

Genomics and Intellectual Property: Considering Alternatives to Traditional Patenting

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I. Introduction

In recent years, significant issues have been raised about the impacts of patenting practices in genomics. Specifically, critics have voiced concern about the possibility of creating an anti-commons where upstream – or early stage – genomic research is patented.¹ Others have suggested that the net effect of wide-scale patenting is to create patent thickets, wherein awareness and access to patents become an issue.² Still others point to the fact that undue concern with patenting and property by practitioners of basic research is contrary to the culture of the scientific community.³ Some have identified the Myriad Genetics case as emblematic of the negative result for patients⁴ (and health care systems) when basic genetic information is protected by patents. Other issues exist as well, such as the applicability of proprietary rights to the type of information generated by genomics research, including sequencing data and databases.⁵

The degree, extent, and even existence of these issues as significant problems for science and society are the subject of ongoing debate.⁶ As the Intellectual Property Policy and Research Group (IPPRG) at the W. Maurice Center for Applied Ethics at the University of British Columbia, we are working to better understand the potential of different alternatives specifically for upstream genomics research.⁷ Thus far, we have focused

our efforts on patent pools⁸ and open source (OS)-like licensing⁹.

With respect to these alternatives, we propose to answer the following questions: Do these alternative approaches address the issues of anti-commons, patent thickets and open science norms, as noted above? In what circumstances and for which specific characteristics might patent pools or OS-like licensing be appropriate? Do alternative upstream regimes create new issues for *downstream* genomics research and commercialization? Are alternative IP regimes realistic options that are attractive to researchers, academic institutions, industry, policy-makers, or the public?

In an attempt to foster robust discussion of these issues and to begin to test our interim answers to these questions, we held a workshop in March 2007 where we convened a small group of scientists, scholars, legal practitioners and industry representatives.¹⁰ Our discussions there suggest that there is a growing interest in the potential benefits of alternative IP mechanisms, even while the debate over open source and patent pools for genomics continues. Further, there is recognition that utilization of these alternative IP regimes would impact the development of downstream health products and that any such impacts need to be better understood. These interim findings are discussed in more detail here in the



interest of continuing to promote further understanding of how and where alternative IP might be applicable to upstream genomics research.

A. Open source/Open science continues to be debated as a model for genomics.

The debate over OS-like models for genomics continues at the granular level of specific research projects. Our efforts at the IPPRG, for example, are focused on the GE³LS portion of the “Dissecting Gene Expression Networks in Mammalian Organogenesis Project” (the MORGEN project). MORGEN is a study mapping organogenesis and gene expression of the mouse genome. It is an upstream research project which generates experimental results and bioinformatic tools related to organogenesis, drug discovery, and stem cells. Our research suggests that some forms of open source may be suitable for MORGEN’s research results – specifically the publication of some data and of bioinformatics software. The latter is a candidate because it is the most analogous to OS uses in Information Technology.¹¹ For example, MORGEN implemented a license based on an open source philosophy known as a Creative Commons license.¹²

One possibility that we are developing is that OS-like licenses could be implemented using a conceptual approach developed by the Biological Innovation for Open Society (BiOS) initiative.¹³ In the BiOS model, standard patents are obtained, but licenses to that IP are granted utilizing OS principles that allow access to enabling technology for development. Those who agree to the terms of sharing have protected access and can make and commercialize products, royalty-free, without the need to renegotiate a commercial license. This approach is potentially appropriate for research results that are candidates for patenting (e.g., information that has some potential value to other researchers or downstream drug development). The BiOS license that we envision might be applied here is the licensing of a patented technology via open source and open access principles.¹⁴ In BiOS’ model, “licensees and those who have used the technology under MTAs may not assert rights to exclude others from use of improvements, even patented improvements, against the licensor and other licensees within the protected commons.”¹⁵ While the BiOS license is conceptually appealing, we recognize that such licenses are difficult to draft, are specifically tailored to the technology, and require a significant investment of time, resources and expertise to develop.

