 683 ("[S]ome legislators and scientists worry that do-it-yourself (DIY) biology might pose a danger to public health and environmental safety, and that unregulated experiments conducted in kitchens and garages might accidentally or intentionally unleash biological disaster.").

[31] *See id.* at 685.

> [W]hen people start assembling complex systems that involve tens to hundreds of genes from a variety of different organisms, those types of experiments outstrip the current biosafety paradigm. There could be unpredictable effects and interactions that might result in self-replicating organisms that escape into the environment and cause ecological damage and even public health threats [. . .] we should not be as casual about the risks as I believe the DIY biologists are.

Id. (quoting Jonathan Tucker, a Senior Fellow at the James Martin Center for Nonproliferation Studies at the Monterey Institute of International Studies).

[32] *See id.* (comparing research conducted in university laboratories versus DIY laboratories and the inherent dangers).

[33] *See id.* (stating that part of the problem is that amateur science is moving faster than regulators and legislators).

[34] *See, e.g.*, John Mauldin, *The Coming Biotech Bubble*, INVESTOR'S INSIGHT (Jan. 11, 2010), http://www.investorsinsight.com/blogs/john_mauldins_outside_the_box/archive/2010/01/11/the-coming-biotech-bubble.aspx.

> blockbuster therapies from current research is enormous and growing. There are going to be some companies, which will simply see their stocks explode. . . . Everyone will want to be in at the beginning of a new home run. As the decade goes along, we will see companies go public before they are really ready, just because they have a great story and people will want to fund that story. [35]

The enthusiasm laying the ground-work for a biotech gold rush also emanates from within the DIY community as evidenced by claims made by the DIY entity known as BioCurious:

> Until recently, biotech has required large start up costs. An ecosystem of mentorship and a network of investors who understand the possibilities for lean-biotech-start ups to leverage shared resources and amplify their creative efforts to have disproportionate commercial impact, is urgently needed. BioCurious will catalyze the formation of this system.[36]

One prominent biohacker, Rob Carlson, likewise acknowledged the profitable potential of biohacking.[37] He said, "We're going to see a lot more at the garage level that will produce a variety of products in the marketplace, one way or another."[38] It is no secret that life science research can be lucrative and is important for the economy, thus the United States needs to be prepared for the possibility of explosive growth in the area with particular attention to biohacker labs.[39] Unfortunately, the report from a Presidential Commission tasked with advising the government on synthetic biology assumed an advocacy role for DIY science by framing it as a legal or moral right.[40] In addition, the Commission explicitly advised the United States against implementing oversight of the DIY community at this time.[41] The Commission did acknowledge that government oversight may be necessary for the DIY community working with synthetic biology at some point in time.[42] But the

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[35] *Id.*

[36] *About BioCurious*, *supra* note 17.

[37] *See* Ledford, *supra* note 2, at 652.

[38] *Id.*

[39] *See, e.g.*, Patrick Cox, *The Coming Biotech Bubble*, INVESTOR'S INSIGHT (Jan. 11, 2010), http://www.investorsinsight.com/blogs/john_mauldins_outside_the_box/archive/2010/01/11/the-coming-biotech-bubble.aspx ("[P]rivate investors will not only profit from this [biotech] revolution, they will power it.").

[40] PRESIDENTIAL COMM'N FOR THE STUDY OF BIOETHICAL ISSUES, NEW DIRECTIONS: THE ETHICS OF SYNTHETIC BIOLOGY AND EMERGING TECHNOLOGIES 142 (2010) [hereinafter NEW DIRECTIONS], http://www.bioethics.gov/documents/synthetic-biology/PCSBI-Synthetic-Biology-Report-12.16.10.pdf ("In academic communities, intellectual freedom is essential. The ability to explore ideas openly and freely—even controversial or unpopular ideas—is fundamental to the mission of education and research.").

[41] *Id.* at 148 ("Scrutiny is required to assure that DIY scientists have an adequate understanding of necessary constraints to protect public safety and security, but at present the Commission sees no need to impose unique limits on this group.").

[42] *Id.* at 146–47 ("To exercise the appropriate level of oversight, the government will need to monitor the growth and capacity of researchers outside of institutional settings. This effort may require the government to expand current oversight or engagement activities with these non-institutional researchers.").

Commission recommended a wait and see approach relying of the expectation that it will take a few years before the DIY community poses serious public health and security threats.[43] The Commission's recommendation, however, was met with criticism by those who see the risk as a near term concern.[44]

The Presidential Commission on synthetic biology addressed DIY science because it is a popular interest for many biohackers, and it is clear that serious biohackers have and are likely to continue investing heavily into their garage investments.[45] An article in *Nature* about a prominent biohacker, Rob Carlson and the biohacker phenomenon captured the sentiment:

> Still, five years after taking science into his garage, Carlson says he's convinced that biohacking has the potential to trigger a technological revolution. "We're going to see a lot more at the garage level that will produce a variety of products in the marketplace, one way or another," he says. Once his tadpoles have been optimized, Carlson hopes that publishing his work will attract further investors. Meanwhile, he feels his experiment in garage-based innovation has so far been a success, despite the delays and personal sacrifices. "Part of the exercise was to determine whether or not we could bootstrap this thing," he says. "The answer appears to be 'yes'. As long as you are willing to be patient and to eat nothing but rice for dinner occasionally."[46]

Carlson's activities are that of a small business, not a DIY hobbyist or a mere curious hacker.[47] Investors do not back hobbies.[48] But the promotional activities of

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[43] *Id.* at 147 ("This recommendation acknowledges that the norms of safe and responsible conduct that have evolved over time for many researchers in institutional settings may not be understood or followed by those new to the field or outside of these settings, but it is not a call for specific restraints upon the DIY community at this time.").

[44] Rob Stein, *Presidential Commission Urges Caution on 'Synthetic Biology,'* WASH. POST, Dec. 16, 2010, at A4.

> Allison A. Snow, a professor of evolution, ecology and organismal biology at Ohio State University, said the report 'sends a mixed message that is too watered down.' A coalition of more than 30 environmental groups sent a joint letter to the commission criticizing the failure to call for tougher precautions, including a moratorium until scientists prove such organisms are safe. 'Our main concern is the potential environmental impacts of synthetic biology,' said Eric Hoffman of Friends of the Earth, one of the groups that sent the letter. 'We think it is a potentially very dangerous technology.'

Id.

[45] *See* Ledford, *supra* note 2, at 651 ("Many biohackers are also keen to tackle projects that involve engineering cells by piecing together new genetic circuits, an approach often called 'synthetic biology'.").

[46] *Id.* at 652.

[47] *Id.* ("[The United States is] going to see a lot more at the garage level that will produce a variety of products in the marketplace, one way or another.").

[48] *Contra* Jim Gorman, *Inventor's Handbook*, POPULAR MECHS., July 1, 2010, at 56 (providing an example of an inventor who took the do-it-yourself approach for his hobby and licensed his design to investors to become wealthy).

> Lonnie Johnson, who fashioned his Super Soaker prototypes using a Unimat hobby lathe and milling machine while moonlighting from his job at NASA's Jet Propulsion Laboratory, intended to manufacture his invention. Bids he received

some academics are accelerating the interests of the DIY hobbyist in contrast to the gold rushing DIYer.[49] Much like the gold rushing DIY advocates, some segments of the academic community are also advancing the use of synthetic biology despite the uncertain public health and security landscape.[50] The Biobrick Foundation and the iGEM competition work aggressively to advance the use of synthetic biology.[51] iGEM is:

> [T]he premiere undergraduate Synthetic Biology competition. Student teams are given a kit of biological parts at the beginning of the summer from the Registry of Standard Biological Parts. Working at their own schools over the summer, they use these parts and new parts of their own design to build biological systems and operate them in living cells.[52]

BioBricks maintains a registry of biological parts that is designed to be open and free from patent protection.[53] The Biobricks program is unrestricted and open to all who are interested in synthetic biology.[54] Any individual or organization is welcome to design, improve, and contribute BioBrick™ standard biological parts to the Registry.[55]

> from injection molding companies quickly killed that idea." When I learned it would cost $200,000 to make 1000 guns, I decided to license," he says. "I didn't have that kind of money." Today he does. Retail sales of the Super Soaker have exceeded $1 billion, and royalties have made Johnson a wealthy man.

