The Tools and Levers of Access to Patented Health Related Genetic Invention in Canada

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INTRODUCTION

This Article argues that there is a prevailing problem of access to genetic invention in Canada caused by disputes over intellectual property ("IP") rights arising from conflicting normative orders. A variety of tools have been suggested and developed to remedy blockages to genetic invention caused by intellectual property ("IP") rights, including proposals for legislative reform, open source licensing initiatives, international standard setting, and information aggregation projects. I argue that determining which tool will work requires comprehending how the tool will interact with the characteristics of the local legal order. I draw on legal pluralist insights that regard state law as merely one form of legal regulation, and the local legal order as comprised of formal and informal rules developed by communities of practice.[1] I also develop the premise that a one-size-fits-all approach to enabling access through IP rights is likely to be as unsuccessful as one-size-fits-all approaches have been to regulating IP rights more generally.[2]

Implemented properly, access-increasing changes could enhance the effectiveness of IP law-making systems. Reforms would consider how the tools could be applied in a contextual manner that reflects

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1. *See* Emmanuel Melissaris, *The More the Merrier? A New Take on Legal Pluralism*, 13 SOC. & LEGAL STUD. 57 (2004); Gunther Teubner, *The Two Faces of Janus: Rethinking Legal Pluralism*, 13 CARDOZO L. REV. 1443 (1992).

2. *See* Robin Jacob, *One Size Fits All?*, *in* PERSPECTIVES ON PROPERTIES OF THE HUMAN GENOME PROJECT 449 (F. Scott Kieff ed., 2003); David Vaver, *Need Intellectual Property Be Everywhere?: Against Ubiquity and Uniformity*, 25 DALHOUSIE L.J. 1 (2002).

the state and characteristics of local IP legal orders. I consider the appropriateness of various forms of legal rule reform in the Canadian context given the institutions that most influence access to innovation. I conclude, based on empirical research, that the most effective lever for ensuring access to health-related genetic invention in Canada is to influence national university technology transfer officers, adapting the tool of voluntary standards developed internationally to suit their purposes rather than formulating legislation or otherwise formally amending state law. I begin by investigating the nature of the access problem.

I. AN ACCESS PROBLEM

Limited access to important genetic health technologies is often a result of the collision of informal rule-making orders with formal IP law regimes. I argue that the observed access problems can be best remedied by understanding and accommodating the formal and informal legal rules that bind parties. This Part investigates, first, how access to important health technologies is structured and limited and, second, the details of two particular conflicts involving access in Canada that highlight the various formal and informal rules at play in access disputes.

Many valuable genetic technologies are patented, principally in the United States and other jurisdictions. Over time, biotechnology patents on genetic invention have increased globally and encompass more and more of the genome. In the United States, for example, more than 13,000 biotechnology patents were granted in 2000, up from 2,000 in 1985.[3] This demonstrates the rapid growth of patents on research tools that surround drug development.[4] Patent claims center around certain gene hotspots valuable for clinical applications, leaving whole expanses of the human genome uncharted. In 2005, researchers concluded that 20% of human genes are held under 4,270 U.S. patents.[5] Much of this innovation rests in private hands: 78% of

3. John P. Walsh et al., *Effects of Research Tool Patents and Licensing on Biomedical Innovation*, *in* PATENTS IN THE KNOWLEDGE-BASED ECONOMY 293 (Wesley M. Cohen & Stephen A. Merrill eds., 2003).

4. *Id*. at 293–94.

5. Kyle Jensen & Fiona Murray, *Intellectual Property Landscape of the Human Genome*,

U.S. DNA patents as of 2004 were held by for-profit institutions, and 22% were held by non-profits.[6] Universities increasingly hold a greater number of life science patents and derive substantial licensing revenue from licensing innovations and technology transfer.[7] General trends also show an increasing level of international collaboration in patent applications.[8]

In this context of increased patenting of genes by private firms and universities and international collaboration, international legal and scientific policy communities mobilized in the 1990s and 2000s to address concerns regarding an "anti-commons" of biomedical research.[9] An over-allocation of proprietary rights, i.e., patents, could block research by creating an "anti-commons" where valuable knowledge remained underexploited. Patent holders could stack royalties to extract monopoly profits, block upstream research with concurrent patents, deter research through over-broad or invalid patents,[10] and exclusively license their innovations, creating a situation where downstream researchers would be unable to research or develop any products.[11] Thus the anti-commons could result not only from the grant of patent rights but also from restrictive downstream licensing practices. This situation was contrasted with the "tragedy of the commons," or the over-exploitation that results from no formal allocation of property rights.[12] Thus, patents would

310 SCIENCE 239, 239 (2005).

6. Lori Pressman et al., *The Licensing of DNA Patents by US Academic Institutions: An Empirical Survey*, 24 NATURE BIOTECHNOLOGY 31, 33 (2006).