Our theory is that the BiOS model could be applied in genomics and could guarantee researchers access to information through royalty-free licenses while providing access to a protected commons.¹⁶ As Per the BiOS model, this OS license could promote liberal uptake of MORGEN data and innovations, but would also ensure the sharing of any further improvements. One of the most challenging issues, of course, is what impacts such an OS approach would have on valuable downstream developments and whether incentives are needed to ensure downstream adoption of this approach.¹⁷ In a separate effort, we are developing a

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proposal that would combine: (1) OS-like licenses with a “tag back”¹⁸ model of royalties based on total sales for upstream developers and, perhaps, (2) a new form of regulatory exclusivity¹⁹ rewarding use of technologies covered by OS-like licenses. The aim would be to encourage use of the OS-like licenses both by upstream genomics researchers and by downstream commercial developers. This is the subject of current work by our team.

An antithetical perspective on the potential application of the open science movement to genomics was set forth at our workshop by Tina Piper, an Assistant Professor of Law at McGill University. In Piper’s view, OS licenses make sense with respect to copyright matters encountered in free software²⁰ and “copyleft” situations²¹ – namely, in the Information Technology (IT) realm where they first arose – but she questioned their applicability to genomics.²² Indeed, Piper suggested that the very fact that no one had yet developed a workable Open Source license for genomics demonstrated the unwieldiness of the approach. She pointed out that there were some instances of OS biotechnology, such as BioForge,²³ but reflected that this success was more about the success of open source software than about the life science aspect.



Instead of forcing the biotechnology situation to fit the IT mould with respect to licenses, Piper argued that many of the worthwhile goals of OS could be achieved by focusing on the education aspect of what she termed IP governance. That is, she recommended building on and extending the work of existent organizations by developing tools and strategies to improve the organization and interpretation of existing patent information, ensuring open access to research publications and focusing on community building. Clearly, the question whether OS-like principles can usefully be applied in genomics is the subject of ongoing discussion and research, and should be closely followed.

B. Public Domain as an Additional Form of Alternative IP: The Worm (*C. Elegans*) Community

There are those in the scientific community who believe that any form of patenting – including alternatives such as patent pools and OS-like licensing – is inappropriate for upstream research. They claim instead that all research results should be freely shared in the public domain with no patent or licensing provisions. At our workshop, University of British Columbia Professor of Zoology Donald Moerman provoked a spirited discussion of this view with his claim that the success of data sharing and community building experienced by the worm community could work for other areas of upstream research.²⁴ Moerman pointed to the fact that the worm community places *all* raw data and information on knockout worms, as well as the knockouts themselves, in the public domain with almost no pursuit of IP protections. In Moerman's view, the net result is a research community free from the legal conflicts that have affected so much of human genomics research. Moerman observed, however, that so far *C. elegans* has not been widely adopted as a model organism by industry and thus the research community is largely academic with relatively little commercial interest.

The wider applicability of the public domain worm model depends in part on a better understanding of how pressure to patent – or put all research into the public domain – impacts scientific research and scientists' behaviour. While many have attempted to address this question through surveys, University of Alberta Professor Tania Bubela proposed a highly empirical set of algorithms to generate new data on the subject.²⁵ Bubela described

her project to track scientists, publications, patents and scientific networks as a novel comprehensive effort to understand and graphically map the links among these factors. The sheer scope of the mapping project ensures a wealth of new hypotheses on the complex relationships among research, patents and the exchange of ideas.