Id.

[49] Ledford, *supra* note 2, at 651 (noting that most DIY biology community are hobbyists rather than businessmen intending to turn a profit).

[50] *See, e.g.*, *Advances in Synthetic Biology: Significance and Implications: Hearing before H. Comm. on Energy and Commerce*, 111th Cong. (2010) (Statement of Anthony S. Fauci, M.D., Dir. of the Nat'l Inst. of Allergy & Infectious Diseases).

> While the advance made by JCVI [J. Craig Venter Institute] scientists potentially could be used by those who intend to do harm, we also must recognize that this was not a simple experiment; it was an extraordinarily complex project that took many years, people, and millions of dollars to complete. While there certainly is a chance that the technology developed by JCVI researchers might be used for nefarious purposes by those with extensive resources, it is important to point out that similar, albeit simpler techniques, are in widespread usage and are an integral and vital tool in life science research and science education, including high school through post-graduate curricula.

Id.

[51] IGEM, http://ung.igem.org/Main_Page (last visited Mar. 25, 2011).

> iGEM and the Registry of Standard Biological Parts have a large and diverse user community. The skill levels run from high-school students who are new to synthetic biology to world-acclaimed experts in the field. Our user community spans the globe with users from over 26 countries and regions participating in the iGEM competition alone last year.

Id.

[52] *About iGEM*, IGEM.ORG, http://ung.igem.org/About (last visited Mar. 25, 2011).

[53] *See About the BioBricks Foundation*, *supra* note 18; *BioBrick™ Public Agreement,* THE BIOBRICK FOUND., http://biobricks.org/programs/biobrick-public-agreement (last visited Mar. 25, 2011).

[54] *See BioBrick™Public Agreement*, *supra* note 53.

[55] *Id.*

The emerging reality, however, is that the life science community is a growing confluence of university, government, for-profit, and non-profit entities which can include DIY scientists. Battelle's 2008 report on behalf of the Biotechnology Industry spoke to the linkages. It stated:

> A new paradigm has emerged in which leading technology companies are looking to universities and innovative emerging companies for new technologies, rather than investing as many resources in internal high-risk R&D work as in the past. As a result, more and more companies are looking for opportunities to partner with research universities. Universities are looking to corporations and entrepreneurs to provide an avenue to move their discoveries into applications. Such relationships are extremely important in the biosciences as the link between basic science and new product development is very strong.[56]

There may be an interesting philosophical rift in the scientific community on the use of patents, which affects security risks. It is argued that the patent seekers are more likely to encourage a broader interest in DIY science, but both camps encourage the proliferation of high consequence science and proponents on both sides of the patent debate do have serious business aspirations.[57] For instance, despite a position against patents for biological parts, Drew Endy was a key player in a high profile multi-million dollar start up called Codon Devices.[58] Thus, both camps are similar in that they welcome all who are interested and it appears that the risks generated by their science outpaces their ability to assure public health and security safeguards.[59] In this connection, a number of these leaders of the open science or DIY movement are unified in their position against U.S. regulation that would be perceived as hindering their cause.[60] Moreover, it is not surprising to see the apparent influence

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[56] BATTELLE TECH. P'SHIP PRACTICE, TECHNOLOGY, TALENT AND CAPITAL: STATE BIOSCIENCE INITIATIVES 2008 58 (2008), http://www.bio.org/local/battelle2008/State_Bioscience_Initiatives_2008.pdf.

[57] *See* Jed Lipinski, *Turning Geek into Chic*, N.Y. TIMES, Dec. 19, 2010, at A1 (stating an entrepreneur helped raise capital for a science lab, while another is building a wet lab in a warehouse-like space); Wolinsky, *supra* note 29, at 684; *see also* Julian Guthrie, *Do-It-Yourself Biology on Rise*, S.F. CHRON., Dec. 20, 2009, at A1 ("Members of this informal network of wannabe biologists, entrepreneurs and artists are buying bacteria online, cobbling together discarded equipment, and holding parties to transect DNA and exchange live cultures.").

[58] Erika Check Hayden & Heidi Ledford, *A Synthetic-Biology Reality Check: Is the Abrupt Closure of Prominent Player Codon Devices An Omen for the Field?*, 458 NATURE 818, 818 (Apr. 15, 2009) ("Codon Devices was backed by a range of top-drawer venture capitalists. The scientific founders, alongside Church, were Drew Endy, then of the Massachusetts Institute of Technology ("MIT") in Cambridge, who was working on the development of small, reusable genetic components known as BioBricks."); *see* Bernadette Tansey, *Leaving MIT for Standford*, S.F. CHRON., Dec. 26, 2007, at D1.

[59] *See* Tansey, *supra* note 58, at D1; Wolinsky, *supra* note 29, at 685.

[60] *See* Wolinksy, *supra* note 29, at 685.

> Carlson also conceded that DIY biology has the potential to go wrong, although he is cautious of too much regulation. "There is probably risk now and it will grow, but you also have to ask what happens if you regulate [. . . .] There are plenty of historical examples of what's happened to markets for distributed technologies when proscription or prohibition is implemented. I use the word prohibition quite

the DIY and open science movement had with the Presidential Commission since leading advocates were invited speakers at Commission meetings.[61] Included among the speakers were Jason Bobe, Robert Carlson associated with DIY, in addition to Drew Endy and Randy D. Rettberg who are behind BioBricks.[62]

The persuasive powers of this group may help explain why the Presidential Commission minimized DIY dangers and went so far as to defend DIY science as a legal right extended from academic freedom.[63] After discussing academic freedom, the report made a segue in support of biohackers with the following statement:

> Second is the right of all individuals to freedom of inquiry. The DIY research communities and other private researchers are exercising such freedom but without the institutional norms and procedures designed to assure responsibility, although these groups often develop their own mechanisms intended to do so. [64]

The market and the money behind it, has faith that biohackers are more akin to small businesses than stamp collectors or gardeners.[65] New equipment created and marketed for biohackers is clearly not intended for the naïve amateur.[66] A recent review of a new personal genomics machine intended for biohackers introduces a piece of equipment that is much cheaper than similar equipment in academic or industrial labs, but well beyond the budget of the typical hobbyist.[67] The potential gold rush appeal of synthetic biology in garage labs also serves to complicate matters even further.[68] Synthetic biology promises to be a lucrative field and the interest in moonlighting in a potentially rewarding endeavor is likely to propel the popularity of home based synthetic biology to even greater heights:

> Thinking of setting up your own genomics lab in the garage? . . . The Personal Genome Machine (PGM) by Ion Torrent is a DIY biologist's fantasy: it's fast, compact, and the first sequencer to come even close to commercial viability. . . . The PGM is their contribution to the growing

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> intentionally: we have a very clear experience with what happened in this country when [fermentation] was proscribed in the 1920s. [. . . .] [It] created markets [for alcohol] that were blacker and more difficult for the federal government to deal with than [before]."

Id.

[61] *See* NEW DIRECTIONS, *supra* note 40, at 175–77.