7. Walsh et al., *supra* note 3, at 295.

8. ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT, 2008 COMPENDIUM OF PATENT STATISTICS 1, 7 (2008), http://www.oecd.org/dataoecd/5/19/37569377.pdf.

9. *See, e.g.*, Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting*, *in* 1 NBER INNOVATION POLICY AND THE ECONOMY 119, 124 (Adam B. Jaffe et al. eds., 2001); Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698 (1998); Michael A. Heller, *The Tragedy of the Anticommons: Property in the Transition from Marx to Markets*, 111 HARV. L. REV. 622 (1998).

10. One study demonstrated that 38% of patent claims filed with the USPTO in a one-year period for nine selected genetic diseases had problems that might lead to their invalidity. Jordan Paradise et al., *Patents on Human Genes: An Analysis of Scope and Claims*, 307 SCIENCE 1566, 1566 (2005).

11. *Id*. at 1567.

12. Garrett Hardin, *The Tragedy of the Commons*, 162 SCIENCE 1243, 1244 (1968).

have the unintended effect of limiting, rather than stimulating, innovation, impeding both research and the provision of clinical genetic products, particularly genetic diagnostic tests. These opinions fed into the moral and practical concerns expressed by policy-makers, health care specialists, and religious groups that granting gene patents could limit access to valuable technologies developed from those genes, increase the costs of healthcare, and commodify the human body.[13] An influential study indicated that 75% of scientists based at government, academic, and private research institutions and corporations were opposed to the commercialization of the results of the Human Genome Project, and 90% of respondents thought that excessive DNA patenting was a problem.[14]

The data were mixed, however, about the extent of commodification, an anti-commons, and a resultant access crisis.[15] Most recently, Caulfield et al. thoroughly surveyed the evidence for and against an access crisis up to 2006.[16] This retrospective study suggests that fears regarding access principally resulted from speculation in the academic and policy fields in the early part of the 21st century rather than strong empirical data.[17] Although there are limited data on the effects of patents on access in general,[18] the one empirical study of the issue concluded that there is a modest "anti-commons" effect that becomes worse the longer an invention has been patented.[19]

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13. *E.g.*, NUFFIELD COUNCIL ON BIOETHICS, THE ETHICS OF PATENTING DNA (2002), *available at* http://www.nuffieldbioethics.org/fileLibrary/pdf/theethicsofpatentingdna.pdf; DANISH COUNCIL OF ETHICS, PATENTING HUMAN GENES AND STEM CELLS 89 (2004), *available at* http://etiskraad.synkron.com/graphics/03_udgivelser/engelske_publikationer/patenting_human_genes/patents04/patenting_human_genes.pdf; David B. Resnik, *DNA Patents and Human Dignity*, 29 J.L. MED. & ETHICS 152 (2001).

14. Isaac Rabino, *How Human Geneticists in U.S. View Commercialization of the Human Genome Project*, 29 NATURE GENETICS 15, 15 (2001).

15. Timothy Caulfield et al., *Evidence and Anecdotes: An Analysis of Human Gene Patenting Controversies*, 24 NATURE BIOTECHNOLOGY 1091, 1091–94 (2006); *see also* STEPHEN HANSEN ET AL., THE EFFECTS OF PATENTING IN THE AAAS SCIENTIFIC COMMUNITY 1 (2006), http://sippi.aaas.org/survey/AAAS_IP_Survey_Report.pdf.

16. Caulfied et al., *supra* note 15, at 1091–94.

17. *Id*.

18. *See* E. Gold et al., *Gene Patents—More Evidence Needed, But Policymakers Must Act*, 25 NATURE BIOTECHNOLOGY 388, 388 (2007) (opining on Caulfield et al., *supra* note 15).