C. Patent Pools Have Emerged as a Tangible Example of Alternative IP Licensing for Genomics

Patent pools have a long history of providing solutions in cases where the presence of patents has threatened to defeat the exploitation of a product or invention. In the U.S, over a dozen examples of patent pools, including pools centered on the early aircraft industry, the early automotive industry, and, more recently, in the IT sector surrounding the use of MPEG technology, have succeeded in enabling and promoting commercial development.²⁶ In essence, a patent pool is a collective arrangement that effects the aggregation of patents in which two or more parties agree to pool their respective technologies and license them as a package. This alternative form of IP licensing has been suggested as a possible solution to overcome the threat of the genomic patent thickets.²⁷ The most emblematic example of a genomics patent pool is the proposed SARS (Severe Acute Respiratory Syndrome) coronavirus pool, which is attempting to aggregate four of the seminal patent applications dealing with the SARS genomic sequence.²⁸ Our group has focused on the SARS pool to help uncover how this alternative might be appropriate for yielding commercial products (e.g. vaccines) from upstream research and to begin to evaluate the general applicability of patent pools in genomics.

The primary claims in favour of genomics patent pools are that by pooling relevant patents it becomes easier to commercialize products since the pool integrates complementary technologies, reduces transaction costs, clears blocking positions, and avoids costly infringement litigation.²⁹ Others point to the fact that patent pools act as a relatively simple method to overcome the potential threat of compulsory licensing.³⁰ The more subtle argument in favour of patent pooling is that this alternative is a move towards promoting the goals of open science. The antitrust guidelines issued by the United States Department of Justice (DOJ) state that all patents included in the pool must be made available on a non-exclusive basis.³¹ By prohibiting exclusive access to



the patents it guarantees that the patented information remains available and open for all who are willing to pay the price to use the patent information in their research and product development.³²

Our preliminary investigation of genomics patent pools has raised potential challenges that patent pools must either accept or attempt to overcome if this alternative is

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to prove useful for genomics. While promoting the goals of open science may be attractive, it may be difficult, absent a real threat of compulsory licensing, to convince patent holders to relinquish their control over their patents.³³ For patent pools to be widely effective and attractive, the economic incentive for a patentee to make its patents widely available, plus other factors such as the avoidance of compulsory licensing, must outweigh the attraction of maintaining control over licensing.³⁴ Genomic patent pools also face the challenge of satisfying antitrust concerns through attempting to determine which patents can and cannot be included in the pool, since the United States Department of Justice guidelines state that only *essential* patents can be included in a pool and that pools cannot include *complementary* patents.³⁵ The special challenge for genomics is that it is difficult to definitively identify the exact uses of a particular genomic discovery, therefore making it difficult to determine which patents are essential.

Of the possible forms of alternative approaches to IP, patent pools face the challenge of only appealing to a small segment of the genomics community, specifically either those who are committed to making upstream

patents widely available so as to promote open science or those who reckon that a patent pool is economically desirable as a means to avoid compulsory licensing or a patent thicket. At our March workshop, Olaf de Jager offered his insight into the emerging SARS patent pool.³⁶ de Jager is Legal Counsel to Viroscope, which is a spin-off company of Erasmus University Medical Centre in the Netherlands, a potential member of the SARS patent pool by virtue of having pending patents covering a portion of the SARS genome. For Viroscope, combining the relevant SARS IP was one way to enable commercialization of the SARS patent and to avoid potential patent thickets.

de Jager's perspective helps illustrate a specific instance of when a patent pool might be operationalized. The larger challenge for our research group is to develop a comprehensive understanding and articulation for the settings in which patent pools can offer a viable and useful alternative to traditional ways of handling IP in the area of genomics.

D. Consideration of Alternatives Must Reflect Changes in Genomics Patenting Practices since the 1990s.

Speakers at our workshop point to the fact that any consideration of alternative IP regimes needs to take place in the context of shifting patenting practices for genomics. This is an important point, as much of the critique over genomics patenting practices reflects a prior era when there was a deluge of gene patent applications. We were fortunate to be able to explore this topic in more depth with Kate Murashige, Counsel at Morrison Foerster in San Diego and a veteran of biotechnology IP debates. Murashige presented data demonstrating that the practice of wide scale gene patenting has subsided. While such patents continue to be granted most frequently in the United States, the rates have declined sharply.³⁷ In Murashige's view, the decline has been due to the minimal rates of return from most gene patents, as well as a growing reluctance by the U.S. and other patent and trademark offices to grant patents for gene sequences absent clear utility. In addition, Murashige claimed that the decision in *Madey v. Duke*³⁸, which appears on its face to limit the applicability of research exemptions, is actually an outlier. That is, both judicially and in practice the research exemptions still appear to have broad applicability.