[62] *See id.* at 176–77; *Board of Directors*, THE BIOBRICKS FOUND., http://biobricks.org/about-foundation/board-of-directors (last visited Mar. 25, 2011).

[63] *See* NEW DIRECTIONS, *supra* note 40, at 142.

[64] *Id.*

[65] *See, e.g.*, Ledford, *supra* note 2, at 652 (reporting that Carlson started out a garage lab as a hobby, but found it too difficult and eventually moved to a commercial space to begin a small business).

[66] *See id.* at 651 (providing examples of the costs associated with purchasing new equipment for biohackers); *see* Drew Halley, *DNA Sequencing for 1/10 the Price: Ion Torrent's Sequencer Arrives*, SINGULARITY HUB (Dec. 27, 2010), http://singularityhub.com/2010/12/27/dna-sequencing-for-110-the-price-ion-torrents-commercial-sequencer-arrives.

[67] *See* Halley, *supra* note 66.

[68] *See* Robert Carlson, *The Pace and Proliferation of Biological Technologies*, 1 BIOSECURITY AND BIOTERRORISM: BIODEFENSE STRATEGY, PRACTICE, SCI. 203, 206 (2003).

> commercial genomics marketplace, and a powerful reminder of how sequencing tech is following Moore's Law. It will set you back $49,500 . . . which still keeps it out of reach for all but the most affluent DIYers. Still, at less than 1/10th the price of competing sequencers . . . don't be surprised if it starts making headway into research labs. [69]

Thus, it is offered that patents, the very mechanism that helps assure financial reward among biohackers, may be used to leverage compliance with a remedy that helps assure a culture of responsibility in a critical segment of the DIY community.[70] Stakeholders have yet to identify the appropriate boundaries or regulations for DIY science, but once the right balance is found, it can be enforced with a segment of the DIY community of concern—those seeking fortune from synthetic biology in their garage.[71] It is proposed within that the DIY community could help assure its public trust by demonstrating that it registered labs with regulatory authorities, completed biosafety training provided by the CDC, and is keeping convicted felons away from risky research.[72]

IV. FORESTALLING OVERSIGHT THROUGH DIY ADVOCACY

Advocates of DIY science have been effective in spreading a message that accentuates the positive and minimizes the negative risks.[73] Perhaps the greatest

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[69] *See* Halley, *supra* note 66.

[70] *See* Andrew W. Torrance, *Synthesizing Law For Synthetic Biology*, 11 MINN. J. L. SCI. & TECH. 629, 650 (2010).

> It has long been widely assumed that technological innovation was best spurred by either governmental funding or property-like incentives, such as patents and copyrights. The United States Constitution explicitly enables Congress '[t]o 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.' However, the rise in importance of open source and free software, as well as insight into the phenomena of user, open, and collaborative innovation, has revealed an increasingly significant alternative to proprietary models of innovation. Within the field of synthetic biology, there are influential scientists, notably Drew Endy, Tom Knight, and Randy Rettberg, who have vigorously tried to push the field in the direction of open innovation.

Id.

[71] *See* NEW DIRECTIONS, *supra* note 40, at 8, 13.

> The Commission sees no need at this time to create additional agencies or oversight bodies focused specifically on synthetic biology. Rather, the Commission urges the Executive Office of the President, in consultation with relevant federal agencies, to develop a clear, defined, and coordinated approach to synthetic biology research and development across the government. A mechanism or body should be identified to: (1) leverage existing resources by providing ongoing and coordinated review of developments in synthetic biology, (2) ensure that regulatory requirements are consistent and non-contradictory, and (3) periodically and on a timely basis inform the public of its findings. Additional activities for this coordinating body or process are described in other recommendations.

Id.

[72] *See id.* at 12.

[73] *See* Wolinsky, *supra* note 29, at 684; Lipinski, *supra* note 2, at 1.

proof of this is found with the support of DIY science in the Presidential Commission report on synthetic biology, and following presentations by DIY advocates.[74] This success was impressive, especially because there are unusually strong feelings and concerns over synthetic biology in the general public.[75] The Hart Foundation recently found that 52% of the population polled believed that synthetic biology should be regulated by the government and 33% thought such science should be banned altogether.[76]

It is in the best interests of biohacker advocates to argue that the DIY community is effective in providing security through self-policing. This claim was even apparently accepted at face value by a Presidential panel addressing synthetic biology.[77] Biohackers may have found a sympathetic ear in the Presidential Commission drawn largely from academia, but that support is of limited value when popular opinions in society support government regulation of synthetic biology and a significant minority of the public actually believe that there should be a ban on synthetic biology research.[78]

The public concern reflected in the Hart poll suggests that the debate over synthetic biology and biohackers will not be confined to elite and rarified panels of insiders.[79] Awareness of synthetic biology is growing and it is likely that such awareness will only grow over time.[80] Therefore, the DIY community must do more than earn the confidence of kindred souls in expert advisory panels.[81] The public and lawmakers to whom they answer will only grow more familiar with the risks associated with synthetic biology of which insiders are cognizant.[82] Concerns and admonitions over the next generation of life science research are both ominous and

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[74] *See* NEW DIRECTIONS, *supra* note 40, at 159–60, 176–77.

[75] *See, e.g.*, Torrance, *supra* note 70, at 661; Jeanne Whalen, *In Attics and Closets, 'Biohackers' Discover Their Inner Frankenstein: Using Mail-Order DNA and Iguana Heaters, Hobbyists Brew New Life Forms; Is It Risky?*, WALL ST. J., May 12, 2009, at A1; Markus Schmidt, *Diffusion of Synthetic Biology: A Challenge to Biosafety*, SYST. SYNTH. BIOL. 1, 2 (2008).

[76] HART RESEARCH ASSOC., *supra* note 25, at 1, 11–12 (2010) ("A ban should be placed on synthetic biology research until we better understand its implications and risks."). "Synthetic biology research should be regulated by the federal government because voluntary research guidelines developed jointly by industry and government cannot provide adequate oversight." *Id.*

[77] *See* NEW DIRECTIONS, *supra* note 40, at 142.

> Intellectual freedom and responsibility can be understood in two senses. First is the special institutional attribute—academic freedom and responsibility—that pertains to the 'academy'. . . . Second is the right of all individuals to freedom of inquiry. The DIY research communities and other private researchers are exercising such freedom but without the institutional norms and procedures designed to assure responsibility, although these groups often develop their own mechanisms intended to do so.

Id.; Ledford, *supra* note 2, at 652.

[78] *See* HART RESEARCH ASSOC., *supra* note 25, at 1, 11–12 (2010); NEW DIRECTIONS, *supra* note 40, at 8, 13, 125.

[79] *See* HART RESEARCH ASSOC., *supra* note 25, at 1, 11–12 (2010).

[80] *See id.* at 3–5.

[81] *See id.* at 13.

[82] *See id.*; Whalen, *supra* note 75 ("A senior official in the FBI's Weapons of Mass Destruction Directorate says the bureau is working with academia and industry to raise awareness about biosecurity, 'particularly in light of the expansion of affordable molecular biology equipment' and genetic databases.").

foreboding.[83] Two examples include the claim that the, "science that may cure some of our worst diseases could be used to create the world's most frightening weapons,"[84] and the fear that synthetic biology could, *"mindlessly screw up the unity of life on earth"*.[85]

Vocal pioneers of the biohacker movement are framing it as benign and romantic.[86] Evidence is found in efforts to eschew terms such as biohacker and replace it with the term "DIY scientist."[87] Rather than drawing association with hackers in the computer industry, DIY scientists portray themselves as idealistic thinkers and tinkerers with nothing but an innocent hobbyist's interest in microbiology.[88] Descriptions of independent life science researchers are, at times, framed with a quixotic aura akin to Rousseau's view embodied in his fictional Emile who has nothing but a noble and idealistic love of learning.[89] Biohackers have been compared to historic efforts of the Wright brothers.[90] Biocurious, a Biohacker lab,

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[83] *See* Tansey, *supra* note 58 (stating that Drew Endy shares "some concerns with critics who fear the technology will unleash engineered microbes with devastating consequences to the environment, increase the danger of biowarfare, and convert rural economies into corporate mega farms that displace food production.").