19. Fiona Murray & Scott Stern, *Do Formal Intellectual Property Rights Hinder the Free Flow of Scientific Knowledge? An Empirical Test of the Anti-Commons Hypothesis* 30–31

The quantitative data cause some concern about an access "problem," particularly given the importance of this area to human health and welfare, and when contrasted with the underlying purpose of patent law to incentivize innovation and dissemination of valuable technologies. The access problem is concretely demonstrated by particular problems of access to patented genetic inventions by healthcare professionals.[20] I will consider two examples that have affected Canada that demonstrate the access problems caused by patents over foundational genetic inventions and their licensing downstream, particularly exclusive licensing.

First, Myriad Genetics obtained patents in the United States, in Canada, at the European Patent Office ("EPO"), and in other jurisdictions for various aspects of the BRCA1 and BRCA2 genes and diagnostic tests for breast cancer.[21] Myriad's goal was to enter into licensing agreements with private laboratories that would then send tests to Myriad's Laboratories in Salt Lake City.[22] Myriad's broader goal was to fund its nascent therapeutics division through diagnostic testing and create a network of healthcare providers who would use its products.[23] In Canada, Myriad entered into an agreement with MDS Laboratories, which then negotiated with provincial governments about providing genetic diagnostic testing through MDS and Myriad.[24] The Ontario provincial government did not respond to Myriad and MDS's requests for six months, a

(Nat'l Bureau of Econ. Research, Working Paper No. 11465, 2005). Referring to the U.S. Bayh-Dole Act to either support or refute an access crisis is of limited probity as most research suggests that the Act has had little effect on patenting and licensing practices. David C. Mowery et al., *The Growth of Patenting and Licensing by U.S. Universities: An Assessment of the Effects of the Bayh-Dole Act of 1980*, 30 RES. POL'Y 99, 103–18 (2001); *see also* Matthew Rafferty, *The Bayh-Dole Act and University Research and Development*, 37 RES. POL'Y 29, 29 (2008) (stating that the Bayh-Dole Act might have provided an incentive for universities to shift focus from basic to applied research in order to generate revenue).

20. I will focus on Canadian "stories" as the later case study reviews Canadian developments.

21. E. RICHARD GOLD & JULIA CARBONE, MYRIAD GENETICS: IN THE EYE OF THE POLICY STORM 10–11 (2008), http://www.theinnovationpartnership.org/data/ieg/documents/cases/TIP_Myriad)_Report.pdf.

22. *Id.* at 21.

23. *Id*. at 9.

24. *Id.* at 11. Myriad repeated or attempted to replicate this business model in numerous other jurisdictions including Australia, Japan, the United States, the U.K., France, and Switzerland. *Id.* at 11–12.

significant time for Myriad but reasonable within government time frames, in order to consider the implications of the increased cost of Myriad's tests on government services.[25]

Public laboratories continued to administer their own tests during that period.[26] Myriad became frustrated with the government's lack of response and, on the advice of MDS, sent public laboratories cease-and-desist letters threatening litigation should they continue in-house testing for the BRCA1 and BRCA2 genes rather than sending samples (at three times the cost) to Myriad's laboratories or exclusive licensee for testing.[27] Myriad's cease-and-desist letters stopped testing at the B.C. Hereditary Cancer Program, but other programs continued their testing activities.[28] Myriad's behavior raised a furor in Canada, particularly after Myriad sent a series of letters to the Ontario government from U.S. representatives threatening trade sanctions and from U.S. scientists criticizing Canadian testing methods.[29] These actions and others were heavily reported by the media,[30] leading to expressed opposition from provincial ministers, premiers, and national breast cancer charities.[31] Conferences and negotiations continued between the provincial governments, the federal government, and Myriad.[32] The government was unable to find a consensus position among the various departments involved, and eventually the dispute petered out in the face of the 2003 SARS crisis in Ontario.[33] The controversy regarding Myriad led to reports and changes to the Canadian Intellectual Property Office's ("CIPO") Manual of Patent Office Practice ("MOPOP").[34] Two influential