Robert Cook-Deegan, Director of the Center for Genome Ethics, Law & Policy at Duke University, reflected further on the shifting pattern of gene patenting. He questioned specifically whether we can tell when patents foster or impede innovation.³⁹ Cook-Deegan pointed to the numerous policies and initiatives – including the Bermuda rules,⁴⁰ SNP Consortium⁴¹ and NIH research tools guidelines⁴² – aimed at preserving freedom to operate in genomics research. Cook-Deegan expressed cautious optimism that such approaches, at least with respect to genomics research, have been generally successful. He claimed that data-sharing policies seem generally to work and he agreed with Murashige’s claim that *de facto* research exemptions (in the U.S.) appear to be intact in spite of *Madey v. Duke*.⁴³

Despite this positive take on the various methods for addressing patent concern, Cook-Deegan questioned complications associated with information flow surrounding cumulative technology that may start in industry, go into academe and back into industry again. Cook-Deegan observed that markets cannot solve all problems and pointed to the existence of products such as instruments and protein therapeutics that are on the market because the patent system worked. At the same time Cook-Deegan noted that in diagnostics where the value is in making a disease association, it is not clear that patenting is the best avenue. Although he argued that many aspects of the IP system have evolved fairly well to deal with genomics (e.g., scientists have, to a large degree, adapted to patenting), some reforms are still needed. In particular, he emphasized the need for increased transparency and noted that research performed with federal dollars should be subject to public accountability, and argued that anti-commons blocking of research should be more readily employable as a reason for “march-in” under Bayh-Dole.⁴⁴

II. Conclusion

IP regimes for upstream genomics research continue to be the subject of much debate. Many have, in fact, targeted the current IP regime as responsible for failure in our current access to health care.⁴⁵ This point was highlighted at our workshop by Tania Bubela. To illustrate the point, Bubela explored responses to the Myriad case, in which one small U.S. company attempted to enforce its IP rights in its diagnostic test for the BRCA gene sequence through exclusive licensing deals, to show that these two concepts were inextricably mixed

in the public perception of the “crisis.”⁴⁶ Research at the Health Law Institute in Alberta revealed that public concerns about Myriad’s actions were widespread and most comments railed against the patent system, and yet, when the Edmonton team examined the discussions more closely, they found that availability of health care was a consistent core issue.

The Myriad case may serve as an important reminder for those studying IP protection of upstream research as well. With upstream research, the issue of access to medicines often appears to be remote and somewhat tangential. Yet our hypothesis is that initial sharing of research information – through some type of open source-like system – can directly affect the flow of knowledge and data, and ultimately impact downstream development and even access to drugs. As in the case of the SARS, an efficient means of sharing upstream research, such as a patent pool, could enable more efficient vaccine development. Similarly, we hypothesize that sharing certain parts of the MORGEN research results through OS licenses *could* trigger a chain reaction and force each downstream development to abide by similar OS licensing principles. The details of how such an approach would impact patent rights in downstream products are still under development and is an issue that we – and others – will continue to research.

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Endnotes

- 1 Michael A. Heller & Rebecca S. Eisenberg, “Can Patents Deter Innovation? The Anticommons in Biomedical Research” (1998) 280 Science 698.
- 2 Carl Shapiro, “Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting” in Adam B. Jaffe, Josh Lerner & Scott Stern, eds., *Innovation Policy and the Economy 1* (Cambridge, Mass.: The MIT Press, 2000) 121.



