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ALTERNATIVE INTELLECTUAL PROPERTY FOR GENOMICS AND THE ACTIVITY OF TECHNOLOGY TRANSFER OFFICES: EMERGING DIRECTIONS IN RESEARCH

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ABSTRACT

Numerous ethical and social issues have arisen over the last decade concerning both the patenting and licensing of genomic inventions. As a result, conventional practices at Technology Transfer Offices, the gatekeepers of intellectual property at universities and research institutions, have been the subject of increased scrutiny, with concerns raised about the impact of Intellectual Property practices upon ongoing research, innovation, and access to technologies by developing countries. On a separate front, proposals for alternatives to traditional Intellectual Property law, including open source, patent pools, and the public domain, are emerging. In this article we assess

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these movements and proposals by Technology Transfer Offices and other stakeholders, as well as the closely related issue of traditional metrics systems that measure technology transfer success. We conclude that traditional metrics models are typically inadequate to validate the broad-spectrum impact of genomic innovation, and are unlikely to accord success to any uses of alternative IP. Alternative IP could impact metrics currently employed by Technology Transfer Offices and conversely, new metrics could influence the adoption of alternative IP approaches and better evaluate the contribution of genomic research to society.

I. INTRODUCTION

Concerns about intellectual property regimes (IPRs) have arisen on many fronts in the biomedical field in recent years, but one area the public has

focused much of its attention on is that of genomics.[2] This focus stems from the very public confrontation between public and private science in one of the largest international scientific efforts ever undertaken, the Human Genome Project. The confrontation there centered largely on the ownership of the information and discoveries generated during the publicly funded sequencing of the human genome. Those who believed science, and particularly publicly funded science, should remain in the public domain – accessible to all – were pitted against others who took the view that turning the Human Genome Project's results into IP was the best way to capture public investment. Notably, this conflict took place against a backdrop of an enormous surge in gene patent applications by both public and private institutions, which made the apparent privatization of publicly funded research a more compelling and controversial issue to the interested public.[3]

More broadly, the rise in gene patents and intellectual property (IP) use in genomics raises concerns about ethics, the norms of science and university values, and the impact on further research and innovation.[4] Conventional practices at Technology Transfer Offices (TTOs) have similarly been the subject of increased scrutiny, with concerns raised about respective impacts upon ongoing research, innovation, and access to medicines/technologies by developing countries.[5] There even are examples of individual researchers and laboratories adopting their own approaches to IP and technology transfer in an effort to address concerns about the practice of science, innovation, and access that have arisen in their own immediate spheres.[6]

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[2] For clarity, the field of "genomics" can be essentially defined as the study of the DNA of organisms in their entirety. This study of genomes generally includes, *inter alia*, sequencing the DNA (genomic), mRNA and proteins found in an organism, and mapping both genes and their regulatory sequences. Structural genomics researchers aim to interpret genomic information to determine the three dimensional structure of proteins coded by the genomes of organisms. Building on these studies, functional genomics aims to use the wealth of data created by genomic research to determine the biological function of each gene and gene product (protein, mRNA, microRNA, etc.).

[3] *See generally* JOHN SULSTON & GEORGINA FERRY, THE COMMON THREAD: A STORY OF SCIENCE, POLITICS, ETHICS AND THE HUMAN GENOME (2002); JAMES SHREEVE, THE GENOME WAR: HOW CRAIG VENTER TRIED TO CAPTURE THE CODE OF LIFE AND SAVE THE WORLD (2004); J. CRAIG VENTER, A LIFE DECODED: MY GENOME, MY LIFE (2007).

[4] *See* Michael Heller & Rebecca Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698 (1998).

[5] *See* Amy Kapczynski, E Tyler Crone & Michael Merson, *Global Health and University Patents*, 301 SCIENCE 1629 (2003); David Chokshi & Rahul Rajkumar, *Leveraging University Research to Advance Global Health*, 298 JAMA 1934 (2007).

[6] Timothy Caulfield, Robert M. Cook-Deegan, F. Scott Kieff & John P. Walsh, *Evidence and Anecdotes: An Analysis of Human Gene Patenting Controversies*, 24 NATURE BIOTECHNOLOGY 1091 (2006).

In this paper we examine two interrelated responses to the IP and TTO concerns in the United States and Canada. The first relates to proposals for alternatives for upstream genomics discoveries. The other focuses on assessments of the performance of TTOs, particularly as that performance is reflected in the metrics these offices employ to assess success. Clearly these two responses are closely related. IPRs refer not only to criteria and practices used in patenting and copyright, but also to the ways in which intellectual property is licensed. TTOs, in this sense, act as gatekeepers both with respect to seeking intellectual property protection and to licensing that IP.

We begin in Section II with a discussion of the growth of patents and the large role that TTOs have assumed since the passage of the Bayh-Dole Act in the United States in 1980. Section III examines the main concerns raised by conventional IPR. In particular, we assess claims that IPRs expanded through gene patenting in the 1990s, that IPRs threaten the norms of science, and that overreliance on IP can lead to anti-commons effects and patent thickets.

Section IV examines some of the leading contenders for alternative IPRs in the genomics arena. These include creative uses of IPRs such as open source approaches and patent pools, as well as strategies that bypass IPRs in favor of the public domain.

In Section V we turn to TTOs and discuss several proposals to reform various examples of their practices. These include guidelines promulgated by National Institutes of Health (NIH) and the Organization for Economic Co-operation and Development (OECD), respectively, and proposals to broaden access. Then, in Section VI, after examining the conventional metrics by which TTOs measure their performance, we describe and analyze several recent proposals for major changes in metrics. The conventional approach is to judge TTO success almost exclusively in terms of either financial criteria or closely related factors, such as the number of patents filed for and granted, the number of spin-off companies created, the amount of royalties received, etc. The new metrics cast the net much wider by attempting to also measure a wide range of societal benefits.

Ultimately, our focus on innovative metrics is driven by a belief that such metrics can be clear and important indicators of the changed focus of TTOs and, in some cases, can be causal contributors in effecting change. We argue that the mutual interaction between TTOs and some forms of alternative IP can in fact begin to create change: in one instance, the determination of one TTO to ensure open access of knowledge around the SARS virus led them to adopt a patent pool strategy, thereby impacting the manner in which potential vaccines or treatments could be developed.[7] Where the productivity of a TTO is measured only by commercial outcomes, this activity may not be gauged as a

[7] Ed Levy, Emily Marden, Ben Warren, David Hartell & Isaac Filaté, *Patent Pools and Genomics: Navigating a Course to Open Science?*, 16 B.U. J. SCI. & TECH. L. 75, 78 (2010).

success. The use of this form of alternative IP, however, reflects a change in focus of certain TTOs and has the potential to change scientific practice for vaccine development, as evidenced by this limited case. Thus, in a complementary manner, changes in TTO metrics for success can ease the way for alternative IP approaches, and the reverse is also true.

II. BACKGROUND

A. Patents

As the development of biotechnology took off in the 1980s, so too did the rates of patents applied for and granted on emerging scientific work. This is especially true in the area of gene patents. The annual number of gene patent applications and the granting of those applications went from a handful per year in the United States, starting in the early 1970s, to over 4,500 in 2001 alone.[8] In Canada prior to 1980 there were no patents issued on genes or nucleic acid sequences.[9] By the beginning of 2002, the Canadian Intellectual Property Office had issued 2,200 patents and received over 15,000 applications in which genes or nucleic acids were claimed.[10] To date, approximately twenty percent of the human genome is patented in the United States.[11]

The race to patent genes and other upstream genetic discoveries quickly attracted attention amongst practitioners and observers alike and began to raise concerns. For many, the issue was an ethical one: how could genetic materials derived from humans,[12] animals, or plants[13] become the property of any single enterprise? Others wondered whether fencing off of these resources would impact medical practice and ethics. Nevertheless, precedent was quickly set in the United States with a series of judicial opinions that clearly allowed for a broad swath of genetic information to be patentable.[14]

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[8] NAT'L RESEARCH COUNCIL OF THE NAT'L ACADEMIES, REAPING THE BENEFITS OF GENOMIC AND PROTEOMIC RESEARCH: INTELLECTUAL PROPERTY RIGHTS, INNOVATION, AND PUBLIC HEALTH 101-02 (Stephen A. Merrill & Anne-Marie Mazza eds., 2006).

[9] *See* ANITA NADOR & JENNIFER JONES, BERESKIN & PARR, PATENTING GENES: CANADA, US AND EUROPE (2002), *available at* http://www.bereskinparr.com/English/publications/pdf/Bio-Patent-Genes-Nador.pdf.

[10] *Id.*

[11] Kyle Jensen & Fiona Murray, *Intellectual Property Landscape of the Human Genome*, 310 SCIENCE 239, 239-40 (2005).

[12] *See generally* LORI ANDREWS & DOROTHY NELKIN, BODY BAZAAR: THE MARKET FOR HUMAN TISSUE IN THE BIOTECHNOLOGY AGE (2001).

[13] *See generally* VANDANA SHIVA, PROTECT OR PLUNDER? UNDERSTANDING INTELLECTUAL PROPERTY RIGHTS (2002).

[14] Note that the usual criteria for patenting still apply, i.e., the invention must be novel, non-obvious, and have industrial application or utility.

In *Diamond v. Chakrabarty*,[15] the U.S. Supreme Court held that "anything under the sun made by man" is patentable, as long as it conforms to the definition of "invention" in the legislation. Consequently, the terms "manufacture" and "composition of matter" that form the definition of "invention" were interpreted to include some higher life forms, such as multi-cellular organisms.[16]

The U.S. Patent and Trademark Office (USPTO) subsequently issued a statement that "[t]he Patent and Trademark Office now considers non-naturally occurring non-human multi-cellular living organisms, including animals, to be patentable subject matter within the scope of [the patent legislation]."[17] Given such a landscape, it is unsurprising that in the United States no litigation ensued when Harvard University applied for a patent on its genetically engineered mouse.[18] Further, in 2001, the U.S. Supreme Court held that sexually reproducing hybrid corn plants were patentable, regardless of whether they were genetically modified.[19]

Canada's approach to life patents followed a different trajectory, but still allows for patents on fundamental genetic discoveries. In *Re Application of Abitibi Co.*,[20] the Canadian patent examiner initially rejected an application by Abitibi Co. to patent a microbial culture on the grounds that living matter is not patentable. This decision, however, was subsequently reversed by the Canadian Patent Appeal Board, relying heavily on the decisions in other jurisdictions, including *Chakrabarty*, to find that courts were consistently interpreting "invention" broadly enough to include living matter.[21]

Canadian law took a divergent turn regarding patenting life in the subsequent case *Harvard College v. Canada (Commissioner of Patents)*,[22] in which the majority of the Supreme Court of Canada (SCC) held that genetically engineered mice do not fall within the definition of an invention, because they do not qualify as a "composition of matter" or a "manufacture."

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[15] *See generally* Diamond v. Chakrabarty, 444 U.S. 1028 (1980).

[16] *Ex parte* Allen, 2 U.S.P.Q.2d 1425, 1427 (B.P.A.I. 1987).

[17] *Animals--Patentability*, 1077 OFF. GAZ. PAT. OFF. 24 (Apr. 21, 1987).

[18] Kathryn Garforth, *Life as Chemistry or Life as Biology? An Ethic of Patents on Genetically Modified Organisms*, *in* PATENTING LIVES: LIFE PATENTS, CULTURE AND DEVELOPMENT, 40 (Johanna Gibson ed. 2008).

[19] J.E.M. Ag Supply Inc. v. Pioneer Hi-Bred Int'l, 534 U.S. 124 (2001).