[84] OFFICE OF TRANT'L ISSUES, CENT. INTELLIGENCE AGENCY, THE DARKER BIOWEAPONS FUTURE, OTI SF 2003-108 (Nov. 3, 2003).

[85] Markus Schmidt et al., *Synbiosafe E-Conference: Online Community discussion on the Societal Aspects of Synthetic Biology*, SYST. SYNTH. BIOL., Sept. 18, 2008, at 12.

[86] *See generally* Wolinsky, *supra* note 29, at 683–85 (2009) (stating DIY scientists argue that demystifying the science behind genetic and medical tests is empowering); *see also* Guthrie, *supra* note 57, at A1 (stating that DIY scientist enthusiasts remain clear that their hobby is a positive development in a world).

[87] *See* Lipinski, *supra* note 57, at A1 (showing an example of the media referring to biohackers as the more friendly term "citizen scientists"); Gary Richmond, *Extending the Free Software Paradigm to DIY Biology,* FREE SOFTWARE MAG. (June 2, 2009), http://fsmsh.com/3146 (explaining that he tries to avoid using the term "biohackers" because of its negative and misleading connotations).

[88] *See* Guthrie, *supra* note 57, at A1 (describing that the term "hacker" to the general public is not good, but it actually mean "someone who takes something apart and puts it back together in a new way, maybe a way that's better"); Richmond, *supra* note 87 (explaining that most DIY scientists just want to create their own data in their garage).

[89] *See Garage Biology: Amateur Scientists Who Experiment at Home Should Be Welcomed By the Professionals*, NATURE, Oct. 7, 2010, at 634.

> Media coverage has taken its toll on the public's perception of "DIYbio". Stories in the press are often peppered with sweeping claims of the monumental advances to be made by unleashing the talents of the public at large on important biological questions. Equally common are breathless warnings that a bioterrorist is busy crafting the next plague in a garage, safe from the watchful eye of the authorities. Neither image rings true. Most biohackers are hobbyists who delight in crafting their own equipment and who tackle projects no more sophisticated than those found in an advanced high-school biology lab.

Id.; *see also* JEAN-JACQUES ROUSSEAU, ÉMILE: OR, CONCERNING EDUCATION 1 (1883) (stating that "Everything is good as it leaves the hands of the Author of things; everything degenerates in the hands of man.").

[90] *See* NEW DIRECTIONS, *supra* note 40, at 141–42.

> Intellectual freedom lies at the heart of America's scientific enterprise. Such freedom facilitates the innovation and industry that have fueled its success. History is rife with examples in which ingenuity, hard work, and unfettered creativity have yielded extraordinary, sometimes unexpected, scientific advances for the betterment of society as a whole. From Benjamin Franklin studying

likewise invites comparisons of their citizen science with the pre-industrial days where "Science was once a cultural activity, carried out by wealthy 'gentlemen scholars' who had the leisure and material resources to experiment."[91] Yet in the next breath, their statement stirs gold rush temptations by promising that prospective biohackers who join them can be a part of a "disproportionate commercial impact,"[92] of their pursuits. More assuring claims, however, are made by a leading advocate of the biohacker movement, Jason Bobe, who equates biohacker activity to the innocence found in the most rudimentary middle school labs.[93] Bobe addressed the biosecurity concerns of biohackers in a recent article in *Nature*:

> Bobe has interacted with and advised the FBI, but says he finds many of the biosecurity fears of the FBI and the public to be unfounded. "The amateur activity right now is at the seventh- or eighth-grade level," he says. "We're making $10 microscopes and all of the discussion around us is about weaponized anthrax."[94]

Concerted or not, there appears to be a grassroots lobbying effort by garage-based bioentrepreneurs who try to frame the biohacker in a quaint light on one hand, while opposing regulation and oversight of their movement in the other.[95] Carlson argued against the regulation of biohackers with the following statement, "A superior alternative is the deliberate creation of an open and expansive research community, which may be better able to respond to crises and better able to keep track of research whether in the university or in the garage."[96] This argument has been proffered to fend off regulation of institutional researchers.[97] Nobel Laureate David

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> electricity with a kite in a raincloud, to the Wright Brothers testing different aerodynamic control systems and building the first successful airplane, students learn every day about the value of intellectual and scientific freedom and exploration.

Id.

91 *See About BioCurious*, *supra* note 17.

92 *Id.* ("Until recently, biotech has required large start up costs. An ecosystem of mentorship and a network of investors who understand the possibilities for lean-biotech-start ups to leverage shared resources and amplify their creative efforts to have disproportionate commercial impact, is urgently needed. BioCurious will catalyze the formation of this system.").

93 *See* Ledford, *supra* note 2, at 652.

94 *Id.*

95 *See* NEW DIRECTIONS, *supra* note 40, at 159.

> As noted, democratic deliberation is based on ongoing interaction among citizens on topics of common interest. For an emerging technology such as synthetic biology, many of these dialogues will be among scientists or other interested citizens and policy makers or regulators. Such interactions are vital to a democracy, but they are not sufficient. Exchanges among individuals and groups of citizens are also important. In particular, grassroots collaborations have been established around synthetic biology. Groups such as DIYbio are loosely organized networks of self-described "citizen scientists" coming together because of a common interest in the tools, methods, and applications of synthetic biology, rather than shared professional affiliations or policy responsibilities. In this way, the "do-it-yourself" community embodies a "do-it-together" ethos.

Id.

96 Carlson, *supra* note 68, at 203.

97 *E.g.*, *id.*

Baltimore used a similar argument to rationalize a position against a biosecurity proposal on Due Process Vetting presented by this author at a closed briefing to the National Academies Committee known as CSANS—the Committee on Scientific Communication and National Security at the National Academy of Sciences.[98] Baltimore assured that a global response to a biological threat from all good scientists is superior delaying the release of dangerous dual use research findings which could be misused by malefactors.[99] Baltimore then cited the response to the SARS epidemic as an example.[100] Baltimore's example was elicited off the cuff rather than by prepared comments and meant to illustrate a robust response from the scientific community, but the fact remains that SARS was controlled by public health interventions, not by the findings of any researchers who scurried to their benches to find a cure.[101]

The question is whether the efforts of the existing Laboratory Response Network ("LRN") established in 1999 is inadequate or needs expansion.[102] The justifications against scientific regulations citing universal response noted by Carlson and Baltimore both failed to note the federal government's LRN.[103] The existing LRN appears to accomplish the need for a unified response to an emergency requiring a research-based approach.[104] One report notes:

> The LRN is charged with maintaining an integrated network of laboratories that can respond to bioterrorism, chemical terrorism and other public health emergencies. The LRN includes federal and state public health facilities, medical institutions, and others. These laboratories are primarily engaged in diagnostic and public health testing of samples, especially in an

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[98] Brian J. Gorman, Balancing Secrecy and Open Science: The Dual Use Dilemma, Address to the Committee on Scientific Communication and National Security at the National Academy of Sciences (Oct. 30, 2006) (on file with The John Marshall Review of Intellectual Property Law).