- 3 Robert K. Merton, *The Sociology of Science: Theoretical and Empirical Investigations*, ed. by Norman W. Storer (Chicago, Ill.: University of Chicago Press, 1973); John Sulston & Georgina Ferry, *The Common Thread: a story of science, politics, ethics and the human genome* (Washington, D.C.: Joseph Henry Press, 2002); Robert Cook-Deegan & Tom Dedeurwaerdere, "The Science Commons in Life Science Research: Structure, Function and Value of Access to Genetic Diversity" (2006) 58 *International Social Science Journal* 299 [Cook-Deegan and Dedeurwaerdere].
- 4 E. Richard Gold & Julia Carbone, *Myriad Genetics: In the Eye of the Policy Storm*, online: International Expert Group on Biotechnology, Innovation and Intellectual Property <http://www.theinnovationpartnership.org/documents/TIP_Myriad_Report.pdf> [Gold & Carbone].
- 5 Rebecca S. Eisenberg, "Patents and data sharing in public science" (2006) 15 *Industrial and Corporate Change* 1013; Cook-Deegan and Dedeurwaerdere, *supra* note 3.
- 6 Organisation for Economic Co-operation and Development, *Guidelines for the Licensing of Genetic Inventions* (Paris: Organisation for Economic Co-operation and Development, 2006), online: Organisation for Economic Co-operation and Development <<http://www.oecd.org/dataoecd/39/38/36198812.pdf>>; John P. Walsh, Charlene Cho & Wesley M. Cohen, "View from the Bench: Patents and Material Transfers" (2005) 309 *Science* 2002; Lori Pressman *et al.*, "The licensing of DNA patents by U.S. Academic Institutions: An Empirical Survey" (2006) 24 *Nature Biotechnology* 31; Timothy Caulfield *et al.*, "Evidence and anecdotes: An analysis of human gene patenting controversies" (2006) 24 *Nature Biotechnology* 1091.
- 7 The members of the IPPRG are Ed Levy, Emily Marden, Cheryl Power, David Hartell and Ben Warren. Collectively, we are working on three Genome Canada projects focused on "ethical, economic, environmental, legal and social issues arising in genomics research" (fields of study collectively known as GE³LS). In two cases we serve as the GE³LS component of the science projects, MORGEN and *C. elegans* (described in this article); the third project is stand alone, the GE³LS ARCH in which we are preparing a case study of patent pools being utilized as an alternative way of handling IP.
- Information about our team and our research can be found at <<http://www.gels.ethics.ubc.ca>>.
- 8 Patent Pools are agreements whereby two or more parties agree to pool their different items of intellectual property and license them as a package to third parties (and to one another) ("Guidelines on the application of article 81 of the EC Treaty to technology transfer agreements" (2004) C101 Official Journal of the European Union 2; United States Department of Justice and Federal Trade Commission, *Antitrust Guidelines for the Licensing of Intellectual Property*, online: United States Department of Justice <<http://www.usdoj.gov/atr/public/guidelines/0558.htm>> [*Antitrust Guidelines*].
- 9 Open source licenses developed as a form of copyright licenses for computer software that make the source code available under terms that allow for modification and redistribution without having to pay the original author. Such licenses may have additional restrictions such as a requirement to preserve the name of the authors and the copyright statement within the code. A popular set of open source software licenses are those approved by the Open Source Initiative (OSI) based on their Open Source Definition (OSD) (Open Source Initiative, online: <<http://www.opensource.org/docs/osd>>). By "OS-like licenses" in this article, we mean licenses that preserve some of the key features and the spirit of openness that motivated the development of open source licenses. We do not strive for a strict application of the software based definition of OS licenses because based on our initial research, we have come to the interim conclusion that efforts to translate OS software licenses quite directly into genomics licenses have little promise for success. Rather, any work on OS-like licenses needs to address the inherent differences between software and genomics, copyright and patents.
- 10 The speakers included (Speaking order): Cheryl Power (Attorney & Research Associate, Center for Applied Ethics, University of British Columbia), Kate Murashige (Partner, Morrison & Foerster, San Diego, Cal.), Tania Bubela (Assistant Professor, Department of Marketing, Business Economics and Law, University of Alberta), Olaf de Jager (Legal Counsel/Business Consultant, Viroscope, Netherlands), Don Moerman (Professor, Department of Zoology, University of British Columbia), Robert Cook-Deegan, M.D. (Director, Center for Genome Ethics, Law & Policy, Duke University), and Tina



Piper (Assistant Professor, Faculty of Law, McGill University).