[20] *Re* Application of Abitibi Co., [1982] 62 C.P.R. (2d) 81, 82 (Pat. App. Bd.) (Can.).

[21] In Canada, the follow-on decision did not follow the expansive parameters set in the United States. For example, in *Pioneer Hi-Bred Ltd. v. Canada (Commissioner of Patents)*, the Federal Court of Appeal held that cross-bred plant varieties did not fall under the scope of the definition of "manufacture" or "composition of matter," even according to the broad definition in *Chakrabarty*. Pioneer Hi-Bred Ltd. v. Canada (Comm'r of Patents), [1987] 14 C.P.R. 491 (Can.).

[22] Harvard Coll. v. Canada (Comm'r of Patents), [2002] 4 S.C.R. 45 (Can.).

In that decision, the majority held that intervention by Parliament was required in order for patents on "higher life forms" to be recognized.[23] The decision turned on the fact that the existence of specific legislation for plant breeders' rights, and an absence of analogous legislation specifically designating "higher life forms" as patentable, indicated an absence of that intent on the part of Parliament.[24] The net impact of the *Harvard College* case in differentiating Canada's approach is unclear in light of *Monsanto Canada Inc. v. Schmeiser*, a subsequent case in which the SCC held that patents held on components of living organisms can effectively grant the patent holder exclusionary rights over a higher life form. [25]

Developments in international law solidified the trend of accepting biological matter as patentable subject matter. With the signing of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) treaty, all members of the World Trade Organization were obligated to issue patents on any inventions in any field of technology, provided they met the criteria of novelty, inventive step, and the presence of industrial application.[26] In addition, the European Directive on the Legal Protection of Biotechnological Inventions specifies that biotechnological inventions are patentable under the law of member states of the European Union if they satisfy the patentability criteria, though this directive allows for national bodies to refuse patents on inventions that are contrary to *ordre public* or morality,[27] an avenue not available under United States and Canadian law.

While the practice of gene patenting has been widely accepted, there has

[23] *Id.* at 46.

[24] *Id.*

[25] Monsanto Canada Inc. v. Schmeiser, [2004] 1 S.C.R. 902 (Can.). Monsanto held a patent on the gene that makes canola plants resistant to Roundup, and on the cells containing that gene, but not on the canola plant itself. Percy Schmeiser, a farmer, discovered Monsanto's Roundup Ready canola growing in his field and subsequently harvested the seeds from the canola and planted them the following season. Consequently, Monsanto sued him for patent infringement. The SCC held that Schmeiser infringed the patent because he relied on the "standby" value of the invention – in other words, he could have sprayed the plants with Roundup. Thus, although Monsanto does not hold a patent on the canola plant itself, it still effectively retains control over the use of Roundup Ready canola. Further, on June 20, 2006, the Canadian Intellectual Property Office took the position that "[a]nimals at any stage of development, from fertilized eggs on, are higher life forms and are not patentable subject matter under s. 2 of the Patent Act . . . ." distinguishing between higher life forms and stem cells for purposes of patentability. *See* Canadian Intellectual Property Office, Patent Notice, June 20, 2006, http://www.opic.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr00295.html.

[26] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, 108 Stat. 4809, 1869 U.N.T.S. 299.

[27] Council Directive 98/44/EC, art. 1, 1998 O.J. (L 213) 13 (EC).

been some recent narrowing in the available scope for such patents. For example in 1999, in the United States the USPTO issued Utility Examination Guidelines that restricted patent utility and that were passed into law in 2001.[28] Of note is that DNA patent application numbers in the United States peaked in 2001 when the guidelines were passed, and have since been declining.[29]

B. Technology Transfer Offices

In the same period that gene patenting became widely accepted and practiced, TTOs began to emerge on United States and Canadian university and research agency campuses. The number of TTOs at United States institutions went from around 21 in 1980 to 176 in 2002.[30] The number of TTOs in Canada also increased during this time. In 1980, only one institution in Canada[31] was a member of the Association of University Technology Managers (AUTM); as of 2007, this number had increased to 37.[32]

Most IP scholars point to the passage of the Bayh-Dole Act in the United States in 1980 as the trigger point for the growing interest in patenting and indeed, for the increase of TTOs at universities.[33] The Bayh-Dole Act, in essence, encouraged institutions to own inventions resulting from federally sponsored research and to exploit those inventions.[34] In addition, Bayh-Dole requires institutions receiving federal research dollars to establish patent policies for its employees, to actively seek patent protection, and to encourage the development of their institutions' innovations.[35]

Although overlooked by many, patenting by research institutions in the United States was possible and practiced even prior to 1980.[36] The Bayh-Dole Act did not, in fact, change this reality. It did, however, serve the important functions of making the process uniform and easier to implement across governmental funding agencies. In addition, the Bayh-Dole Act helped to

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[28] Utility Examination Guidelines, 66 Fed. Reg. 1092 (Jan. 5, 2001).

[29] Lori Pressman et al., *The Licensing of DNA Patents by US Academic Institutions: An Empirical Survey*, 24 NATURE BIOTECH 31, 35 (2006).

[30] As measured by membership in AUTM. *See* ASS'N OF UNIV. TECHNOLOGY MANAGERS, *CANADIAN LICENSING ACTIVITY SURVEY: FY2007 SURVEY SUMMARY*, DATA APPENDIX: SUMMARY OF FY 2005-07.

[31] The Univ. of Toronto was the first member of AUTM from Canada. *See id.* at 52.

[32] *See id.* at 51-53.

[33] *See* 35 U.S.C. §§ 200-12 (2006); 37 C.F.R. 401 (2009).

[34] *See* 35 U.S.C. §§ 200-12; 37 C.F.R. 401.

[35] *See* 35 U.S.C. §§ 202 (establishing a regime for disposing of patent rights in federally-funded research); 37 C.F.R. 401.

[36] *See* David. C. Mowery & Bhaven N. Sampat, *The Bayh-Dole Act of 1980 and University-Industry Technology Transfer: A Model for Other OECD Governments?*, 30 J. TECH. TRANSFER 115, 115 (2005).

focus attention and priority on activities that, its supporters argued, could effectively capture the value of federal research dollars by moving new knowledge into the commercial world.[37] The Bayh-Dole Act reflects the efforts of those who believed that patent rights should be available on government funded research, characterizing this availability as a boon to competitiveness and a solution to a perceived "technology gap" between the United States and other industrialized countries.[38] This justification continues to form the basis of much work by TTOs.[39]

Although there is no Bayh-Dole legislative analogue in Canada, universities and research institutions have embraced a similar policy of technology transfer,[40] and the role of TTOs has grown. While the general trend in the United States was to direct university research towards the market through a series of legislative initiatives, the Canadian government chose a more indirect approach by creating a "climate of commercialization," in which both federal and provincial governments cooperated with universities, industry and labor.[41]

In their current form at most United States and Canadian research institutions, TTOs are key actors in the assessment of a technology's patentability, applying for and maintaining patents, and the negotiation of material transfer and licensing agreements for material access and IP use, respectively. As such, TTOs intimately manage IP choices in publicly-funded research institutions even though, as part of university administrations, they may not be entirely autonomous.[42] Research-funding bodies acknowledge that individual intellectual property interests should be explored through institutional TTOs.[43]

III. CONCERNS ABOUT IP PRACTICES

Large numbers of patents related to genomics research have been granted

[37] *See* Elizabeth Popp Berman, *Why Did Universities Start Patenting? Institution-Building and the Road to the Bayh-Dole Act*, 38 SOC. STUDIES SCI. 835, 849-51 (2008).

[38] *See id.* at 836, 858.

[39] *See generally* MATTHEW HERDER & JOSEPHINE JOHNSTON, LICENSING FOR KNOWLEDGE TRANSFER IN HUMAN GENETICS RESEARCH, *available at* http://www.theinnovationpartnership.org/data/documents/00000015-2.doc.

[40] *See id.*

[41] *See* Janet Atkinson-Grosjean, *Science Policy and University Research: Canada and the USA, 1979-1999*, 2 INT'L J. TECH. POL'Y MGMT. 102, 112 (2002).

[42] *See* HERDER & JOHNSTON, *supra* note 39.

[43] There are various examples of intellectual property agreements for collaborative or industry-sponsored research. *See* National Cancer Institute, Intellectual Property (IP) Management Plans, http://ttc.nci.nih.gov/intellectualproperty/sample.php; *see also* GENOME CANADA, DATA RELEASED AND RESOURCE SHARING (2008), *available at* http://www.genomecanada.ca/medias/PDF/EN/DataReleaseandResourceSharingPolicy.pdf.

over the past several decades and TTOs, by their own measures, license these technologies with success, generating – in some cases – significant income for their institutions.[44] With respect to genomics research,[45] however, there are growing statements of concern about how IP is utilized and the appropriate role of TTOs in managing innovation.[46] These include worries about the impact of patent practices on the open practice of science[47] and on the pursuit of research and innovation.[48] We examine each of these issues briefly in turn.

A. Practice of Science

Open science is a term loosely used to refer to practices of transparency and sharing in science; such practices arguably advance both collegiality and the potential for research advances. This concept is often attributed to Robert K. Merton's writings on the history of sciences,[49] but has continued to be the subject of commentary in more contemporary discussions.[50] Stated broadly, the concern for open science is that the focus on patents fostered by the growth of gene patenting, the strong emergence of a biotechnology industry and the

[44] *See* ASS'N OF UNIV. TECHNOLOGY MANAGERS, AUTM U.S. LICENSING ACTIVITY SURVEY, FY 2007 SURVEY SUMMARY, DATA APPENDIX: U.S. (Robert Tieckelmann et al. eds.).

[45] We have concentrated on addressing this array of concerns with a focus on upstream academic research. We recognize, of course, that there are significant issues to consider with respect to IP practices on applied genomic research, from research tools to drug development.

[46] In Intellectual Property Law, questions have long been raised about the ethics of allowing ownership of genetic material. *See* Andrews, *supra* note 12. This paper acknowledges these continuing concerns about the ethics of patenting. *See, e.g.*, *ACLU v. Myriad Genetics Suit: Legitimate Challenge or Publicity Stunt?*, GENOMICS L. REP., June 4, 2009, http://www.genomicslawreport.com/index.php/2009/06/04/aclu-v-myriad-genetics-suit-legitimate-challenge-or-publicity-stunt/. These concerns, however, are not the focus of this paper.

[47] See SULSTON, *supra* note 3; *see also* Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting*, *in* INNOVATION POLICY AND THE ECONOMY 1 (Adam B. Jaffe et al. eds. 2000), *available at* http://faculty.haas.berkeley.edu/shapiro/thicket.pdf.

[48] Heller & Eisenberg, *supra* note 4, at 698; *see also* Rebecca S. Eisenberg, *Patents and Data-Sharing in Public Science*, 15 INDUS. AND CORP. CHANGE 1013 (2006); Robert Cook-Deegan & Tom Dedeurwaerdere, *The Science Commons in Life Science Research: Structure, Function and Value of Access to Genetic Diversity*, 58 INT'L SOC. SCI. J. 299, 313 (2006).

[49] ROBERT K. MERTON, ON THE SHOULDERS OF GIANTS; A SHANDEAN POSTSCRIPT (Free Press 1965); *see also* ROBERT K. MERTON, THE SOCIOLOGY OF SCIENCE: THEORETICAL AND EMPIRICAL INVESTIGATIONS (Norman W. Storer ed., Univ. of Chicago Press 1973).