25. *Id.* at 24–25.
26. *Id.* at 26.
27. Bryan Williams-Jones, *History of a Gene Patent: Tracing the Development and Application of Commercial BRCA Testing*, 10 HEALTH L.J. 123, 141–42 (2002) (detailing the situation that arose in Canada).
28. *Id.*; NUFFIELD COUNCIL ON BIOETHICS, *supra* note 13, at 40.
29. GOLD & CARBONE, *supra* note 21, at 25–26.
30. *Id.* at 26.
31. William-Jones, *supra* note 27, at 143–44.
32. GOLD & CARBONE, *supra* note 21, at 26–28.
33. *Id.*
34. CANADIAN BIOTECHNOLOGY ADVISORY COMM., PATENTING OF HIGHER LIFE FORMS AND RELATED ISSUES: REPORT TO THE GOVERNMENT OF CANADA BIOTECHNOLOGY MINISTERIAL COORDINATING COMMITTEE (2002), *available at* http://www.ic.gc/eic/site/cbac-cccb.nsf/vwapj/E980_IC_IntelProp_e.pdf/$FILE/E980_IC_IntelProp_e.pdf; ONTARIO

Canadian reports, spurred on by the Myriad crisis, recommended expanding and clarifying the research use exemption in patent law.[35] Although agencies in B.C. and Ontario voluntarily suspended some testing, Myriad did not bring legal action or refuse to license its tests to public health agencies.[36]

Myriad bridged two interpretive communities, each with its own norms and practices: the research community governed principally by norms of science, and the business community driven by a different set of rules and formal patent law.[37] Myriad had exclusively licensed its test to a commercial test provider and paid insufficient attention to the fact that this decision limited or appeared to limit research and access to its test.[38] Judging from its response and previous practice, the community of researchers and health practitioners was governed by a norm of communalism, particularly where technologies with valuable public health applications might be concerned.[39] Although state law had legitimized Myriad's actions through granting a patent, the informal normative order worked differently. Myriad failed to appreciate how the norms that governed its business decisions in the United States might not be the same as the informal rules that governed such decisions in Canada's public healthcare and research environment. The working solution to the dispute was that Myriad's patents were eventually ignored in Canada by diagnostic test providers in the public healthcare system, one possible response to a formal assertion of rights.

The second example of an access problem to health-related genetic invention is that of Warnex Inc.,[40] resulting again from apparently conflicting normative orders. Warnex sent letters across Canada stating that the company had an exclusive licence to a genetic

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MINISTRY OF HEALTH, GENETICS, TESTING & GENE PATENTING: CHARTING NEW TERRITORY IN HEALTHCARE 89 (2002), *available at* http://www.health.gov.on.ca/english/public/pub/ministry_reports/geneticsrep02/genetics.html.

35. CANADIAN BIOTECHNOLOGY ADVISORY COMM., *supra* note 34, at 15; ONTARIO MINISTRY OF HEALTH, *supra* note 34, at 88.

36. GOLD & CARBONE, *supra* note 21, at 28.

37. ROBERT K. MERTON, THE SOCIOLOGY OF SCIENCE: THEORETICAL AND EMPIRICAL INVESTIGATIONS (Norman W. Storer ed., 1973).

38. *See supra* notes 21–37 and accompanying text.

39. Further empirical research would be required to fully describe those norms.

40. Warnex, http://warnex.ca (last visited Apr. 10, 2009).

test for the JAK2 gene and myeloproliferative disorders (affecting blood cells).[41] Warnex followed the letter with site visits in some instances.[42] Upon publication of the scientific results underpinning the test, "Canadian laboratories quickly developed [their own version of the] genetic [diagnostic] tests" for use by Canadian healthcare providers at cost.[43] The Institut Gustave Roussy ("IGR") "has applied for a patent over the [JAK2] gene and related diagnostic methods," together with other French public institutions, and has "exclusively licensed the . . . gene and [related diagnostic tests] to Ipsogen, a French private company."[44] No patent has issued for either the gene or the diagnostic test in Canada.[45] The responses obtained from laboratory directors suggest that some believe that Warnex was proposing to sue them, but Warnex says that it merely hopes to provide a service to public laboratories.[46] Ultimately, IGR is seeking a patent on the gene; it has exclusively licensed the technology, and there remains a perception that Warnex may limit access to the diagnostic test. This contrasts with the established practices of directors of diagnostic laboratories, who embrace a more communal philosophy toward the availability of their research results for public health purposes.[47] Thus I conclude, based on the data and cases discussed, that an access dilemma exists in Canada. Resolving it will bridge normative communities and thus require subtle legal tools.