- 11 Janet Elizabeth Hope, *Open Source Biotechnology* (Ph. D. Thesis, Australian National University, Canberra, 2004), online: Free/OpenSource Research Community <<http://opensource.mit.edu/papers/hope.pdf>>.
- 12 Creative Commons licenses are copyright licenses released by Creative Commons, a U.S. non-profit corporation founded in 2001. Many of the licenses grant certain “baseline rights”, such as the right to distribute the copyrighted work without changes, at no charge. Creative Commons licenses are currently available in 34 different jurisdictions worldwide, with nine others under development (Creative Commons, online: <<http://creativecommons.org>>).
- 13 The BiOS Initiative is aimed at increasing the ability to innovate in the agricultural biotechnology sector. The BiOS Initiative emerged in response to current business and legal landscapes which are perceived as preventing some within the developed and developing world from accessing and harnessing biological science technologies. The initiative aims to foster democratic innovation in biological technologies through the use of novel alternative intellectual property informatics and analysis, innovation system structural reform and cooperative open access technology development activities.

The initiative advocates common access to the tools of innovation, to promote the development of these tools, and to make such developments freely accessible to both academic and commercial parties under substantially similar conditions (BiOS Initiative for Open Innovation, online: <<http://www.bios.net>>).

- 14 Andrés Guadamuz González, “Open Science: Open Source Licenses in Scientific Research” (2006) 7 North Carolina Journal of Law and Technology 321.
- 15 BiOS Initiative for Open Innovation, *Biological Open Source’ is not a new way to patent, but a new way to share the capability to use patented technology*, online: BiOS Initiative for Open Innovation <<http://www.bios.net/daisy/bios/licenses/398/2532.html>>; MTA refers to a Material Transfer Agreement which is a contract that governs the transfer of tangible research materials between two organizations. The MTA defines the rights of the provider and the

recipient with respect to the materials. Biological materials, such as reagents, cell lines, plasmids, and vectors, are the most frequently transferred materials. The three most common types of MTAs are: transfer between academic or research institutions, transfer from academia to industry, and transfer from industry to academia (see: Council on Governmental Relations, *Materials Transfer in Academia: 20 Questions and Answers*, online: Council on Governmental Relations <http://www.cogr.edu/docs/MTA_Final.pdf>).

- 16 Cheryl Power et al., “MORGEN GE3LS : Balancing Norms of Open Science and Genome Canada’s mandate to commercialize” (Address delivered at the Genomics and Intellectual Property: Considering Alternatives to Traditional Patenting Workshop, Vancouver, 9 March 2007) [unpublished].
- 17 For an interesting discussion of this problem with respect to the pharmaceutical industry see: Neil B. Niman & Brian T. Kench, “Open Source in the Pharmaceutical Industry”, online: (2003) Proceedings of the Midwest Business Economics Association 124 <<http://www.usi.edu/business/mbea/2003/WordFiles/NIMAN-KENCH.doc>>.
- 18 By “tag back,” we mean that any royalties should accrue not only to the developer of the innovation, but also to the upstream developers of any data and information that is utilized under the BiOS license.
- 19 By “regulatory exclusivity,” we mean a form of market exclusivity that is operated by regulatory authorities, such as the U.S. Food and Drug Administration or Health Canada. Currently, regulatory exclusivities exist in a variety of forms including orphan drug exclusivity and new chemical entity exclusivity. In a general sense, regulatory exclusivities provide similar commercial protection as patent exclusivities but do not require a patent to operate.
- 20 Free software is software that can be used, studied, and modified without restriction, and which can be copied and redistributed in modified or unmodified form either without restriction, or with restrictions only to ensure that further recipients can also do these things (GNU Operating System, *The Free Software Definition*, online: GNU Operating System <<http://www.gnu.org/philosophy/free-sw.html>>).
- 21 Copyleft is a play on the word copyright and is the practice of using copyright law to remove restrictions on distributing copies and modified versions of a work for others and requiring that the