[50] *See, e.g.*, Sulston, *supra* note 3, at ix; *see also* Deegan, *supra* note 44.

directives offered by the Bayh-Dole Act, diminish open practices and turn universities away from public-minded research in favor of potential commercial pursuits.[51] The implication is that genomics scientists may be less open and collaborative in the pure pursuit of knowledge as they might have been before the advent of widespread IP in this area. Some scholars have identified impacts on the types of science and the interchange between scientific practitioners as a function of the pursuit of IP rights.[52]

B. Concerns about Anti-Commons and Patent Thickets

There are also concerns about the impact of IP practices on the potential for future innovation. The fear is that if the genomics research landscape is characterized by numerous patents on basic upstream research, there is, consequently, a potential for the creation of an "anti-commons" and/or patent thickets which could block further scientific development and possibly the production of healthcare products.[53]

The "anti-commons" is a term that was first used in the biosciences context by Michael Heller and Rebecca Eisenberg to describe a situation "in which people underuse scarce resources because too many owners can block each other."[54] A patent thicket, in turn, is commonly understood as "a dense web of overlapping intellectual property rights that a company must [get] through in order to actually commercialize [a] new technology."[55] Both of these concepts reflect genuine concerns about the relationship between genomic research and IP and have resonated within and outside the research community.

In reality, the extent of the impact of an anti-commons in genomics is not entirely clear. As articulated in Heller and Eisenberg's seminal article, the anti-commons could result in a potential decline in scientific research as researchers are blocked from access to, or use of, key ideas. Empirical studies carried out in recent years have questioned the extent or impact of this effect.[56]

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[51] *See* SHELDON KRIMSKY, SCIENCE IN THE PRIVATE INTEREST: HAS THE LURE OF PROFITS CORRUPTED BIOMEDICAL RESEARCH? 55 (Rowman & Littlefield 2003).

[52] *See, e.g.*, Subhashini Chandrasekharan, Sapna Kumar, Cory M. Valley & Arti Rai, *Proprietary Science, Open Science and the Role of Patent Disclosure: The Case of Zinc-Finger Proteins*, 27 NATURE BIOTECH. 140, 140 (2009); *see also* Joe Fore Jr., Ilse R Weichers and Robert Cook-Deegan, *The Effects of Business Practices, Licensing, and Intellectual Property on Development and Dissemination of the Polymerase Chain Reaction: Case Study*, J. BIOMEDICAL DISCOVERY & COLLABORATION, July 2006, http://www.j-biomed-discovery.com/content/1/1/7.

[53] *See* Shapiro, *supra* note 47; *see also* Heller & Eisenberg, *supra* note 4.

[54] Heller & Eisenberg, *supra* note 4, at 698.

[55] Gavin Clarkson & David DeKorte, *The Problem of Patent Thickets in Convergent Technologies*, 1093 ANNALS N.Y. ACAD. SCI., 180, 180 (2006).

[56] *See* John P. Walsh, Ashish Arora & Wesley M. Cohen, *Working Through the Patent*

For example, Caulfield asserts that gene patents per se have not impacted how scientists pursue research, postulating instead that academic researchers are influenced more by funding opportunities and career incentives within the academic community.[57] In a different vein, Eisenberg has suggested that researchers are largely oblivious to patents and IP. Her implication might be, therefore, that patents are considered by researchers to be largely irrelevant to academic research.

At the same time, others have pointed to the fact that, even absent direct licensing-related obstacles, the existence of numerous patents poses a challenge for scientists attempting to access and use the work of others.[58] Taken together, this work suggests that even in the absence of a full-scale anti-commons, there are reasons to be concerned about the impact of widespread patenting practices on upstream genomics.

Many have also identified ethical concerns with patenting, such as the question of whether life should be patentable,[59] the issues raised by the patenting of traditional knowledge and the corresponding threat of bio-piracy,[60] and the devastating effects of lack of access on the part of marginalized communities, developing countries in particular, to proprietary innovations.[61] Some have identified the *Myriad Genetics* case as emblematic of all of these concerns, ultimately resulting in negative results for patients –

Problem, 299 SCIENCE 1021, 1021 (2003) (suggesting that in fact the anticommons has little impact because of a conglomeration of factors including licensing activity, non-exclusive licensing of foundational research tools, inventing around, ignoring patents and challenging patents).

[57] Timothy Caulfield, Robert M Cook-Deegan, F Scott Kieff & John P Walsh, *Evidence and Anecdotes: An Analysis of Human Gene Patenting Controversies*, 24:9 NATURE BIOTECH. 1091, 1091 (2006).

[58] *See generally* DIANNE NICOL & JANE NIELSEN, PATENTS AND MEDICAL BIOTECHNOLOGY: AN EMPIRICAL ANALYSIS OF ISSUES FACING THE AUSTRALIAN INDUSTRY, CENTRE FOR LAW AND GENETICS OCCASIONAL PAPER (2003), http://www.ipria.com/publications/reports/BiotechReportFinal.pdf.

[59] Lori B. Andrews & Dorothy Nelkin, *Propriety and Property: The Tissue Market Meets the Courts in* WHO OWNS LIFE?, 197 (David Magnus, Arthur Caplan & Glenn McGee eds. 2002).

[60] *See Pacific Genes and Life Patents* (Aroha Te Pareake Mead & Steven Ratuva, eds. 2007), http://www.unutki.org/news.php?news_id=35 &doc_id=101; *see also* Emily Marden, *The Neem Tree Patent: International Controversy Over the Commodification of Life*, 22 B.C. INT'L & COMP. L. REV. 279, 280 (1999).

[61] *See* Adejoke Oyewunmi, *The Right to Development, African Countries and the Patenting of Living Organisms: A Human Rights Dilemma*, *in* PATENTING LIVES: LIFE PATENTS, CULTURE AND DEVELOPMENT 53-72 (2008); *see also* Kapczynski et. al., *supra* note 5; Diane V. Havlir & Scott M. Hammer, *Patents Versus Patients? Antiretroviral Therapy in India*, 353 N. ENG. J. MED. 749, 749 (2005).

and health care systems – when basic genetic information is protected by patents and access to necessary diagnostics may interfere with health care treatment.[62]

In light of the plethora of issues that scholars, activists, and other researchers have raised regarding patenting in upstream biomedical research, in particular with genetic inventions/gene patents, different movements have gained momentum to address the potentially negative effects of such IPRs. In the next section, we canvass some of those movements that have gained the most traction.

IV. EMERGING ALTERNATIVES TO CONVENTIONAL IP PRACTICES

The move to develop alternative approaches to IP for genomic research comes largely in response to concerns about the effects of conventional IP practices in this area. The notion is that by using IP and patents differently, one can control or alter the impact of IP practices on the conduct of science and on ongoing scientific research and innovation and thus avoid difficulties presented by conventional patenting. The alternatives are varied and include open source licensing practices (in both copyright and patent spheres), patent pools, and public domain. These alternatives offer the possibility of different kinds of change and each utilizes IP – or an absence of IP in the case of public domain – to address issues raised by the use of conventional IPRs. We briefly review them each to demonstrate the nature and extent of current reactions to conventional IP in the genomics arena.

A. Open Source Patent Licensing

The aim of open source (OS) licensing, whether with respect to copyright or patent, is to direct the use of IP in a manner that ensures openness and access to information. An OS patent license is essentially a contract that obligates the licensee (or user) of patented material to share that material and improvements in a certain way, and in some instances, obligates any further innovations or sublicensing to be conducted in the same manner. In this way, OS licensing can, in principle, be a very effective tool for directing the use of IP in a style that reflects values of open science and access to research information.

Open source licensing was first used as a mechanism to promote collaborative innovation in the software industry.[63] Conventional copyright

[62] *See* Edward Richard Gold & Julia Carbone, *Myriad Genetics: In the Eye of a Policy Storm* (Sept. 9, 2008), *available at* http://ssrn.com/abstract=1260098; *see also* Robert Cook-Deegan, Subhashini Chandrasekharan & Misha Angrist, *The Dangers of Diagnostic Monopolies*, NATURE, Mar. 26, 2009 at 405.

[63] RICHARD M. STALLMAN, FREE SOFTWARE, FREE SOCIETY: SELECTED ESSAYS OF RICHARD M. STALLMAN 20-24, 31-32 (Joshua Gay ed. 2002), *available at* http://www.gnu.org/philosophy/fsfs/rms-essays.pdf.

protection on software requires licensees to refrain from copying, distributing or altering the program. In contrast, the prototype OS software license, the General Public License (GPL), is often referred to as a "copyleft" license,[64] since it is the opposite of the copyright licenses. The copyleft license seeks to increase the distribution of the source code by making it freely available, per the license, as long as it continues to be made available on the same terms to others.[65] It thus prescribes the way the 'protected' information is shared. The GPL also has a viral clause, which requires that improvements to the software are also shared.[66]

The OS movement in biotechnology is modeled on the software movement and aims to create a system that will allow contributors and users greater freedom to use innovation in productive ways.[67] Just as OS software was a reaction to the restrictions placed on programmers and users by proprietary practices in that sphere, the OS biotechnology movement arose largely in response to perceptions that traditional use of patents in biotechnology has negative implications for the practice of science, for research, and for access to ultimate end products.[68]

In theory, OS genomics starts with a patent on relevant material. The material is then licensed on OS terms: non-exclusively and, generally, royalty-free. Often an OS license will include a viral clause that obligates licensees to share improvements and/or modifications on similar OS terms in order to ensure that the OS objectives continue to be met. There can also be an obligation to "grant-back" to the licensor on OS terms, any improvements to the licensed technology.[69] The idea here is that the original licensor would become a repository of all knowledge relating to the originally licensed technology and would ensure that all such knowledge was then available to licensees, with the aim of maximizing possible knowledge production. However, putting such licenses into practice has proven to be complicated, as there are important differences between software and genomics that make application of the open source patent model to genomics complex (see Table

[64] SAM WILLIAMS, FREE AS IN FREEDOM: RICHARD STALLMAN'S CRUSADE FOR FREE SOFTWARE 128 (2002).

[65] Free Software Foundation, GNU General Public License, http://www.gnu.org/copyleft/gpl.html (last visited Apr. 3, 2010).

[66] *Id.*

[67] JANET HOPE, BIOBAZAAR: THE OPEN SOURCE REVOLUTION AND BIOTECHNOLOGY 329 (2008).

[68] *Id.* at 20; *see also* Emily Marden, *Open Source Drug Development: A Path to More Accessible Drugs and Diagnostics?*, 11 MINN. J. L SCI. & TECH. 217, 219-22 (2010).

[69] Katherine M. Nolan-Stevaux, *Open Source Biology: A Means to Address the Access & Research Gaps?*, 23 SANTA CLARA COMPUTER & HIGH TECH. L.J. 271, 284-85 (2007); *see also* ANDREWS & NELKIN, *supra* note 12.

1).

Table 1: Differences Between Open Source Software and Genomics

	Software	Genomics
Form of IP protection	Copyright	Patent
Development Timeline	Short, with short product life	Long
Need for equipment/laboratory space	Low	High
Regulatory review and oversight	Low	High

There currently exist a number of attempts to implement the OS patent model in the biosciences, though these attempts continue to be works in progress. For example, the Biological Innovation for Open Society (BiOS), which was founded by CAMBIA,[70] aims to support biotechnology innovations that serve marginalized or underserved communities by establishing an open source platform to share knowledge. The idea is that users could have access to shared patents through open source licenses that would obligate improvements or derivative works to be similarly shared with BiOS and other licensees.