[99] *Id.*

[100] *Id.*

[101] Chad T. Marley, Marc E. Levsky, Timothy S. Talbot, and Christopher S. Kang, *SARS and its Impact on Current and Future Emergency Department Operations*, 26 J. OF EMERGENCY MED. 415, 419 (2004) ("Over the past year, SARS has adversely affected millions of people and cost international economies hundreds of billions of dollars. It has frustrated public health officials and stymied research efforts. Recent successes have occurred in controlling the SARS epidemic despite the lack of specific details; primarily through general health measures and coordinated public health policies.").

[102] *See* CTR. FOR DISEASE CONTROL & PREVENTION, FACTS ABOUT THE LABORATORY RESPONSE NETWORK 1 (2011), http://www.bt.cdc.gov/lrn/factsheet.asp.

> In 1999, the Centers for Disease Control and Prevention (CDC) established the Laboratory Response Network (LRN). The LRN's purpose is to run a network of labs that can respond to biological and chemical terrorism, and other public health emergencies. The LRN has grown since its inception. It now includes state and local public health, veterinary, military, and international labs. This fact sheet provides a brief description of the LRN, and how it works.

Id.

[103] *See* David Baltimore, *Limiting Science: A Biologist's Perspective*, 107 DAEDALUS 37, 44 (1978); Carlson, *supra* note 68, at 203–14.

[104] FRANK GOTTRON & DANA SHEA, CONG. RESEARCH SERV., R40418, OVERSIGHT OF HIGH-CONTAINMENT BIOLOGICAL LABORATORIES: ISSUES FOR CONGRESS 13 (2009).

emergency situation where additional capacity for such testing is needed. Many of these laboratories possess BSL-3 capabilities.[105]

The approach to controlling dangerous dual use research findings is worthy of serious debate, and Baltimore's argument deserves due consideration, but the notion of investing a nation's biosecurity in the hands of gold rushing biohackers or gentlemen hobbyists simply fails the giggle test.

V. Assessing Risk

It appears that sophisticated scientists looking to strike out on their own without the encumbrances of university oversight and profit sharing are the biohackers leading the DIY movement.[106] Thus far there are distinct types of biohackers emerging.[107] Focus on these distinctions will help an otherwise imprecise dialogue that has started with regard to the biohacker. This is especially necessary in breaking down DIY science risks to assess the emerging problems in development in this area. There appear to be three types of DIY researchers which breakdown further and present different challenges:

A. DIY-Professional Scientist.[108]

  i. Either gainfully employed in a traditional scientific setting, but moonlighting; or

  ii. a full-time DIY scientist working as an independent researcher.

B. DIY-Amateur Scientist.[109]

  i. The mere curious hobbyist; or

  ii. a gold rush amateur looking to obtain a profitable patent; or

  iii. an amateur responding to a personal health crisis.

C. DIY-Malefactor.[110]

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[105] *Id.*

[106] *See* Ledford, *supra* note 2, at 651.

> Carlson [a physics PhD student at the time] started his garage lab as something of a hobby, but he needed to do it without sapping resources from his lab at the University of Washingtonin Seattle. He bought equipment such as refurbished micropipettes—a staple in any molecular biology lab—and a used centrifuge on eBay. In 2007, fed up with grant applications and eager to spend more time working in his garage lab, he gave up his position at the university altogether.

Id.

[107] *See id.*

[108] *See id.*

[109] *See id.*

i. Either a biohacker who acts in the tradition of computer hackers by engaging in illegal or improper activity in pursuit of gratuitous harm; or

ii. a lone actor working on criminal application of biotechnology; or

iii. a terrorist working alone or in concert with others with training that may be expert or self-taught.

Approximate risk levels can be attributed to the three categories of DIY scientists in relation to types of risk (see table 1). Five types of risks are evaluated as either high or low against the class of DIY scientist. For instance, the use of a garage lab for intentional harm is a risk for any scientist, even an industry professional working at a high-containment government lab.[111] The findings of the Amerithrax investigation concluded that it was indeed an inside government scientist behind the anthrax attacks of 2001.[112] This insider threat, although apparently low, is being taken very seriously by the United States.[113] Thus far, the United States commissioned a series of expert committees to make recommendations to address this threat.[114] President Obama issued an Executive Order, "Optimizing the Security of Biological Select Agents and Toxins in the United States," on July 2, 2010, which calls for specific recommendations to address this threat.[115] The results of this committee are expected in summer 2011.[116]

Thus, all threats should be taken seriously and be addressed in the most judicious manner that balances scientific progress and security. An estimation of intentional harm, however, places the insider threat from a high-containment lab as low. It would likewise exist, but be low for the DIY-moonlighter, DIY amateur, and the professional scientists in industry. It is quite clear, however, that the risk of intentional harm is high for the DIY-Malefactor. Each of four additional risk factors present with varying results with each class of scientist. For example, DIY-scientists investing valued personal resources of time and money would be at risk of committing lab errors and other inadvertent actions associated with lab safety that one would expect by an individual in a gold rush for a lucrative and patentable discovery. The risk of a professional scientist moonlighting was similarly deemed high because the risk they can take may be greater in a garage lab given their expertise. Dangerous experiments would be a risk for all scientists but more likely to be high for the risk taking professional in a garage working on vaccine or biosurveillance device or a malefactor looking to exploit the potential harm of an

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[110] *Malefactor Definition*, DICTIONARY.COM, http://dictionary.reference.com/browse/Malefactor (last visited Mar. 25, 2011).

[111] *See* U.S. DEP'T. OF JUSTICE, AMERITHRAX INVESTIGATIVE SUMMARY 1 (2009), *available at* http://documents.nytimes.com/amerithrax-investigation-report.

[112] *Id.*

[113] *Id.*

[114] *See* PRESIDENT OF THE U.S., EXECUTIVE ORDER: OPTIMIZING THE SECURITY OF BIOLOGICAL SELECT AGENTS AND TOXINS IN THE UNITED STATES (July 2, 2010), http://www.whitehouse.gov/the-press-office/executive-order-optimizing-security-biological-select-agents-and-toxins-united-stat.

[115] *Id.*

[116] *See* Matishak, *supra* note 26 ("A panel of federal experts convened by an Executive Order in July 2010, has made recommendations in this regard which be made public in late 2011.").

experiment of concern. The Fink Report identified seven dual use experiments of concern to be cautious about.[117]

Risk Matrix	Intentional Harm	Lab Error	Dangerous Experiments (Fink 7)	Synthetic Biology	Gold Rush Biology	High/ Low Ratio	Regulations/ Oversight	Oversight Mechanism
DIY-Malefactor	High	High	High	High	Low	4/1	No	No
DIY-Amateur	Low	High	Low	High	High	3/1	No	No
DIY-Prof. Moonlighter	Low	Low	High	High	High	3/2	No	No
Industry Professional	Low	Low	Low	High	High	2/3	Yes	Yes

VI. PENDING OVERSIGHT LANDSCAPE

Despite general concern over synthetic biology there is no call for a ban from either the National Science Advisory Board for Biosecurity ("NSABB")[118] or the Presidential Commission.[119] It does appear, however, that NSABB leaned more heavily toward oversight than the Presidential Commission.[120] The Presidential Commission recommended that the White House Office of Science and Technology Policy merely keep an eye on the field rather than create a new oversight agency.[121] The Commission was very sympathetic to the biohacker, but did speak favorably of education and training:

> This effort may require the government to expand current oversight or engagement activities with these non-institutional researchers. NIH or the Department of Energy, for example, could be charged to sponsor education programs and workshops that bring together these groups. They could fund training grants or related programs to promote responsibility among this community. To exercise the appropriate level of oversight, the government

[117] NAT'L RESEARCH COUNCIL, *supra* note 13, at 114–15 (2004).