II. ACCESS TOOLS AND LEVERS

Scholars, international policy-makers, civil society, industry, and politicians have proposed a variety of sites of regulation to effect "increased access." These prescriptions often focus on state law as the most promising site of regulation through legislation and judicial

41. TINA PIPER & E. RICHARD GOLD, PRACTICES, POLICES AND POSSIBILITIES IN LICENSING IN HUMAN GENETICS 12–14 (2008), http://www.theinnovationpartnership.org/data/documents/00000015-1.pdf.

42. *Id.*

43. *Id.*

44. *Id.* at 12–13.

45. *Id.* at 13.

46. *Id.* Even if a patent eventually is granted, it is unlikely that the damages Warnex could obtain ever would match the cost of bringing suit and the damage to its public image. *Id.*

47. *Id.*

norm creation principally by case law. I argue that the solution to access problems created by IP rights in Canada likely will arise from informal para-lawmaking rather than through state-based law-making. The nature and scope of these informal rules and practices will depend on contextual factors that will vary in each jurisdiction and require gradual institutional change. Thus a subtle understanding of the Canadian policy context is critical to unearthing those levers of change, data that will be presented in the third part. In the final section of this paper I discuss private ordering (IP licensing practices including open source licensing), international standard setting, and information aggregation initiatives as possible levers that could be (or have been) adapted to Canadian conditions to enable success.

A. State Law: Legislative Reform

The first approach has been to address access problems to genetic technologies in the health sector through state-based initiatives to reform, amend, or improve the function of formal legal rules. These mechanisms include proposals such as legislative reform (e.g., an exception for health technologies in the Patent Act),[48] broadening the research use exemption in patent law, prohibiting gene patents entirely, and improving patent quality, specifically by ensuring that criteria of novelty and obviousness are strictly enforced.[49] In Canada, for example, the Canadian Biotechnology Advisory Committee recommended that Parliament institute a legislative research (experimental use) exception to ensure that health research was not stalled due to real or perceived fears regarding patent infringement.[50] Legislation has the advantage of being highly authoritative, clear, and universally enforceable by the State, generally taking precedence over all law except the Constitution in common-law jurisdictions. For

48. Canada Patent Act, R.S.C., ch. P-4 (1985).

49. AUSTRALIAN LAW REFORM COMM'N, GENES AND INGENUITY: GENE PATENTING AND HUMAN HEALTH (2004), http://www.austlii.edu.au/au/other/alrc/publications/reports/99; NUFFIELD COUNCIL ON BIOETHICS, *supra* note 13; W.R. CORNISH, M. LLEWELYN & M. ADCOCK, INTELLECTUAL PROPERTY RIGHTS (IPRS) AND GENETICS: A STUDY INTO THE IMPACT AND MANAGEMENT OF INTELLECTUAL PROPERTY RIGHTS WITHIN THE HEALTHCARE SECTOR (2003).

50. CANADIAN BIOTECHNOLOGY ADVISORY COMM., *supra* note 34, at 14–16.

that reason, legislative reform is a popular solution recommended by policy-makers and others seeking to remedy access problems.[51]

Legislative reform is slow, however, and its direct link to practical outcomes is unclear. Passing legislation does not often "make it so," as state-based rule-making often "shares" jurisdiction with other, more informal, rule-making processes. While legislative reform may clearly change behavior in some instances, in many others it is irrelevant, ignored, or ineffective; IP legislation is no exception.[52] Following the international Myriad controversy, only Belgium formally legislated a research exemption in its patent law;[53] the European Parliament passed a resolution opposing the patenting of BRCA1 in October 2001,[54] and France amended its patent laws to permit the grant of a compulsory license over diagnostics.[55] Legislation to limit the patenting of genetic technologies was tabled in the United States but never progressed.[56] The effect of legislation on access in each of these jurisdictions is unknown, but there is no evidence to suggest that access concerns have alleviated as a result. Legislative reform suffers from the further drawback of being slow: Legislators often adopt a wait-and-see attitude, particularly when balancing the interests of private-sector actors critical to economic growth and development. Thus legislation is an unwieldy tool when technology is evolving quickly.

B. State Law: Judicial Norm Creation (Case Law)

Even if legislation proves unwieldy, the courts might step into the breach, evolving case law through precedent to adapt to new realities.