Despite efforts to implement OS licensing in the biosciences sphere, key questions about the practice remain, such as:

- What happens to OS information once licensed?
- Can a licensee make improvements and then patent that information?
- Can a licensee patent innovations derived from OS material?
- Is there an obligation to share improvements with the licensor or other licensees?
- Is there any incentive for participation in such a system?
- Fundamentally, what happens to OS-licensed material as it moves downstream to commercial products, e.g., in the context of drug

[70] CAMBIA (Center of Applications of Molecular Biology to International Agriculture) is a non-profit research institute developed in response to concerns about the increasingly centralized nature of the production of life sciences technology. CAMBIA intends to facilitate the development of agricultural technology by making plant transformation tools and other genetic technologies available on an OS basis to facilitate ongoing research and the development of commercial start-ups. *See* CambiaLabs, Welcome to CambiaLabs, http://www.cambia.org/daisy/cambialabs/home.html (last visited May 5, 2010).

development?

B. Open Source Copyright License

There are a number of OS databases for scientific information that use Creative Commons licenses to govern genomic information.[71] The aim of the Creative Commons licenses is similar to the aims of an OS patent license regime; that is, both are designed to open access to scientific information while placing obligations on the user to continue a similar practice. For example, the mammalian organogenesis gene network of expression (MORGEN) project, with which the IPPRG collaborates, deposits all gene expression data that it generates in a database that has a Creative Commons attribution-only license[72] with the aim of ensuring maximum access and use of that material. Under this license, the limitations imposed on using the information are minimal: the only requirement to use the data is that the user must appropriately attribute the original source in any future publication or patent application. In addition, there appears to be no systematic enforcement of the CC license.[73]

In the context of neglected diseases (NDs)[74] drug discovery, there are two genomics initiatives that employ open source licensing: the Tropical Disease Initiative (TDI) and Open Source Drug Discovery (OSDD). TDI is an attempt to identify new solutions to address the dearth of available treatments for NDs, and focuses its efforts on coordinating charities to create nonprofit venture-capital firms (Virtual Pharmas) to search out and develop promising treatments.[75] In contrast, OSDD is funded by the Government of India (US

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[71] A creative commons license is an open source copyright license that only requires attribution of the scientific information to the original author(s), e.g., MORGEN. *See* Creative Commons, About Licenses, http://creativecommons.org/about/licenses/ (last visited May 20, 2010).

[72] There are several types of Creative Commons licenses including "Attribution," "Share Alike," "Noncommercial" and "No Derivative Works." *See id*.

[73] *Id.*

[74] Neglected diseases are a collection of helminth, protozoal, bacterial and viral infections, which causes significant global burden of disease, but for which treatments are toxic, unavailable or non-existent.

[75] *See* Tropical Disease Initiative, http://tropicaldisease.org/ (last visited May 20, 2010) (The Tropical Disease Initiative plays the role of a "kernel" in this process, providing a platform for scientists from laboratories, universities, institutes, and corporations to collaborate in order to find new drugs to treat neglected tropical diseases such that drug discoveries made from this process would not be patented and sponsors could award contracts to the lowest bidders who would then develop the discovery into a treatment for use in the developing world.); *see also* Leticia Ortí, Rodrigo J. Carbajo, Ursula Pieper, Narayanan Eswar, Stephen M. Maurer, Arti K. Rai, Ginger Taylor, Matthew H. Todd, Antonio Pineda-Lucena, Andrej Sali & Marc A. Marti-Renom, *A Kernel for the Tropical Disease Initiative*, 27 NATURE BIOTECH. 320, 320-21 (2009).

$38 million) to provide an open source platform for aggregating scientific knowledge in order to discover drugs to treat diseases that are prevalent in the developing world with the aim of providing affordable healthcare to people around the world, particularly in developing countries.[76] These emerging platforms reflect the growing interest in OS as an alternative IP platform for neglected disease research that may ensure greater openness and access to information.[77]

C. Patent Pools

The other significant development in alternative IP for genomics is an expanded use of "patent pools." There is no single definition of a "patent pool" in U.S. or Canadian law.[78] As a general matter, however, patent pools are understood as an arrangement of two or more patent holders assigning or licensing their individual IP rights to one another or to an administrative entity specifically created for this purpose.[79] The patents in the pool are then made available, usually through non-exclusive licenses and at a pre-established rate, to all comers and not only to the other members of the pool. There are multiple potential aims in establishing patent pools, depending on the context and participants. Historically, pools have arisen in a number of disparate industries, when several patents were required to develop or manufacture a

[76] *See* Open Source Drug Discovery, What is OSDD, http://www.osdd.net/what-is-osdd (last visited May 20, 2010) (Much like the TDI, students, scientists, researchers, academics, institutions, and corporations from around the world may become partners in OSDD, where they can contribute to and synthesize available knowledge in order to discover new drugs. New molecular entities (NMEs) will not be patented, but instead will put into the public domain. With the aid of the Government of India or philanthropic funding, the development of drugs is to be outsourced to contract research organizations and other private industry partners.).

[77] *See* Stephen M. Maurer, Arti Rai, & Andrej Sali, *Finding Cures for Tropical Diseases: Is Open Source an Answer?*, 1 PLOS MED. 183 (2004); Bernard Munos, *Can Open-Source R&D Reinvigorate Drug Research?*, 5 NATURE REVIEWS DRUG DISCOVERY 723 (2006); Thomas B. Kepler, Marc A. Marti-Renom, Stephen M. Maurer, Arti K. Rai, Ginger Taylor, & Matthew H. Todd, *Open Source Research – the Power of Us*, 59 AUST. J. CHEM. 291 (2006); Seema Singh¸ *India Takes an Open Source Approach to Drug Discovery*, 133 CELL 201, 201-03 (2008); Fernán Agüero et al., *Genomic-scale Prioritization of Drug Targets: the TDR Targets Database*, 7 NATURE REVIEWS DRUG DISCOVERY 900 (2008).

[78] Laws and litigation relating to patent pools vary by jurisdiction. For the purposes of this discussion we are focusing on patent pools in the United States unless noted otherwise.

[79] Levy et. al., *supra* note 7 at 82 (citing JEANNE CLARK ET AL., UNITED STATES PATENT AND TRADEMARK OFFICE, PATENT POOLS: A SOLUTION TO THE PROBLEM OF ACCESS IN BIOTECHNOLOGY PATENTS? 11 (2000), http://www.uspto.gov/web/offices/pac/dapp/opla/patentpool.pdf, *reprinted in* 20 BIOTECH L. REP. 607, 618 (2001), *available at* http://www.liebertonline.com/toc/blr/20/4).

particular technology[80] with the aim of ensuring the licensee freedom to operate in the space covered by the included patents.[81] In the context of genomics related research, patent pools have been proposed as a way to eliminate the risks of patent thickets and to ensure the potential for ongoing research and innovation.[82]

In theory, a patent pool in genomics would be formulated to include sufficient numbers of patents in a particular area to allow a licensee the freedom to continue research and development in that area without having to seek out other licenses. In essence, it would be a one-stop, efficient licensing step. In addition, it is our view that patent pools on upstream genomics, when accompanied by progressive licensing terms, can preserve a zone of open science, allowing the patent pool members to ensure that there is access to the patented information that might otherwise only be available through multiple, potentially blocking, licenses.[83]

The formation of a patent pool covering upstream research has proven to be less than straightforward. In fact, no genomics-based patent pool has been formed thus far.[84] Without an identifiable end-product, it is challenging to determine what patents are complementary and essential to the pool and to ensure that the pool does not violate antitrust law (in the United States) or anti-competition law (in Canada).

Our group has looked into this issue extensively with respect to forming a

[80] A well-known example is the airplane patent pool, called the Manufacturers Aircraft Association, which was formed in the United States during World War I in response to government threats of compulsory licensing. That is, the government exerted pressure to avert the situation where patent thickets exerted a blocking effect on the efficient development and manufacture of aircraft during a time of high need. *See* IGWG, COLLECTIVE MANAGEMENT OF INTELLECTUAL PROPERTY – THE USE OF PATENT POOLS TO EXPAND ACCESS TO ESSENTIAL MEDICAL TECHNOLOGIES (Jan. 23, 2007), http://www.keionline.org/content/view/65/1 (citing Harry T. Dykman, *Patent Licensing within the Manufacturer's Aircraft Association (MAA)*, 46 PAT. OFF. SOC'Y 646, 647-48 (1964)).

[81] *See* Dianne Nicol, *Strategies for Dissemination of University Knowledge*, 16 HEALTH L. J. 207, 226 (2008).

[82] *See* Birgit Verbeure, Esther van Zimmerman, Gert Matthijs & Geertrui Van Overwalle, *Patent Pools and Diagnostic Testing*, 24 TRENDS IN BIOTECHNOLOGY 115, 115-20 (2006).

[83] *See* Levy et. al., *supra* note 7, at 97.

[84] An entity intending to form a patent pool in the United States has the option of submitting its proposed terms to the Department of Justice (DOJ) and requesting a Business Review. The DOJ must then respond as to whether the proposal is in accord with the Guidelines and thus whether it would, at that time, pursue anti-trust actions should the entity form a patent pool. 28 C.F.R. § 50.6 (2010). Thus far no Business Review letters have been issued in respect to genomics-based patent pools.

patent pool for the gene sequences making up the SARS virus.[85] The SARS patent pool was initiated by the TTOs of five research groups that identified - and filed patent applications on the SARS gene sequence. The aim in patenting and pooling the sequences was to prevent them from becoming proprietary information. That is, the objective was to ensure that this necessary information could remain highly accessible should it be needed for urgent vaccine and/or treatment development in the face of an epidemic.[86] Formation of the pool stalled largely because the threat of a SARS pandemic died out. In addition, we believe that issues arose around how to form a genomics patent pool that complied with antitrust or anti-competition law that held up pool formation.[87]

Others have attempted a less restrictive form of a patent pool, in that patent pools of this nature would not be structured around a single product and technical standards, as are the most prominent recent patent pools in the electronics industry.[88] We think it useful to refer to the new, looser arrangements as "patent ponds." As collective arrangements subject to antitrust scrutiny, ponds of course have much in common with pools, but it seems to us that ponds will have to develop some new, innovative mechanisms, as can be seen by considering two of the leading candidates, one under development by UNITAID and one proposed by GlaxoSmithKlein.

UNITAID is currently working on establishing a medicines patent pool for HIV/AIDS anti-retroviral medication in the developing world. The pool or pond would be ". . . designed to address the fact that patent-holders are not producing either the fixed-dose combinations (FDCs) or the new formulations required by developing countries [to treat HIV/AIDS] and that anti-retrovirals

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[85] *See generally* Levy et. al., *supra* note 7.

[86] *Id.* at 78, 92.

[87] Just as there is no formal legal definition of the term "patent pool," there are no national or international laws or regulations guiding the formation of patent pools. However, the common hurdles that patent pools have to clear are standards for anti-competitiveness that are embodied in anti-trust laws in various jurisdictions. Toward this end, the United States Department of Justice and Federal Trade Commission (FTC) have taken an interest in the formation of patent pools that conform to anti-trust laws, and jointly addressed patent pools in their 1995 publication providing guidance relating to licensing of Intellectual Property. *See* THE U.S. DEPARTMENT OF JUSTICE & THE FEDERAL TRADE COMMISSION, ANTITRUST GUIDELINES FOR THE LICENSING OF INTELLECTUAL PROPERTY 1, 27-29 (1995), *available at* http://www.justice.gov/atr/public/guidelines/0558.htm (last visited Feb. 22, 2010) ("unlikely to have anticompetitive effects unless (1) excluded firms cannot effectively compete in the relevant market for the good incorporating the licensed technologies and (2) the pool participants collectively possess market power in the relevant market").