- same freedoms be preserved in modified versions (GNU Operating System, *What is Copyleft?*, online: GNU Operating System <<http://www.gnu.org/copyleft/copyleft.html>>).
- 22 Tina Piper, "Open Source in Biotechnology: A Question of Governance" (Address delivered at the Genomics and Intellectual Property: Considering Alternatives to Traditional Patenting Workshop, Vancouver, 9 March 2007) [unpublished].
 - 23 The BioForge is a portal for protocol-sharing, comments on patents, and discussion tools in both public and secure environments (Cambia Initiative for Open Innovation, online: <<http://www.bioforge.net/forge/index.jspa>>).
 - 24 Don Moerman, "Is public domain community research effective?: The nematode *Caenorhabditis elegans* as a positive case study" (Address delivered at the Genomics and Intellectual Property: Considering Alternatives to Traditional Patenting Workshop, Vancouver, 9 March 2007) [unpublished]; Robert P. Merges, "A New Dynamism in the Public Domain" (2004) 71 U. Chicago L. Rev. 183; Rebecca S. Eisenberg, "Genomics in the public domain: strategy and policy" (2000) 1 Nature Reviews. Genetics 70.
 - 25 Tania Bubela, "Mouse genomics project: Collecting and defining metrics to measure the impact of different organisational structure in IP on research and innovation" (Address delivered at the Genomics and Intellectual Property: Considering Alternatives to Traditional Patenting Workshop, Vancouver, 9 March 2007) [unpublished].
 - 26 Richard J. Gilbert, "Antitrust for Patent Pools: A Century of Policy Evolution", online: (2004) Stan. Tech. L. Rev. 3 <http://stlr.stanford.edu/STLR/Articles/04_STLR_3>.
 - 27 David B. Resnik, "A Biotechnology Patent Pool: An Idea Whose Time Has Come", online: (2003) 3 The Journal of Philosophy, Science & Law <<http://www6.miami.edu/ethics/jpsl/archives/papers/biotechPatent.html>>; Frank Grassler & Mary Ann Capria, "Patent pooling: Uncorking a technology transfer bottleneck and creating value in the biomedical research field" (2003) 9 Journal of Commercial Biotechnology 111; David Castle, "Open Source and Patent Pooling in Canadian Science and Biotechnology Policy" (2007) (unpublished, archived at University of British Columbia, W. Maurice Young Centre for Applied Ethics).
 - 28 Matthew Rimmer, "The Race to Patent the SARS Virus: The TRIPS Agreement and Access to Essential Medicines" (2004) 5 Melbourne Journal of International Law 335; James H. M. Simon et al., "Managing Severe Acute Respiratory Syndrome (SARS) Intellectual Property Rights: the possible role of patent pooling" (2005) 83 Bulletin of the World Health Organization 707.
 - 29 Jeanne Clark et al., *Patent Pools: A Solution to the Problem of Access in Biotechnology Patents?* (Alexandria, Va.: United States Patent and Trademark Office, 2000), online: United States Patent and Trademark Office <<http://www.uspto.gov/web/offices/pac/dapp/opla/patentpool.pdf>>.
 - 30 Robert P. Merges, *Institutions for Intellectual Property Transactions: The Case of Patent Pools*, online: Berkeley Center for Law & Technology, University of California, Berkeley School of Law <<http://www.law.berkeley.edu/institutes/bclt/pubs/merges/pools.pdf>>.
 - 31 *Antitrust Guidelines*, supra note 8.
 - 32 The argument that patent pools would help promote the goals of open science would not satisfy strong open science advocates who believe that upstream discoveries should be freely available to academic and perhaps other researchers. Patent Pool members could of course elect to include research exemptions in the collective license, which would further align patent pools with open science. The research exemption is an exemption to the rights conferred by patents. According to this exemption, despite the patent rights, performing research and tests for preparing regulatory approval does not constitute infringement for a limited term before the end of patent term. In 2002, the Court of Appeals for the Federal Circuit dramatically limited the scope of the research exemption in *Madey v. Duke University*, 307 F.3d 1351 (Fed. Cir. 2002) [*Madey v. Duke University*]. The court did not reject the defense, but left only a "very narrow and strictly limited experimental use defense" for "amusement, to satisfy idle curiosity, or for strictly philosophical inquiry." The court also precludes the defense where, regardless of profit motive, the research was done "in furtherance of the alleged infringer's legitimate business." The actual impact of *Madey v. Duke University* is unclear as illustrated by Kate Murashige's comments discussed herein.
 - 33 Patrick Gaulé, "Towards Patent Pools in Biotechnology?", online: (2006) 2 Innovation