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51. AUSTRALIAN LAW REFORM COMM'N, *supra* note 49; CANADIAN BIOTECHNOLOGY ADVISORY COMM., *supra* note 34; CORNISH, LLEWELYN & ADCOCK, *supra* note 49; NUFFIELD COUNCIL ON BIOETHICS, *supra* note 13.

52. *See* Paul H. Robinson, *Are Criminal Codes Irrelevant?*, 68 S. CAL. L. REV. 159 (1994). For an example more particular to the IP context, see Andrew E. Burke, *How Effective Are International Copyright Conventions in the Music Industry?*, 20 J. CULT. ECON. 51 (1996).

53. GOLD & CARBONE, *supra* note 21, at 35.

54. NUFFIELD COUNCIL ON BIOETHICS, *supra* note 13, at 40.

55. Law No. 182 of Aug. 6, 2004, Journal Officiel de la Republique Francaise [J.O.] [Official Gazette of France], Aug. 7, 2004, p. 14040, *available at* http://www.lexinter.net/lois4/loi_du_b_aout_2004_relative_a_la_bioethique.htm.

56. Genomic Research and Diagnostic Accessibility Act of 2002, H.R. 3967, 107th Cong. (2002), *available at* http://www.govtrack.us/congress/bill.xpd?bill=h107-3967.

Case law is, however, notoriously unpredictable, for it depends on the facts of the dispute brought before a court (unless one pursues a test case), the legal grounds, and the quality of advocacy, among numerous other factors. The effect of a case as precedent depends on a multitude of factors that include the nature of the legal system (common or civil law), the reputation of the judge deciding the case, the level of court, the legal framing of the dispute at hand, and even the accessibility and clarity of the written judgment. Judge-made law is also of limited effectiveness as it excludes other sources of norm creation that do not originate from the state. Myriad's aggressive defense of its gene patents did not result in litigation that could act as judicial precedent in any of the jurisdictions involved. Only the relatively litigious United States recently decided two cases that might affect access to patented genetic diagnostic technologies, neither directly related to the Myriad dispute. In the first case, the U.S. Supreme Court foreclosed an opportunity to consider the patentability of a diagnostic test when it denied certiorari in *Laboratory Corporation of America Holdings v. Metabolite Laboratories, Inc.*,[57] thus limiting the decision's legal effect.[58] In 2002, the U.S. Court of Appeals for the Federal Circuit ("CAFC") considered the scope of the research exemption in patent law in *Madey v. Duke University*.[59] The CAFC decided that although there was a research use exception, it was limited (in this case, in universities) to activities "to satisfy idle curiosity, or for strictly philosophical enquiry."[60] The decision led to speculation about its likely effect on researcher practices because it stood to limit research using patented tools and contribute to an access problem.[61] A subsequent study of researcher practice by Walsh et al.,[62] however,

57. Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 548 U.S. 124 (2006).

58. The lower court's finding of patent infringement by the petitioner was thus upheld. *Id.* at 125; *see also* Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings, 370 F.3d 1354 (Fed. Cir. 2004).

59. 307 F.3d 1351 (Fed. Cir. 2002).

60. *Id.* at 1362 (quoting Embrex, Inc. v. Serv. Eng'g Corp., 216 F.3d 1343, 1349 (Fed. Cir. 2000)).

61. *See* Rebecca S. Eisenberg, *Patent Swords and Shields*, 299 SCIENCE 1018 (2003); Richard R. Nelson, *The Market Economy, and the Scientific Commons*, 33 RES. POL'Y 455 (2004).

62. John P. Walsh et al., *View from the Bench: Patents and Material Transfers*, 309

found that *Madey v. Duke University*, although legally significant, had a negligible effect on the actual practice of research, demonstrating the importance of non-state sources of law-making to the legal regulation of IP.[63] Walsh et al. found that only 5% of scientists regularly check for patents on knowledge inputs related to their research, and only 2% of those have begun checking for patents in the two years since the case was decided.[64] Thus the available evidence, limited to U.S. sources, suggests that state-based law, whether in the form of legislation or case law, may have to work in tandem with other types of informal and influential rule-making to leverage access to health-related genetic invention.