[88] *See, e.g.*, MPEG LA – The Standard for Standards, http://www.mpegla.com/main/Pages/About.aspx (last visited Feb. 17, 2010).

are not affordable in those countries."[89] Thus, the organizing principle of a pond would be treatments for a particular disease or related conditions. Patents would cover multiple products or formulations, so criteria for eligibility for membership in the pond may well become a challenge, as would sharing of royalties among patent holders. Such a pond will likely be established under Swiss law and operate in a dozen or so developing nations and thus would not be subject to United States regulations.[90]

Recently Andrew Witty, the CEO of GlaxoSmithKline, argued in an address to Harvard Medical School that big pharma could be a catalyst for change.[91] One of his proposals was a patent pool as a source of IP to address neglected tropical diseases in the poorest regions of the world:

> One idea we are proposing is a Least Developed Country (LDC) Patent Pool for medicines for neglected tropical diseases. We would put our relevant small molecule compounds or process patents for neglected tropical diseases into the pool, allowing others access to develop and produce new products. The pool would be voluntary so as to encourage others to participate and any benefits from the pool must go in full and solely to LDCs.[92]

It appears that the proposed pond/pool would include a mosaic of different patents probably covering both non-approved and approved drugs. The details of the arrangement have not been announced. But, even if a multitude of pools/ponds were created each centered on a particular therapeutic area or condition, such a structure would be much more diverse than the traditional pools.

D. Public Domain

Technically, the "public domain" is not an alternative form of IP protection, but rather the absence of IP altogether and refers to the practice of placing material that may be patentable in the public sphere where it may be adopted or used in any manner without permission from any party. The public domain has been embraced by a wide variety of researchers in genomics who believe that open science mandates that publicly funded knowledge that results from genomics research should be disseminated and useable without restriction.

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[89] E. RICHARD GOLD, TINA PIPER, JEAN-FRÉDÉRIC MORIN, L. KAREN DURELL, JULIA CARBONE & ELISA HENRY, THE INNOVATION PARTNERSHIP, PRELIMINARY LEGAL REVIEW OF PROPOSED MEDICINES PATENT POOL iv (2007), *available at* http://www.theinnovationpartnership.org/data/documents/00000003-1.pdf.

[90] *See generally id.*

[91] *See* Press Release, GlaxoSmithKline, Big Pharma as a Catalyst for Change: Speech to Harvard Medical School – Andrew Witty, CEO (Feb. 13, 2009), *available at* http://www.gsk.com/media/Witty-Harvard-Speech-Summary.pdf.

[92] *Id.*

The public domain can also be used in other ways as part of an effort to preserve access to certain types of genetic material. Publicly-funded researchers frequently place their research results in the public domain (via publications and databases) immediately, rather than wait for IP rights. This practice is used to achieve scientific recognition, to make such information more available for widespread use, and to try to prevent patenting of that data and information.[93] From the perspective of patent law, this public sharing of information – in a publication or otherwise – can cause the information to be considered "prior art" and prevent a patent from being granted for its discovery.[94] Indeed, by actively putting information into the public domain, a patent application may be refused on the basis that the invention is "obvious" based on such information.[95] A strategy of intentional public disclosure was perhaps most famously used by scientists working on the Human Genome Project who, in response to concerns about patents and sharing of information, agreed upon the so-called Bermuda Rules, which require publicly-funded investigators to deposit all newly identified DNA sequences and mutations in the publicly-accessible GenBank database within 24 hours.[96] This strategy made it difficult for publicly-funded investigators and their institutions to patent the material within applicable timeframes and created a database of "prior art" that could be used to deter or defeat patent applications made by the private sector.[97] While it is well-accepted amongst most practicing scientists

[93] *See* Rebecca Eisenberg, *Genomics in the Public Domain: Strategy and Policy*, 1 NATURE REVIEWS GENETICS 70, 71-72 (2000).

[94] *See id.* at 72. In many jurisdictions, as soon as information is publicly disclosed it immediately becomes part of prior art and cannot be the basis of a patent. However in the United States and Canada there is a one-year grace period after public disclosure during which time the information can form the basis of a patent.

[95] *See id.*

[96] *See* David R. Bently, *Genomic Sequence Information Should Be Released Immediately and Freely in the Public Domain*, 274 SCIENCE 533, 533, 534 n.1 (1996).

[97] *See* Robert Merges, *A New Dynamism in the Public Domain*, 71 U. CHI. L. REV. 183 (2004). Indeed, it is the potential for use of public domain in this proactive manner that has led some to reflect that public domain allows for potential internal corrections of the IP system to ensure that necessary information remains available. *See also* Eisenberg, *supra* note 93, at 72. Other well-known examples of this approach are Merck's Genome Initiative to generate expressed sequence tags (ESTs) in the public domain and the Single Nucleotide Polymorphism (SNP) Consortium that was formed by a number of pharmaceutical companies. In both of these examples, private companies put resources into ensuring that certain types of data were preserved in the public domain, presumably to ensure that this basic genomic information would be available for drug development and research and that this valuable information would not be subject to potentially expensive licensing arrangements.

that the public domain supports/serves their basic scientific research interests,[98] in certain circumstances the public domain can also serve downstream commercial interests by allowing access to valuable information.[99] Eisenberg suggests that access to information could accelerate progress in fundamental areas of biological research, which are often viewed as too expensive for organizations to engage in, and in so doing may potentially stimulate the development of new commercial products.[100] On the other hand, private companies may make data publically available in order to inhibit excessive patent claims in a particular research area. One example of this is an expressed sequence tag library database by Merck, whose aim was to create prior art through public disclosure via the public domain and thus avoid patenting in this upstream area by other industry organizations.[101]

The *Caenorhabiditis elegans* (*C. elegans*) Gene Knockout Consortium (GKC), which is studied by our group, exemplifies this approach.[102] The GKC is a collaboration of three large research institutions, Oklahoma Medical Research Foundation, the University of British Columbia and the Genome Sciences Centre, BC Cancer Research Centre, which aims to facilitate genetic research by producing deletion alleles at specific *C. elegans* gene targets.[103] Requests for specific gene targets can be made to the consortium, which aims to establish a norm of using the public domain so that the worm research space remains accessible for all researchers and preserves the potential for innovation.[104]

It is important to recognize that the use of the public domain does not guarantee ongoing access to publicly shared information. Indeed, the main concern is that others using the information available in the public domain may conduct further research and then patent the resulting innovation with the net effect of cutting off access to aspects of the public domain information.[105]

Ultimately, use of any of these IP alternatives – whether public domain, open source licensing, or patent pools – provides a counterpoint to concerns about widespread IP implications in genomics. Yet, the reality is that in a university context, these efforts are unlikely to have significant impacts on how knowledge is transferred until investigators and TTOs are motivated to

[98] *See* SULSTON, *supra* note 3, at 54-55.

[99] *See* Eisenberg, *supra* note 93, at 71.

[100] *See id.* at 71-72.

[101] Jerry E. Bishop, *Plan May Blow Lid Off Secret Gene Research*, WALL ST. J., Sept. 28 1994, at B1.

[102] The *C. elegans* Gene Knockout Consortium, http://celeganskoconsortium.omrf.org (last visited Feb. 11, 2010).

[103] *See id.*

[104] *See id.*

[105] *See* Eisenberg, *supra* note 93, at 73.

use these approaches.

At the same time, it appears that users and stakeholders in TTOs are, without reference to the alternative IP movement, moving away from current practices as well. Though the proposals being explored in that context do not specifically reference these types of alternative IP, it is clear that many of the same issues – namely concern about the open practice of science, a view toward continued innovation and the embrace of expanded licensing practices – similarly underlie the proposals.

V. CONCERNS AND PROPOSALS BY TTOS AND OTHER STAKEHOLDERS – LICENSING

As discussed in detail below, concerns over the potential of an anti-commons effect have motivated several governmental, intergovernmental and university institutions to reassess licensing policies related to research tools, particularly for genetic or biomedical inventions, and to issue their own proposals on how to best handle these innovations. Others have raised issues about the impact of conventional TTO measures on anti-commons effects in specific research areas.[106] In addition, moves to change TTO licensing practices also grew out of concerns raised by advocacy groups surrounding HIV/AIDS treatments, which highlighted the lack of access vulnerable populations in developing countries were afforded to university technologies, in particular medicines, vaccines and diagnostics.[107]

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[106] For example, with the Oncomouse, U.S. Patent No. 4,736,866 (filed June 22, 1984), and Cre-lox technology, U.S. Patent No. 4,959,317 (filed Apr. 29, 1987), certain institutions including the NIH, University of California and Jackson Laboratories (a not-for-profit mouse model breeding, distribution and research facility) refused to sign a restrictive license with DuPont, the company that controlled the IPRs to these two patented research tools. *See* Eliot Marshall, *The Mouse That Prompted a Roar*, 277 SCIENCE 24, 24-25 (1997). The resulting lack of access to these mice for research purposes at these large and influential institutions was perceived to have a significant effect on researchers in many areas of bioscience research, including genomics. *See id.* After three years of negotiation, DuPont, University of California, NIH and Jackson Laboratories signed memoranda of understanding (MoUs) that allowed increased access/inter-institutional distribution and removed reach-through rights to downstream commercialization associated with the Oncomouse and Cre-lox models. *See* Fiona Murray, Philippe Aghion, Mathias Dewatripont, Julian Kolev & Scott Stern, *Of Mice and Academics: Examining the Effect of Openness on Innovation* 3, 12-14 (Nat'l Bureau of Econ. Research, Working Paper No. 14819, 2009), *available at* http://ssrn.com/abstract=1369055. There is some empirical evidence that in the case of the Cre-lox technology, this access delay lead to significant negative impact on scientific discovery. *See id.*

[107] *See* Kapczynski et al., *Global Health and University Patents*, *supra* note 5, at 1629; *see also* David A. Chokshi *Improving Access to Medicines in Poor Countries: The Role of Universities*, 3 PLOS MED. 0723 (2006), *available at* http://www.plosmedicine.org/article/

Currently, several groups are proposing changes in TTOs' practices starting from the position that conventional approaches are not sufficient guiding principles for TTOs. The proposals themselves differ, however, in scope and intent. As outlined below, while the goal of the National Institutes of Health in the U.S. is to avoid patent thickets that could impede further research, the aim of non-governmental organization (NGOs) such as Universities Allied for Essential Medicines (UAEM) is to encourage alternative technology transfer IP strategies to bolster access to medicine and medical devices in developing countries. Others, such as certain TTOs themselves, simply aim to advance the cause of knowledge transfer as opposed to simply patent and license generation. All have in common a starting position that simple adherence to conventional practices is not sufficient to support a judgment of successful technology transfer. We outline the significant proposals made by a range of groups below.

A. Funding Bodies: NIH Guidelines on Access to and Licensing of Biomedical Research Resources

The NIH is a significant player in genomics research in the U.S. providing U.S. $571 million in funding in this area in 2006 alone.[108] The NIH weighed into the discussion on the appropriate practices of TTOs in 1999 with the publication of "Sharing Biomedical Resources: Principles and Guidelines on the Acquisition and Dissemination of Biomedical Research Resources"[109] (NIH Guidelines), which were directed at recipients of NIH research grants and contracts. The NIH Guidelines are thought to have been in part a response to ethical concerns related to the patenting and patent enforcement of BRCA1 and BRCA2 genetic diagnostic test inventions by Myriad Genetics.[110] It is also possible that these guidelines arose as a response to a difficult period of negotiation of separate memoranda of understanding (MoUs) regarding licensing agreements related to two research tools, the Oncomouse and Cre-lox technology.[111]

The principles set forth in the NIH Guidelines aim to preserve a zone of

info%3Adoi%2F10.1371%2Fjournal.pmed.0030136.