[118] NAT'L SCI. ADVISORY BD. FOR BIOSECURITY, ADDRESSING BIOSECURITY CONCERNS RELATED TO SYNTHETIC BIOLOGY 13 (2010) [hereinafter ADDRESSING BIOSECURITY] ("Biosafety concerns can be adequately addressed by the application of current biosafety practices and procedures.").

[119] NEW DIRECTIONS, *supra* note 40, at 8 ("The Commission endorses neither a moratorium on synthetic biology until all risks are identified . . . .").

[120] *Compare* ADDRESSING BIOSECURITY, *supra* note 118, at 13 (2010), *with* NEW DIRECTIONS, *supra* note 40, at 101–02.

[121] NEW DIRECTIONS, *supra* note 40, at 8 ("[N]o need at this time to create additional agencies or oversight bodies focused specifically on synthetic biology.").

will need to monitor the growth and capacity of researchers outside of institutional settings.[122]

Yet the Commission explicitly advocated against "unique limits on this group."[123] The NSABB made recommendations that arguably extend to biohackers.[124] The NSABB offered several important recommendations with regard to synthetic biology that should pertain to all life science researchers including biohackers.[125] NSABB stated that:

1. Synthetic biology should be subject to institutional review and oversight since some aspects of this field pose biosecurity risks;

2. Oversight of dual use research should extend beyond the boundaries of life sciences and academia; and

3. Outreach and education strategies should be developed that address dual use research issues and engage the research communities that are most likely to undertake work under the umbrella of synthetic biology.[126]

Pending legislation, H.R. 5498, specifically targets synthetic biology.[127] The bill mandates an assessment of the current capability of synthetic nucleic acid providers to effectively screen orders for sequences of homeland security concern.[128] Another bill, H.R. 5057, does propose regulation of individual biohacker labs if they possess, use, or transfer the new class of potentially dangerous agents and toxins.[129]

There are some red flags for the DIY community, however, in the language of extant and proposed laws. For instance, when H.R. 5057 addresses the necessity of research on variola, it qualifies the statement as being within the "legitimate scientific community."[130] A similar issue over language concerning biohackers arises in 18 U.S.C. § 175(b), which states that "Whoever knowingly possesses any biological agent, toxin, or delivery system of a type or in a quantity that, under the

[122] *Id.* at 12.

[123] *Id.* at 13 ("Scrutiny is required to assure that DIY scientists have an adequate understanding of necessary constraints to protect public safety and security, but at present the Commission sees no need to impose unique limits on this group.").

[124] ADDRESSING BIOSECURITY, *supra* note 118, at iii–iv.

[125] *Id.* at 13–14.

[126] *Id.*

[127] H.R. 5498 111th Cong. § 203 (2010).

> SEC. 203. DUAL-USE TERRORIST RISKS FROM SYNTHETIC GENOMICS. (a) SENSE OF CONGRESS.—It is the sense of Congress that the field of synthetic genomics has the potential to facilitate enormous gains in fundamental discovery and biotechnological applications, but it also has inherent dual use homeland security risks that must be managed.

Id.

[128] *Id.* § 203(b)(1).

[129] H.R. 5057 111th Cong. § 318(b) (2010).

[130] *Id.* § 107(b)(2).

circumstances, is not reasonably justified by a prophylactic, protective, bona fide research, or other peaceful purpose, shall be fined under this title."[131]

Thus, the questions remain over the meaning of "legitimate scientific community," and "bona fide research."[132] It is probably safe to assume that biohackers are not contemplated as part of the legitimate scientific community with when it comes to variola. There appears to be more flexibility with bona fide research, but it would probably need to be judged on a case-by-case basis without more guidance from legal authority.[133] The U.S. Code does have a definition for bona fide research with regard to marine mammal protection, which may be instructive.[134] Relevant elements of the definition include research which: "(A) likely would be accepted for publication in a referred scientific journal; (B) are likely to contribute to the basic knowledge of marine mammal biology or ecology; or (C) are likely to identify, evaluate, or resolve conservation problems."[135]

The marine science definition, which requires a peer review scholarship standard—a contribution of basic knowledge to the field or help address problems in the field, makes for a reasonable test for bona fide research.[136] The question is whether or not such a test would or could be applied to biohackers in determining whether there are subject to oversight or accorded certain rights or privileges.

VII. THE PATENT FOR SECURITY EXCHANGE

The term "consideration" is used herein as a term of art in its legal context. Consideration is a well-established legal concept underlying legal contracts.[137] Consideration is defined in a number of ways, but it fundamentally encompasses an exchange between two parties.[138] The exchange need not be equal or close to it, but a fundamental notion of fairness in society rests on exchanges of value between parties.[139] Ballentine's law dictionary defined consideration as, "an act or a forbearance, the creation, modification, or destruction of a legal relation, or a return promise bargained for and given in exchange for a promise."[140] The patent system can actually provide an opportunity for governments to elicit voluntary compliance with security requirements that may otherwise remain beyond government reach. Moreover, the Patent Office is an appropriate place to infuse security requirements since the patent system is actually a government incentive system designed to promote industrial activity.[141] It would actually be irresponsible for governments to create incentives for high-risk activities without a compatible regulatory framework.

[131] 18 U.S.C. § 175(b) (2006).
[132] *See id.*; H.R. 5057, 111th Cong. § 318 (2010).
[133] 18 U.S.C. § 175(b); *see* H.R. 5057, 111th Cong. § 107.
[134] 16 U.S.C. § 1362(22) (2006).
[135] *Id.*
[136] *Id.*
[137] BLACK'S LAW DICTIONARY 347–49 (9th ed., 2009).
[138] *Id.*
[139] *Id.* at 134 ("Consideration that is fair and reasonable under the circumstances of the agreement.").
[140] BALLENTINE'S LAW DICTIONARY 129 (1995).
[141] John A. Dienner, *Patents for Biological Specimens and Products*, 35 J. PAT. OFF. SOC'Y 286 (1953).

The United States has yet to adhere to the warnings put forth in the *World at Risk* report with institutional labs although some efforts for improved lab security are pending.[142] Thus, providing oversight of DIY labs will present unique challenges.[143] It is offered, however, that the United States could establish a measure of oversight by mandating biohacker compliance with a number of security protocols as a condition precedent to patent eligibility. The United States could require lab registration, screen for personnel unfit for work in synthetic biology, and CDC biosafety training. The requirements would not reach all biohackers, but it could enlist the cooperation of a great many of concern and serve as a mechanism to put others on notice that they too need to comply with the garage lab oversight requirements.

The U.S. Patent Office has played an important role in furtherance of national security since the Invention Secrecy Act of 1951 became law.[144] The Patent Office routinely screens patent applications for novel discoveries with implications for national security and issues a secrecy order that classifies the information if the federal agency with expertise in the discipline covered in the application concurs with the decision to classify.[145] The procedures are still in effect and a modest number of secrecy orders are issued on private patent applicants each year.[146] In the fiscal year of 2010 there were twenty-six secrecy orders imposed on private parties seeking patents.[147] Given the successful functioning of this program it is fair to say that the Patent Office could also serve as an effective gatekeeper for the screening of biohackers.

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[142] *See* Matishak, *supra* note 26 (stating that a panel of federal experts convened by an Executive Order in July 2010, has made recommendations in this regard which be made public in late 2011).

[143] *See id.*

[144] Invention Secrecy Act, 35 U.S.C. § 181 (2006).

[145] *Id.*

> Whenever publication or disclosure by the publication of an application or by the grant of a patent on an invention in which the Government has a property interest might, in the opinion of the head of the interested Government agency, be detrimental to the national security, the Commissioner of Patents upon being so notified shall order that the invention be *kept secret* and shall withhold the publication of the application or the grant of a patent there for under the conditions set forth hereinafter.