- Strategy Today 123 <<http://www.biodevelopments.org/innovation/ist5.pdf>>.
- 34 Josh Lerner & Jean Tirole, *Efficient Patent Pools: NBER Working Paper No. 9175*, online: National Bureau of Economic Research <<http://www.nber.org/papers/w9175>>.
- 35 *Antitrust Guidelines*, *supra* note 8.
- 36 Olaf de Jager, *Patent Pooling and Biotech* (Address delivered at the Genomics and Intellectual Property: Considering Alternatives to Traditional Patenting Workshop, Vancouver, 9 March, 2007) [unpublished].
- 37 Kate Murashige, "US Patent Practice in the Genomics/Research Arena" (Address delivered at the Genomics and Intellectual Property: Considering Alternatives to Traditional Patenting Workshop, Vancouver, 9 March 2007) [unpublished]; Michael M. Hopkins *et. al*, "DNA Patenting: the end of an era" (2007) 25 *Nature Biotechnology* 185.
- 38 *Madey v. Duke*, *supra* note 33.
- 39 Robert Cook-Deegan, "Tales of the Genome: Can we tell when patents foster or impede innovation" (Address delivered at the Genomics and Intellectual Property: Considering Alternatives to Traditional Patenting Workshop, Vancouver, 9 March 2007) [unpublished].
- 40 The Bermuda rules require publicly-funded investigators to deposit all newly identified DNA sequences and mutations in the publicly-accessible GenBank database within 24 hours. The name is from an agreement entered into at the International Strategy Meeting on Human Genome Sequencing held in Bermuda in 1996 (David R. Bentley, "Genomic Sequence Information Should Be Released Immediately and Freely in the Public Domain" (1996) 274 *Science* 533).
- 41 The SNPs consortium is a joint funding initiative of major pharmaceutical firms and a private foundation to provide a public domain collection of single nucleotide polymorphisms, or points of variance in the human genome (International HapMap Project, online: <<http://snp.cshl.org>>).
- 42 The U.S. National Institutes of Health, Office of Technology Transfer, *NIH Principles and Guidelines for Sharing of Biomedical Resources*, online: National Institute of Health, Office of Technology Transfer <http://ott.od.nih.gov/policy/research_tool.html>.
- 43 *Madey v. Duke*, *supra* note 33.
- 44 Avital Bar-Shalom & Robert Cook-Deegan, "Patents and innovation in cancer therapeutics: lessons from CellPro" (2002) 80 *Milbank Quarterly* 637.
- 45 Michael Crichton, "Patenting Life" *New York Times* (13 February 2007) A23; Lori B. Andrews & Dorothy Nelkin, *Body bazaar: the market for human tissue in the biotechnology age* (New York: Crown Publishers, 2001).
- 46 Gold & Carbone, *supra* note 4.