[108] Jennifer Reineke Pohlhaus & Robert M Cook-Deegan, *Genomics Research: World Survey of Public Funding*, 9 BMC GENOMICS 472 (2008), *available at* http://www.biomedcentral.com/1471-2164/9/472.

[109] Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice, 64 Fed. Reg. 72090 (Dec. 23, 1999).

[110] *See* HERDER & JOHNSTON, *supra* note 39, at 14-15.

[111] *See* Marshall, *supra* note 106, at 24-25. These near identical MoUs served to improve access to these important applications by non-commercial researchers.

research freedom around research tools.[112] As general principles, they encourage NIH funded researchers and their institutions to ensure: (1) academic freedom and publication; (2) the appropriate implementation of the Bayh-Dole Act; and (3) dissemination of research resources developed with NIH funds, while minimizing administrative impediments to academic research. To achieve these goals, the NIH recommends that funding recipients ensure that their intellectual property strategy for research resources (which are themselves defined in the document) enhances rather than restricts the ultimate availability of the resource. In addition, a simple letter agreement is recommended for the transfer of materials to not-for-profit entities. The NIH also recommends that the use of exclusive licenses for biomedical research resources should be limited to an appropriate field of use.[113]

As a follow-up to these guidelines, in 2005 the NIH published "Best Practices for the Licensing of Genomic Inventions"[114] (NIH Best Practices), which are recommendations aimed at the intramural Public Health Service (PHS) technology transfer community and researchers funded by the PHS, regarding the licensing of any genomic invention (whether it is a research tool or not). It is likely that the controversy surrounding the Myriad Genetics story also motivated the publication of these Best Practices.[115]

The primary mission of the PHS is to "acquire new knowledge through the conduct and support of biomedical research to improve the health of the American people."[116] In accordance with this mission, the NIH Best Practices aims to prioritize public benefit when technologies owned or funded by the PHS are transferred to the private sector. The NIH Best Practices encourages that "public health-oriented technology transfer must balance the rewards of broad intellectual property protection afforded to founders of enabling genomic inventions with the benefits of fostering opportunities for those striving to improve upon those innovations."[117] Therefore, the recommendations urge that patents on genomic inventions should only be sought when significant further research and development is required to bring the invention to practical and commercial application. The NIH Best Practices also state: "Therefore, in considering whether to seek patent protection on genomic inventions, institutional officials should consider whether significant further research and

[112] *See* Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice, *supra* note 109, at 72093.

[113] *See id*. at 72094-95.

[114] Best Practices for the Licensing of Genomic Inventions: Final Notice, 70 Fed. Reg. 18413 (Apr. 11, 2005) [hereinafter NIH Best Practices].

[115] *See* HERDER & JOHNSTON, *supra* note 39, at 14-15.

[116] NIH Best Practices, *supra* note 114, at 18414.

[117] *Id.* at 18415.

development by the private sector is required to bring the invention to practical and commercial application."[118]

With respect to licensing, the NIH Best Practices encourage non-exclusive licensing, unless exclusive licensing is necessary to encourage research and development by private partners. For example, therapeutic applications are likely candidates for exclusive licensing because of the protracted time and extensive resources required for development. If using exclusive licensing, NIH Best Practices suggest restrictions, such as field of use, should be employed to limit the scope of the license to what the licensees are likely to be able to bring to the market. The use of non-exclusive licensing and restrictions that limit field of use of exclusive licenses can also be defined as alternative intellectual property strategies, alongside the open source, patent pool and public domain strategies described above.

B. Intergovernmental Policy: OECD Licensing Guidelines

While the NIH Guidelines and Best Practices are directed at the goal of avoiding patent thickets and ensuring the ongoing ability of researchers to use innovative tools, positions put forward by others move beyond these goals and suggest that alternative TTO practices could also impact global health research and unmet health needs. For example, the OECD "Guidelines for the Licensing of Genetic Inventions"[119] (OECD Guidelines) suggest that TTOs should be considering more than conventional "success" when licensing and making patented technologies available.

The OECD Guidelines came about as a result of end-user frustration.[120] Specifically, the OECD began to focus on how patents impact certain countries' ability to access information relevant to healthcare developments. The net result was a meeting in January 2002 to work on guidelines to discuss how such patents should be licensed to support – rather than thwart – positive health impacts.[121] These Guidelines were finalized and published in 2006, and were designed to help governments develop policies that would encourage appropriate behavior in the licensing and transferring of genetic inventions. The OECD Guidelines state that "foundational genetic inventions" should be non-exclusively licensed and that all genetic inventions should be licensed "broadly" with the goal of increasing access.[122]

The University of British Columbia (UBC) UILO has embraced non-

[118] *Id.*

[119] ORGANIZATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT, GUIDELINES FOR THE LICENSING OF GENETIC INVENTIONS (2006), *available at* http://www.oecd.org/dataoecd/39/38/36198812.pdf.

[120] *See generally id.*

[121] *See id. at* 3.

[122] *Id.* at 11.

exclusive licensing through the West Coast Licensing Partnership (WCLP) with the goal of promoting knowledge transfer.[123] Initiated by UBC in 2006, the WCLP is a group of seven leading universities that provides a "one-stop shop for access to proprietary technologies and research tools."[124] Under this arrangement, licensees can choose a variety of combinations or bundles of technologies and tools for new drug discovery and/or research development (e.g., animal models, biomarkers, etc.) and they can obtain rights to the selection of technologies under a single license. All of the licenses in the WCLP are non-exclusive and all institutions sign-on to a governing memorandum of understanding.

C. Student-led Initiatives: Universities Allied for Essential Medicines Proposed Licensing Schemes

The NGO Universities Allied for Essential Medicines Proposed Licensing Schemes has taken a leadership position in pushing TTOs to alter terms of licenses so as to encourage accessibility of essential medicines for the developing world. UAEM starts from the view that conventional practices by TTOs plays a part in the lack of access to healthcare products that currently exist.

In its initial suggestion to TTOs to change their practices, UAEM proposed the Equitable Access License[125] (EAL) as an example of a licensing structure that would promote increased access to medical technologies in low-middle income countries (LMICs).[126] UAEM intended that university TTOs would be guided by the EAL as part of their measured licensing strategies.[127] The UAEM EAL proposal encourages universities to include clauses in their licenses that retain rights that give freedom to operate in low-middle income countries with respect to products that rely on the licensed technology. These rights also allow the university to grant a non-exclusive license to a third party

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[123] *See* West Coast Licensing Partnership, http://www.westcoastlicensing.com (last visited May. 20, 2010).

[124] *Id.*

[125] *See Model Provisions for an "Equitable Access and Neglected DiseaseLicense"*, ESSENTIALMEDICINE.ORG, http://essentialmedicine.org/sites/default/files/archive/EAL.pdf (last visited May 20, 2010); Amy Kapczynski, Samantha Chaifetz, Yochai Benkler & Zachary Katz, *Addressing Global Health Inequities: An Open Licensing Approach for University Innovations*, 20 BERKELEY TECH. L.J. 1031 (2005); Katherine M. Nolan-Stevaux, *Open Source Biology: A Means to Address the Access & Research Gaps?*, 23 SANTA CLARA COMPUTER & HIGH TECH. L.J. 271 (2006).

[126] *See* Universities Allied for Essential Medicine, *A Brief Introduction to the EAL*, at 2-3, http://essentialmedicine.org/sites/default/files/archive/Intro%20to%20EAL%20(students).pdf (last visited Apr. 5, 2010).

[127] *See* Kapczynski et. al., *supra* note 5, at 1031.

to make the technology available in LMICs. As such, the proposed EAL contains grant-back provisions, which gives rights to the licensor (the university) in the "end product"[128] developed by the licensee (commercial entity). Under the EAL, the licensee grants the university a license to the "Associated Licensee Rights"[129] so that the university can grant an open license to third parties either to produce the "end product" or to conduct neglected disease research.

More recently UAEM has worked on a new strategy for increasing access to university medical inventions in its Global Access Licensing Framework (GALF).[130] This approach is less prescriptive than the EAL and calls on universities to implement global access policies, which are a set of principles that align licensing practices with objectives of global access to essential medicines and encourage, though do not require, cost-effective production of end products. The GALF endorses generic production as "the best way to ensure access in resource-limited countries for products that also have markets in developed countries."[131] UAEM's GALF also calls for appropriate levels of transparency associated with university licensing and that metrics of licensing success should measure impact on "access and continued innovation."[132]

UAEM continues lobbying many universities, including the University of California, to implement policies aligned with the GALF, which aims to "ensure that every relevant university technology is licensed as part of an effective and transparent strategy to make affordable versions available in developing countries."[133]

D. TTOs: Nine Points Document and Global Access Licensing

A number of universities have responded to the growing concerns regarding access to licensed technologies. This goal was stated broadly in "In the Public Interest: Nine Points to Consider in Licensing University Technology," a document that was issued by a group at Stanford University in 2007 (Nine

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[128] In the EAL, an "end product" is defined as "any product whose manufacture or use relies or is covered by the Licensed Technology." *Global Access Licensing Framework*, ESSENTIALMEDICINE.ORG, *available at* http://essentialmedicine.org/sites/default/files/archive/galf-1-1.pdf 1 (last visited May 20, 2010).

[129] In the EAL, "Associated Licensee Rights" include all rights in data, information, know-how, methods and processes necessary to make, use, sell, import or export the end product.

[130] *See* ESSENTIALMEDICINE.ORG, *supra* note 128, at 1

[131] *Id.*

[132] *Id.*

[133] Rebecca Mitchell, *Student Group Seeks Lower Prices on UC-Discovered Medicines*, SYNAPSE, (Aug. 20, 2009), *available at* http://synapse.ucsf.edu/articles/2009/march/19/ucmedicine.html.

Points) and signed by a number of prominent university TTOs.[134]

The Nine Points document is a reflection of discussions amongst certain TTO offices about societal, policy, legislative and other issues in technology transfer. The stated aim is to encourage colleagues in that field to "analyze each licensing opportunity individually in a manner that reflects the business needs and values of their institution, but at the same time, to the extent appropriate, also to bear in mind the concepts articulated" in the document.[135] Those concepts include, among other things, ensuring broad access to research tools, and "provisions that address unmet needs, such as those of neglected patient populations or geographic areas, giving particular attention to improved therapeutics, diagnostics and agricultural technologies for the developing world."[136] The Nine Points document is only advisory; its significance, however, is clear in that it reflects some movement on the part of those in prominent TTOs in the United States to consider more than the simple quantitative measures in making licensing decisions.

Individual TTOs have also taken the initiative to try to change operating principles. In 2008, after working with UAEM and other stakeholders and following a public consultation process, the UBC UILO issued a statement of principles and has licensed a number of technologies with global access terms.[137] These principles are designed to aid the development, patenting, and licensing of UBC technologies in order to:

> [p]romote global access by entering public/private partnerships to develop new technologies to benefit the developing world, [p]rioritize environmentally friendly research and green alternatives, and take the lead in community sustainability, [r]espect biodiversity, ensuring value return to countries of origin, [and] [e]ndeavour to ensure that under privileged populations have "at cost" access to UBC research innovations through negotiated global access terms whenever appropriate.[138]

UBC's global access principles include the promotion of non-exclusive licensing practices for research tools.[139] One of the technologies that has been licensed with the global access principles is an oral reformulation of Amphotericin B for treatment of the neglected disease leishmaniasis and

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[134] *See In the Public Interest: Nine Points to Consider in Licensing University Technology* (Mar. 6, 2007), http://news-service.stanford.edu/news/2007/march7/gifs/whitepaper.pdf.