Id. (emphasis added).

[146] Edmund Andrews, *Cold War Secrecy Still Shrouds Inventions*, N.Y. TIMES, May 23, 1992, at A35.

> Newly available data, obtained from the Patent Office under the Freedom of Information Act by the Federation of American Scientists, show that the number of new secrecy orders increased steadily from 290 in 1979 to 774 in 1991 and that some of the biggest increases took place in the last three years. The total number of secrecy orders in effect has grown steadily in the last decade, from 3,600 in 1979 to 5,893 in 1991.

Id.

[147] *Invention Secrecy Activity*, FED'N AM. SCIENTISTS, http://www.fas.org/sgp/othergov/invention/stats.html (last visited Mar. 25, 2011).

VIII. PERSONNEL RELIABILITY PROGRAMS FOR THE GARAGE LABS

Personnel reliability programs ("PRPs") refers to the screening of personnel for loyalty and stability.[148] PRPs are structured efforts designed to, "help ensure that individuals with access to sensitive materials are trustworthy and reliable. . . . PRPs may include background investigations, security clearances, medical examinations, psychological evaluations, polygraph testing, drug and alcohol screening, credit checks, and systems of ongoing monitoring."[149] Lawrence Livermore National Laboratory already uses a PRP with life science researchers.[150] The United States is close to making regulations on personnel reliability programs, which are designed keep unstable and disloyal personnel away from dangerous pathogens in high containment labs.[151]

The United States began looking at the application of personnel reliability programs to scientists working in high containment labs in response to three significant events.[152] Firstly, there was the F.B.I.'s finding that an inside researcher working for the government was responsible for the anthrax attacks of 2001.[153] Secondly, there was an alarming report from the U.K. that terrorists tried to infiltrate labs as postgraduate students to acquire WMD expertise and materials.[154] Thirdly, the discovery of the A. Q. Khan proliferation network added to the urgency for enhanced lab security.[155]

It is unlikely that the United States could implement a comprehensive PRP for the DIY community.[156] It could, however, be successful in running a basic program that screens for easy to identify records that speak to the trustworthiness of an individual, *i.e.* a criminal record.[157] It would be quite reasonable to deny convicted felons the benefit of patent protection in synthetic biology.[158] A great deal of trust is required of DIY researchers working on synthetic biology and it is reasonable to conclude that convicted felons are not worth risk of granting that trust.[159] Serious consideration, however, must go in to applying PRP's further. For instance, an argument could be made that researchers terminated from academic and institutional settings for improper research conduct should likewise be restricted

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[148] *See* NAT'L SCI. ADVISORY BD. FOR BIOSECURITY, ENHANCING PERSONNEL RELIABILITY AMONG INDIVIDUALS WITH ACCESS TO SELECT AGENTS 5 (2009).

[149] *See id.* at iii.

[150] *See* Eric Gard, Lawrence Livermore Nat'l Lab., LLNL Select Human Agent Reliability Program (Dec. 10, 2008).

[151] *See* NAT'L SCI. ADVISORY BD. FOR BIOSECURITY, *supra* note 148, at ii.

[152] *See id.*

[153] *See The F.B.I.'s Anthrax Case*, N.Y. TIMES, Feb. 28, 2010, at WK9.

[154] NAT'L SCIENCE ADVISORY BD. FOR BIOSECURITY, NAT'L HEALTH INSTS. MINUTES OF MEETING 3 (Dec. 10, 2008).

[155] Mark Lander, *Pakistan Chief Says it Appears Scientists Sold Nuclear Data*, N.Y. TIMES, Jan. 24, 2004, at A7.

[156] Michael Greenberger, Talley Kovacs & Marita Mike, *Governance and Biosecurity: Strengthening Security and Oversight of the Nation's Biological Agent Laboratories*, 13 DEPAUL J. HEALTH CARE L. 77, 86 (2010).

[157] *See* NAT'L SCI. ADVISORY BD. FOR BIOSECURITY, *supra* note 148, at iii.

[158] *See, e.g.*, 735 ILCS § 5/24-1.1 (showing an example of other things convicted felons cannot do, including possessing a firearm).

[159] *Id.*

from obtaining synthetic biology patents as a biohacker.[160] But such an expansion of oversight would require due process for the applicant.[161] Other factors that could possibly justify denial of garage lab privileges and patent protection include those researchers found to have violated key rules and regulations related to biosecurity and those deemed mentally unfit.[162] The question of mental fitness is a challenging policy issue that requires further deliberation beyond the scope of this paper. The recently released report that assessed the mental state of the man the F.B.I. deemed responsible for the Antrhax attacks, will no doubt fuel debate on mental fitness and personnel reliability screening for some time to come.[163]

IX. TRAINING

The NSABB and the Presidential Commission both recommended that the United States provide training and education for researchers in regard to synthetic biology.[164] Proper training could help reduce the inadvertent safety lapses that are more likely to take place in a garage lab.[165] A number of approaches could be used to address the safety education requirement. DIY researchers could be tested on their comprehension of various biosafety materials such as the CDC biosafety course,[166] and literature such as the *NIH Guidelines for Research Involving Recombinant DNA Molecules*,[167] *Biological Safety: Principles and Practices*, from the ASM Press,[168] in addition to any other relevant occupational and safety resources.

The training should also include the role of peer reporting when suspicious activity is discovered.[169] Peer reporting was advocated in Report of the Working Group on Strengthening the Biosecurity of the United States in 2009.[170] It was also

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[160] *Id.* (showing the similarity between a convicted felon losing the right to possess a firearm as analogous to a terminated researcher being banned from obtaining synthetic biology patents).

[161] *See* U.S. CONST. amend. 14, § 1.

[162] *See* NAT'L SCI. ADVISORY BD. FOR BIOSECURITY, *supra* note 148, at iii.

[163] *See generally Report of the Expert Behavioral Analysis Panel,* RESEARCH STRATEGIES NETWORK 1 (Aug. 23, 2010), https://www.researchstrategiesnetwork.org/images/docs/EBAP_Report_ExSum_Redacted_Version.pdf (discussing Dr. Ivins, the man behind the Anthrax case and stating "The Panel's review of the sealed psychiatric records, however, does support the Department of Justice's (DOJ's) determination that he was responsible. Dr. Ivins was psychologically disposed to undertake the mailings; his behavioral history demonstrated his potential for carrying them out; and he had the motivation and the means. The psychiatric records offer considerable additional circumstantial evidence in support of the DOJ's findings.").

[164] *See* NAT'L SCI. ADVISORY BD. FOR BIOSECURITY, *supra* note 118, at 13; NEW DIRECTIONS, *supra* note 40, at 146.

[165] *See* NEW DIRECTIONS, *supra* note 40, at 146–47.

[166] *See* CTRS. FOR DISEASE CONTROL & PREVENTION, BIOSAFETY IN MICROBIOLOGICAL AND BIOMEDICAL LABORATORIES 22 (2009).

[167] *See* DEPT. OF HEALTH & HUMAN SERVS., NIH GUIDELINES FOR RESEARCH INVOLVING RECOMBINANT DNA MOLECULES, 1–135 (2011).

[168] *See generally* DIANE O. FLEMING & DEBRA L. HUNT, BIOLOGICAL SAFETY: PRINCIPLES AND PRACTICE, 1–640 (3d ed. 2000) (describing the practice of laboratory safety when dealing with various biological organisms).

[169] *See* DEPT. OF HEALTH & HUMAN SERV., REPORT OF THE WORKING GROUP ON STRENGTHENING THE BIOSECURITY OF THE UNITED STATES 136 (2009).