[135] *Id.* at 1.

[136] *Id.* at 8.

[137] *See* UILO, "Global Access", *available at* http://www.uilo.ubc.ca/about/initiatives/global.html (last visited May 20, 2010).

[138] *Id.*

[139] *See id.*

fungal infections.[140]

Other universities have taken similar steps. Recently, Edinburgh University administration issued a blanket statement in support of a global access policy, although no specific information has been circulated.[141] In their 2008 paper on global social responsibility and academic licensing, Ashley Stevens, president-elect of the board of trustees of the AUTM, and April Effort concluded that ". . . [u]niversities should act, and should be seen to be acting to ensure that their innovations reach the developing world affordably and expeditiously before either the federal government or state legislatures act for them."[142]

In early 2010, AUTM proposed the Statement of Principles and Strategies for the Equitable Dissemination of Medical Technologies (SPS), which has been signed by 20 institutions (as of March 15, 2010) including AUTM, Harvard University, Yale University, UBC, and the NIH.[143] Alongside a commitment "to develop creative and effective licensing strategies that help promote global access to health-related technologies,"[144] the SPS asserts that assignees will only seek patent protection in developing countries "in a manner that is consistent with our objective of facilitating global access."[145] While recognizing that the SPS is a movement forward for university policy and practice for access to essential medicines, UAEM criticized this document for neglecting to ensure access to medicines in India, Brazil, and China where over 60 percent of the world's poor reside.[146] UAEM also advocates for university

[140] *See* UILO, "Sample of UBC Global Access Projects", *available at* http://www.uilo.ubc.ca/about/initiatives/global/global_projects.html (last visited May 20, 2010).

[141] *See* The University of Edinburgh, *Initiative boosts access to medicines*, *available at* http://www.ed.ac.uk/news/all-news/access-medicines-070509 (last visited Feb. 18, 2010); Paul Kelbie, *University Forces Firms to Supply Cheap Medicines*, THE OBSERVER, April 26, 2009, *available at* http://www.guardian.co.uk/science/2009/apr/26/cheaper-medicines-edinburgh-university.

[142] Ashley J. Stevens & April E. Effort, *Using Academic Licensing Agreements to Promote Global Social Responsibility*, 43:2 LES NOUVELLES 85, 100 (2008).

[143] The Ass'n of Univ. Technology Managers, Endorse the Statement of Principles and Strategies for the Equitable Dissemination of Medical Technologies, http://www.autm.net/source/Endorsement/endorsement.cfm?section=endorsement (last visited May 19, 2010) [hereinafter Statement of Principles and Strategies].

[144] Statements of Principles and Strategies for the Equitable Dissemination of Medical Technologies 2, http://www.autm.net/Content/NavigationMenu/TechTransfer/GlobalHealth/statementofprincliples.pdf (last visited Apr. 22, 2010).

[145] *Id.*

[146] Andrew Gray, *BIG VICTORY: 6 Universities, AUTM and NIH agree to access*, Universities Allied for Essential Medicines, Nov. 11, 2009, http://essentialmedicine.org/story/2009/11/11/big-victory-6-universities-autm-and-nih-agree-access-principles.

licensing policies and practices that encourage generic competition as a means of reducing essential medicine prices, thereby facilitating access.[147]

VI. CONCERNS AND PROPOSALS BY TTOS – METRICS

A. Conventional Metrics

Metrics – or measures of success – developed by TTOs validate and reinforce the pursuit of patents for innovations that are handled by these offices. Currently, TTOs in the U.S. and Canada use a common set of metrics that allow their performance characteristics to be measured and compared.[148] These metrics specifically measure invention disclosures, filed and issued patents, licenses/options, spin-off companies, licensing revenue, and sponsored research funding.

These metrics were initially developed as a tool by some TTOs in the 1990s to measure research outputs that could most reliably make the case for continuing investments in the development of "technology."[149] Over time, these tracking measures were adopted by AUTM,[150] an association of business executives and technology managers who manage IP at universities, research institutions, teaching hospitals and government agencies. AUTM is the most comprehensive organization that collects knowledge transfer data on United States and Canadian universities[151] as there are no governmental organizations that perform a similar function.[152] AUTM has adopted the conventional metrics listed above as the reporting standard for the publication of annual

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[147] *Id.*

[148] *See* TINA PIPER & E. RICHARD GOLD, PRACTICES, POLICIES AND POSSIBILITIES IN LICENSING IN HUMAN GENETICS 20 (2008), http://www.theinnovationpartnership.org/data/documents/00000015-1.pdf.

[149] *See* The Association of University Technology Managers, Licensing Surveys – AUTM, http://www.autm.net/Licensing_Surveys_AUTM.htm (last visited April 2, 2010).

[150] *See* Jill Ann Tarzian Sorensen & Donald A. Chambers, *Evaluating Academic Technology Transfer Performance by How Well Access to Knowledge is Facilitated—Defining an Access Metric*, 33 J. OF TECH. TRANSFER 534, 535 (2008).

[151] In addition, the Alliance for Commercialization of Canadian Technology (ACCT) focuses exclusively on technology transfer that benefits Canadians. *See* About ACCT Canada, http://www.acctcanada.ca/index.php?option=com_content&view=article&id=10&Itemid=7 (last visited May 20, 2010).

[152] In comparison, in the United Kingdom knowledge transfer is measured by several governmental organizations including the Higher Education Funding Council for England (HEFCE), the Higher Education Statistics Agency (HESA), the Scottish Funding Council (SFC) and Unico (Metrics for the Evaluation of Knowledge Transfer Activities at Universities Report, Unico).

surveys.[153] In anticipation of the annual AUTM surveys and in order to measure their own effectiveness, TTOs routinely track and measure the success of their licensed technologies using these criteria.

The AUTM metrics were not developed specifically to track gene patents and licenses, but to serve as a measure of success for TTOs in this research sector as well. The net impact is that the number of patents – and licenses – issued in this area (as in other research areas) operates as a measure of success or productivity for the TTO. Depending on the TTO and its host institution, these measures may be very important in determining how the TTO is supported.

While AUTM metrics are used by TTOs, there seems to be a widespread consensus amongst Canadian and United States universities that measures that determine the success of technology transfers need to be broadened beyond these conventional measures.[154] In signing the SPS recently proposed by AUTM, assignees agree to: "... work together to develop and apply meaningful metrics to evaluate the success of our efforts to facilitate global access and support continued innovation with particular relevance to global health."[155]

B. New Metrics

Discussions of alternative IP for genomics and different approaches for TTOs point to a movement for change. As discussed above, the use of alternative IP strategies has been posited by many as a way to address ethical, social and legal concerns surrounding the patenting of genetic inventions.[156] It is possible that if broadly implemented, alternative models of IP could impact the manner in which upstream genomics research is undertaken and shared. Those practices could, in turn, have profound effects on the numbers of patents applied for and issued as well as the amount of revenue earned from licenses. It is thus possible that the use of traditional metrics to assess the success of the transfer of technologies that are governed by alternative IP may yield a poor "report card" under the conventional AUTM metrics. This, in turn may disincentivize the TTO from experimenting with any form of alternative IP.

Similarly, the proposals being made to enhance knowledge transfer and access in TTO patenting and licensing practices could change the licensing

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[153] *See* The Association of University Technology Managers, *supra* note 149.

[154] *See generally* Statement of Principles and Strategies, *supra* note 143, at 1.

[155] *Id*. at 4.

[156] *See* Emily Marden, Cheryl Power, David Hartell, Ed Levy & Ben Warren, *Genomics and Intellectual Property: Considering Alternatives to Traditional Patenting*, 17:1 HEALTH L. REV. 12-6 (2008); *see also* Richard Gold, *Toward A New Era of Intellectual Property: From Confrontation to Negotiation* (2008), http://www.theinnovationpartnership.org/data/ieg/documents/report/TIP_Report_E.pdf; Stevens &. Effort, *supra* note 141.

decisions made by TTOs in a manner that would impact how technology arising from genomic research is made available or shared. For example, a university might license a promising technology differently if, per the Nine Points, its goal were to address an unmet need, rather than simply generating the greatest revenue for the licensor. However, to be in a position where such alternative goals reflect success, it is likely that there needs to be innovative ways to measure TTOs' success.

Traditional metrics represent measures that primarily address quantifiable financial activities.[157] The measures were never designed to gauge anything other than commercial impacts and it is widely accepted that the metrics fail to measure the overall social and economic impact of innovation.[158] The emergence of new policy directions encouraged by major institutions like the NIH and OECD and the evolution of practices at various TTOs suggest that TTOs are no longer solely focusing on standard commercial and financial measures, such as, *inter alia*, licenses granted and license income, as specified in the traditional AUTM measurements.

To some degree, shifting perspectives on the aims of TTOs has laid the groundwork for the development of novel metrics. What could TTOs measure that would better assess their success at knowledge mobilization and in so doing address some of the concerns about IP and genomics that are cited as interfering with open science, access and innovation? We start with the assumption that the development of each university-derived technology has the potential to differentially impact a range of outcomes such as academic (e.g., publications, further inquiry, training), social (e.g., advances related to health or environment), economic (job creation, training) and financial (profit) outputs. Depending on the technology, these impacts may be interrelated or interdependent. In this section we review novel metrics strategies that assess the success of knowledge mobilization.

Certainly, novel metrics will not by themselves alter the way IP is conceptualized or shared. Metrics remain a measurement of what is being done. Our belief, however, is that these metrics have a critical role to play to create reasons for adopting alternative IP and for exploring additional – or non-traditional – goals for patented technologies.

1. Impact Metrics

One approach to novel metrics focuses on the need to appropriately measure the outcomes of transferred technologies. Identifying the relevant impacts and

[157] *See* Angus Livingstone, New Methods – New Metrics: Re-evaluating Technology Transfer, Presentation at the workshop for Alternative Intellectual Property for Genomics and the Activity of Technology Transfer Offices: Emerging Directions in Research (May 8-9, 2008).

[158] Sorensen & Chambers, *supra* note 149, at 541-43.

choosing what to measure is no easy task; there are many different impacts that could be associated with a technology and choices made about what to measure could have further impacts on future IP choices. One possibility is to recognize both the regional and global social and economic outcomes of a technology, rather than simply quantifying financial gain to the university. Alternatively, there are many significant factors that can be measured as successful markers of technology transfer at the academic level, which are less tangibly connected with social and economic impacts.

The UBC UILO is considering a novel metric system to evaluate the technologies it licenses in terms of social, economic, academic and financial benefit. The UILO's "Impact-Metric System" aims to measure these four categories using ratings that are based on set criteria within each category.[159] Table 2 shows examples of the measurable outputs of each category.

The UILO recently completed a retrospective analysis of 237 active license and assignment agreements to determine the impact of each technology. This was done semi-quantitatively scoring the licenses using as a reference benchmark paragraphs previously generated for each impact category.[160] The impact category grades ranged from negligible (0), minor (1), fair (2), good (3), excellent (4), and outstanding (5). The study found that 68 percent of all licenses had a minor or negligible total actual impact while 4 percent had a good or better impact.[161] Additionally, the study also found that biosciences were more likely to achieve high impacts, although research tools and software licenses performed poorly.[162] That said, this analysis also showed that the actual versus potential impact of licenses differed depending on the impact category. For example, "societal" impact was the most difficult to achieve, which is not surprising given the difficulty of measuring social impacts in the short term,[163] especially considering that some technologies may take a generation to reach their full social potential.

Table 2: UBC's UILO Impact Category and Novel Metrics to Assess Technology Transfer Success

[159] *See* Livingstone, *supra* note 157.

[160] *See id.*

[161] *See id.*

[162] *See id.*

[163] *See id.*

Impact Category	Innovative Metrics
Academic	- number of students trained during technology development - number of publications based on the technology and impact rating of journals - level of R&D funding stimulated by the technology, ability to further assist future innovation and academic progress
Economic	- number of employees in spin-off and affiliated companies - total revenues of spin-off and affiliated companies
Financial	- level of annual royalities of other payments received from the licensing arrangements, - value of equity holdings in the licensee company
Societal	- subcategories including human health, animal health, the environment, seriousness of the issue being adressed - prepardness of the problem, role of the technology in lessening the threat or prevalence of the issues

The UBC UILO is continuing to digest the findings from this analysis and, in our understanding, intends to use this study to focus its efforts on putting each technology to the most effective use, as measured by the metrics used in its retrospective analysis. This process relies on the view of the TTO as an enabler of knowledge transfer and not simply as a revenue generator for the relevant university. Thus, a technology whose transfer yields high scores on societal impacts may not score highly on the conventional AUTM metrics. The methodology is likely subject to further examination and in the future, the UBC UILO may choose different approaches for individual technologies to enable the best outcome, whether that outcome is financial remuneration for the university, social impact in terms of health outcomes, or the furtherance of research goals.

2. Access Metrics

An alternative strategy is to approach novel metrics through the window of access. Access can be interpreted in many ways, including access to knowledge (e.g., publications, databases, know-how), access to the rights to use technologies (e.g., research tools), or access to the end products (e.g., essential medicines). Motivated by a desire to enhance the public good mission of universities, Sorensen and Chambers[164] propose that academic technology transfer should be evaluated in terms of how successful access to knowledge has been achieved. The authors suggest indicators of success, including citation analysis (per patent, publication, inventor and faculty), alliance management (industry partners, collaborations, and affiliation agreements), outreach (education and communication) and economic factors

[164] *See* Sorensen, *supra* note 150.

(job creation, capital raised to operate a start-up, start-up sales, growth and business location), to measure the access to knowledge has been delivered. In addition, Sorensen and Chambers propose that alternative licensing practices can be used strategically to achieve access, and therefore evaluating the terms of licenses can also serve as a useful metric of access success.[165] Accordingly, they suggest that the use of research exemption clauses, global access and socially responsible licensing terms, in addition to patent pools/bundles, open source and non-exclusive licensing could be measured to provide an indication of the level of access afforded by such agreements. One potential issue with this approach is that it relies on alternative IP to achieve access, while the reality is that alternative IP has not been widely adopted.

Another effort to frame access metrics is the development of an "Access Metrics Index" (AMI) by UAEM.[166] The AMI is currently defining "access-based parameters" that can be used to measure the transfer of university technologies,[167] and is conducting a pilot survey to "gather the collective knowledge of TTOs on the successful implementation of the policies provisions that are effective in ensuring broad access to university-derived technologies."[168]

3. Developing New Metrics

As explored in the preceding discussion, the proposals for impact and access metrics remain in a development phase and have not been widely adopted or explored. Our view is that metrics should be used flexibly to reflect an array of potential societal, academic, financial and/or economic goals. Under such a system, TTOs would have a broader role to play in assessing technologies. Assessment would not be simply for potential numbers of licenses or revenue; rather technologies would be assessed for the potential to have a broad range of impacts.

Key questions remain about how novel metrics should be formulated and what should be taken into consideration. It is clear that the process of choosing what to measure and how it is measured includes non-objective factors and very much reflects the intent of those deploying the measurements. For this reason, any effort to proffer an alternative to AUTM's metric should take into

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[165] *See id.* at 538-39.

[166] *See* Universities Allied for Essential Medicines, Access Metrics Index, http://essentialmedicine.org/sites/default/files/archive/access-metrics-index-background.pdf; *see also* PIPER & GOLD, *supra* note 147, at 20.

[167] Universities Allied for Essential Medicines, University Technology Transfer, http://essentialmedicine.org/projects/university-technology-transfer (last visited Apr. 18, 2010).

[168] Universities Allied for Essential Medicines, Technology Transfer Metrics, (Sept. 19, 2009) http://essentialmedicine.org/projects/metrics (last visited May 19, 2010).

account the view from the technology transfer community as well as the university administration (including the research office and other senior university management), government departments and research agencies.[169]

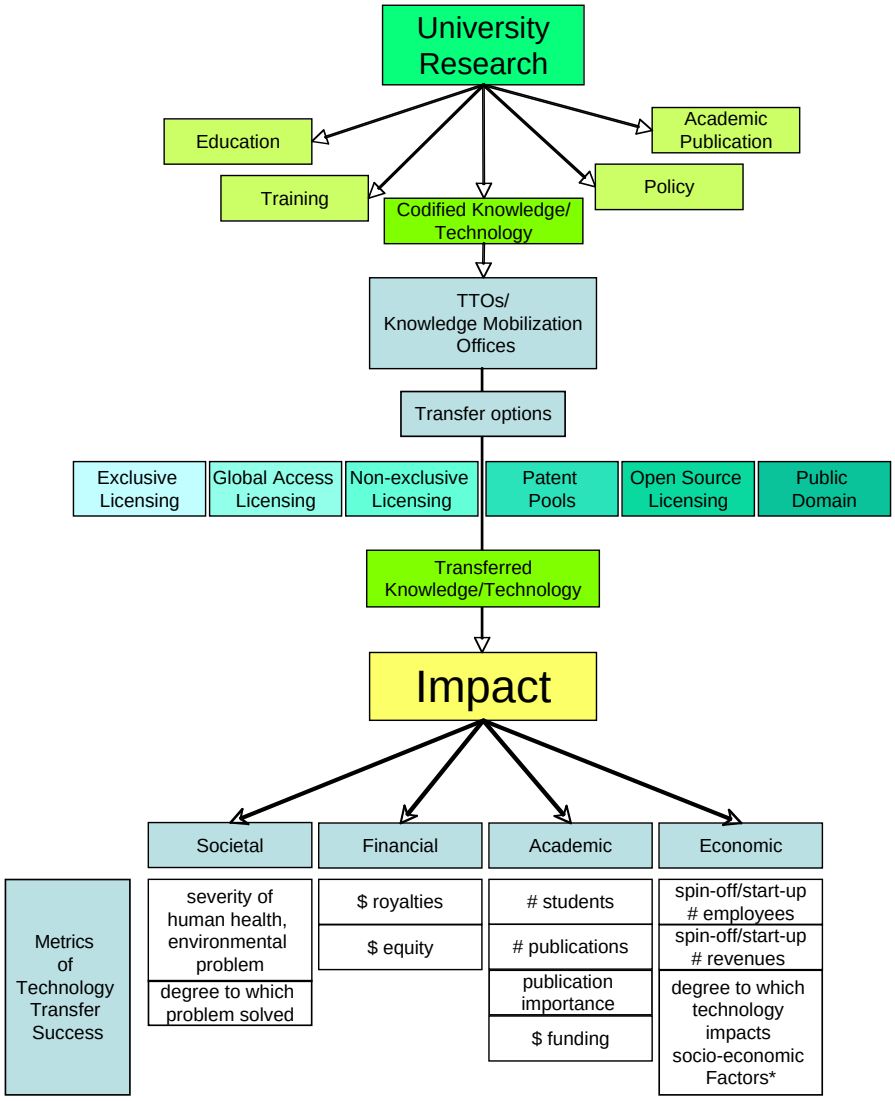
New metrics systems might also be structured to measure negative impacts of technologies as well the positive. As part of a longitudinal monitoring and improvement approach, the TTO could keep track of both positive and negative technology transfer impact/access metrics. The potential criticism of such a system is that it leaves a great deal of discretion to the TTO to determine the appropriate uses of a technology. There may be external pressures on the TTO to make decisions based on revenue or other factors. This situation is the current reality at TTOs and the key to managing innovative metrics is to ensure that the purpose and type of metrics are appropriate, reproducible, reliable and clear to all engaged. Another concern might be that adoption of novel metrics as measures of success may not be possible in light of financial pressures exerted within universities and by funding bodies. However, the reality is that a great majority of innovations patented and licensed by TTOs generate very little if any revenue. We would argue that the university is likely to benefit from a broadening of the scope of metrics. If technology transfer is measured in a way that clearly assesses a complete picture of societal benefit, universities will be better recognized for their contributions. This effort is, in this sense, consistent with the Bayh-Dole Act in the United States and analogous policies in Canada.

Innovative metrics are clearly emerging as a more nuanced strategy for evaluating technology transfer. If TTOs start to measure success along different lines, the role of IP will likely be evaluated differently. Ultimately, the goal of this system of metrics is to achieve a multiplicity of impacts for innovation, thus broadening the goals associated with technology transfer. Applying novel metrics to the assessment of genomics technology transfer may pose special challenges since the benefits may be so far downstream that they are difficult to assess at an early stage. Nevertheless, the issues we have addressed are highly relevant to the evaluation of genomics knowledge transfer.

VII. MOVING FORWARD

Figure 1: Flow of Technology Transfer and associated Societal, Financial, Academic and Economic Impact Metrics

[169] *See* PIPER & GOLD, *supra* note 147, at 24-25.



As we discuss above, alternative IP strategies may be used to address issues related to access and scientific openness. Increased access and scientific openness may in turn lead to an increase in desirable societal, financial, academic and economic impacts. By placing a value on these impacts, they are more likely to be pursued as explicit goals for technology transfer. Further pursuit of desirable social, financial, academic and economic impact, in turn, sets the stage for the adoption of novel metrics. The interaction could happen in the reverse as well, whereby the adoption of novel metrics acknowledging

certain goals could support the utilization of alternative IP designed to achieve those ends.

Our model of mutual interaction between TTOs and some forms of alternative IP are outlined in Figure 1. Universities create different forms of knowledge that can be transferred through education, training, academic publication, policy and technology. Based on the TTO's impact goals and related system of metrics, a technology transfer path for university discoveries and inventions will be chosen and an appropriate IP "transfer option" will be applied. If, for example, an invention (e.g., protein: drug candidate binding assay microarray) could be important for developing a drug that could be used both to treat a neglected disease as well as for a condition that had a conventional market, the TTO would identify these possibilities and use its arsenal of IP choices to ensure that those measures could be met (e.g., global access licensing terms, see Figure 1). Alternatively, if the benefit from an upstream technology could simply be to enable further research (e.g., database of gene expression), the TTO might consider use of the public domain, but would credit itself with a measure of success for impacting knowledge under the academic category.[170]

The net goals, therefore, are interrelated and incremental moves forward with respect to alternative IP and to the evolution of TTOs as effectors of more than patents and licenses. Both alternative IP and metrics are tools in an effort toward greater openness in science, access and potential social and economic impacts. TTOs stand at the intersection of movements in both areas, and it will be their efforts that ultimately effect change in IP for genomics.

[170] *See generally*, UNICO, METRICS FOR THE EVALUATION OF KNOWLEDGE TRANSFER ACTIVITIES AT UNIVERSITIES 1-2 (2008), *available at* http://ec.europa.eu/invest-in-research/pdf/download_en/library_house_2008_unico.pdf (showing some aspects of this system have been built into the UNICO model of knowledge transfer in the U.K.).