[170] *Id.*

advocated by Special Agent You of the FBI, who referred to it in the context of "situational awareness."[171]

X. Lab Registration

Registration is accepted practice in the United States and imposing an exception for DIY biologists cannot be reconciled easily.[172] Moreover, registries will be used to help researchers advance their work, thus it is entirely appropriate to use registries for security purposes.[173] The NIH is creating a Genetic Testing Registry that is intended to help researchers.[174] The GTR will be designed to "Facilitate genomic data-sharing for research and new scientific discoveries."[175] Health and Human Services successfully maintains a registry of tens of thousands of labs.[176] The registry serves an important public disclosure purpose. Under the program the Centers for Medicaid and Medicare make a public list of those labs that have been convicted under state and federal law of fraud, abuse, or received sanctions from the governing authority.[177] In this connection, a proposed bill would create a new government registry, which would list agents and toxins that have the potential to be used in a biological attack.[178] A national database with the location of labs or individuals housing these agents and toxins is included in the bill.[179]

XI. The Private Sector Policy Gap

The lab security reports of 2009 issued for the United States, on the whole, failed to provide strong guidance to the U.S. government on how to manage the emerging need for lab regulations in the private sector.[180] It is true that at present, the private biotechnology sector generally presents less risk compared to government and university labs, but risk is generated in that sector as well.[181] The private biotechnology sector is diverse and would need varying degrees of oversight in like manner to labs in other sectors.[182] Thus, the government should formulate a stratified regulatory framework that matches the risk generated by the work

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[171] Edward You, FBI Special Agent, Presentation at the Open Science Summit: Safety and Security Concerns: Open Source BioDefense (July 30, 2010).

[172] *See* 42 U.S.C. § 262 (2006).

[173] *See id.* § 263(a).

[174] Press Release, NIH Office of Commc'ns, NIH Announces Genetic Testing Registry (Mar. 18, 2010), http://www.nih.gov/news/health/mar2010/od-18.htm.

[175] *Id.*

[176] *See* 42 C.F.R. § 493.1850 (2010).

[177] *Id.*

[178] H.R. 5057 111th Cong. § 103(a) (2010) (amending Section 351A of the Public Health Service Act, 42 U.S.C. § 262(a)).

[179] *Id.*

[180] *See* Health & Human Services, *supra* note 169, at 3; Brian J. Gorman & J. Corey Creek, *Risk & Reliability of Laboratory Personnel in* Biosecurity Commons Rev. 28–48 (May 2010), http://www.scribd.com/doc/30902475/Bio-Security-Commons-AR-May-2010.

[181] *See id.* at 27.

[182] *Id.*

undertaken in each type of lab rather than over-look some labs simply because they lack government ties.

The regulatory framework needs to be even across the life science community as recommended in the World at Risk Report because regardless of their affiliation or form of incorporation.[183] The U.S. government clearly has authority to impose regulations on all labs in the United States that generate a threat to national security.[184] The challenge at hand, however, is fostering good faith compliance with security initiatives in the gray areas, i.e. those labs that present lesser but substantial or inconsistent risks that may go unnoticed by authorities as the biotechnology sector expands.[185] Future growth in biotechnology will come in large part from young biotechnology companies, which are developing their first products and depend on investor capital for survival.[186] Therefore, a framework based on the equitable notion of consideration could arguably generate the cooperation the U.S. government needs to reach labs in the vast areas of the private sector.[187]

The patent for security exchange paradigm should also help reduce the fears associated with unilateral government regulations in the scientific community. This approach could help foster a culture of responsibility in the private sector since those seeking the benefits of patent protection would have a vested interest in fostering the culture of responsibility at their growing startup and amongst their peers. The benefits bestowed through government issued patents are critical for continued growth of the biosciences.[188] In this connection, the fact that 82,000 bioscience patents were issued from 2002 and 2007, speaks to the potential strength of the relationship between industry growth and a culture of regulatory responsibility.[189]

Many experts, including those voices represented in the many lab security reports of 2009, tend to view the life science community as distinct sectors.[190] The emerging reality, however, is that the life science community is a growing confluence of university, government, for-profit and non-profit entities.[191] Thus the private sector cannot simply be ignored; even the Department of Defense relies on private contractors for work on Biological Select Agents and Toxins ("BSAT").[192]

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[183] *See* BOB GRAHAM ET AL., WORLD AT RISK: THE REPORT OF THE COMMISSION ON THE PREVENTION OF WMD PROLIFERATION AND TERRORISM 25 (2008).

[184] *See, e.g.*, Nat'l Aeronautics & Space Admin. v. Nelson, 131 S. Ct. 746 (2011) (holding that two parts of a standard employment background investigation in connection with NASA laboratories did not violate a constitutional right to information privacy).

[185] *See* HEALTH & HUMAN SERVICES, *supra* note 176, at 25.

[186] Paul E. Schaafsma, *The Case for Financial Product Patents: What the Supreme Court Got Right and Wrong in Bilski v. Kappos, and a Suggestion for a Reasonable Line of Business Method Patents*, 92 J. PAT. & TRADEMARK OFF. SOC'Y 398, 417 (2010).

[187] *See* GRAHAM ET AL., *supra* note 183, at 25–26.

[188] *See* Schaafsma, *supra* note 186, at 417.

[189] BATTELLE TECH. P'SHIP PRACTICE, *supra* note 56, at ES-3.

[190] *See* HEALTH & HUMAN SERVICES, *supra* note 169, at 29.

[191] *See* BATTELLE TECH. P'SHIP PRACTICE, *supra* note 56, at ES-3.

[192] DEPT. OF DEFENSE, INSTRUCTION: MINIMUM SECURITY STANDARDS FOR SAFEGUARDING BIOLOGICAL SELECT AGENTS AND TOXINS § 2.2 (2006).

XII. TOWARD GLOBAL HARMONIZATION OF BIOSECURITY REGULATIONS

Finally, but equally important, the utilization of the patent office as a critical intersection of security and intellectual property protection may help with the great challenge of international harmonization. The establishment of a successful U.S. patent for security paradigm could help establish linkages with further global efforts. For instance, the World Intellectual Property Organization ("WIPO") could play a role since it already works to harmonize intellectual property rights.[193] WIPO is in a unique position to help bring harmonization of security measures to those seeking patent protection in many nations.[194] In fact a number of the WIPO's strategic goals are consistent with the global harmonization of a lab security framework.[195] The WIPO seeks, among other things, a balanced evolution of the international normative framework for intellectual property ("IP"), coordination and development of a global IP infrastructure, international cooperation on building respect for IP, and it also seeks to address IP in relation to global policy issues.[196] Thus, the WIPO may be able to serve as a persuasive entrée for international linkages between patent for security programs in other nations. U.N.'s interest in harmonizing biosecurity oversight likewise speaks to likelihood of success of international patent for security programs.[197]

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[193] Michael Taylor & Jerry Cayford, *American Patent Policy, Biotechnology, and African Agriculture: The Case for Policy Change*, 17 HARV. J. LAW & TECH. 321, 326 (2004) (stating that the WTO and WIPO harmonize patent law and policy across international borders).

[194] Debra M. Strauss, *The Application of TRIPS to GMOS: International Intellectual Property Rights and Technology*, 45 STAN J. INT'L L. 287, 318–19 (2009).

[195] *What Is WIPO?*, WORLD INTELL. PROP. ORG., http://www.wipo.int/about-wipo/en/what_is_wipo.html (last visited Mar. 25, 2011).

[196] *Id.*

[197] Jonathan B. Tucker, *Dual Use Dangers: Biotechnology and Global Security Are Intertwined*, SCI. PROGRESS (Oct. 16, 2007), http://www.scienceprogress.org/2007/10/dual-use-dangers/.