C. State Law: Canadian Intellectual Property Rules and Institutions

State law is a possible nexus for ensuring access to valuable health-related innovation, but it is rarely adapted or amended in Canada, suggesting that the rules governing access to new innovation are being made elsewhere. State-based IP law in Canada is governed by federal statute, a power granted by the Constitution to the federal government over "Copyrights" and "Patents of Invention and Discovery."[65] Canadian patent law enforces strict subject-matter exceptions, practices strong examination standards, and includes an exception for medical methods of treatment.[66] The last major reform to the legislation came into force October 1, 1996; reforms to patent office practice and procedure happen through regulations, particularly the Patent Rules,[67] and the Manual of Patent Office Practice.[68] No

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SCIENCE 2002 (2005).

63. *Id.* at 2002–03.

64. *Id.*

65. Constitution Act, 1867, 30 & 31 Vict. Ch. 3 (U.K.), *as reprinted in* R.S.C., No. 5 (Appendix 1985). Trademarks are not explicitly addressed by the Constitution and are regulated under the federal government's authority over trade and commerce. *Id.*

66. I.e., does not practise 'instantpatentgratification.' David Vaver, *Canada's Intellectual Property Framework: A Comparative Overview*, *in* INTELLECTUAL PROPERTY AND INNOVATION IN THE KNOWLEDGE-BASED ECONOMY 1-1, 1-22 (Jonathan Putnam ed., 2006), *available at* http://www.ic.gc.ca/eic/site/ippd-dppi.nsf/vwapj/01-EN%20Vaver.pdf/$file/01-EN%20Vaver.pdf.

67. Patent Rules, SOR/96-423 (1996) (Can.).

68. CANADIAN INTELLECTUAL PROP. OFFICE, MANUAL OF PATENT OFFICE PRACTICE (1998), *available at* http://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/h_wr00720.

legislative reform is planned and the "Biotechnology" portion of MOPOP, although currently under review, has not been revised for more than a decade.[69]

Although state law is formally expressed in legislation, the government has created two administrative agencies pursuant to powers granted by the Patent Act that provide access to health innovation in Canada.[70] Neither, however, facilitates access to the type of patented genetic innovation in question in this Article. The first, the Patent Medicines Prices Review Board ("PMPRB"), established in 1987, sets the prices of patented medicines in the Canadian market and has met with sufficient success in fulfilling its mandate that U.S. citizens have imported in bulk lower-cost Canadian medicines.[71] Second, Canada was the first developed nation to implement an access-to-medicines regime pursuant to a 2003 decision of the World Trade Organization ("WTO").[72] It did this a year after the WTO decision,[73] and the Canadian Access to Medicines Regime ("CAMR") gives members with manufacturing capacity the right to grant compulsory licenses authorizing the export of patented pharmaceutical products to countries that are unable to manufacture their own.[74] CAMR has yet to be used successfully to provide medicines for health emergencies in developing countries, but Rwanda has recently initiated the regulatory machinery to export 15 million tablets of a drug used to treat AIDS manufactured by a Canadian generic drug company.[75] Both agencies demonstrate that where political will exists (in this case, on the issue of access to medicines), the Canadian government can develop state-based solutions of varying degrees of efficacy to ensure access. These

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html. The MOPOP is currently under review to incorporate the Supreme Court of Canada's decision in *Harvard College v. Canada*, [2002] 4 S.C.R. 45, 2002 SCC 76 (Can.).

69. CANADIAN INTELLECTUAL PROP. OFFICE, *supra* note 68.

70. The PMPRB was established by section 91 of the Canada Patent Act, R.S.C., ch. P-4 (1985), and the Patented Medicines Regulations, SOR/94-688 (Can.). The CAMR was established by the Jean Chrétien Pledge to Africa Act, 2004 S.C., ch. 23 (Can.).

71. Rebecca Voelker, *Northern Rexposure: U.S., Canada Clash on Cross-Border Medication Sales*, 290 J. AM. MED. ASS'N 2921 (2003).

72. Canada's Access to Medicines Regime, http://camr-rcam.hc-sc.gc.ca/intro/context_e.html (last visited Apr. 10, 2009).

73. *Id.*

74. *Id.*

75. *Id.*

levers are not ideally suited to addressing the access concerns presented in this Article, however, because they rely on centralized control measures focused on one aspect of the access problem (price) in respect of one type of product. Disputes regarding access to valuable genetic innovation are polycentric and not obviously amenable to a single source or type of regulation and control. In addition, the access disputes over genetic innovation relate to many different types of innovation and rely on a continuously changing cast of characters and are thus less clearly adaptable to centralized control.

Judge-made law is another ineffectual lever to ensure access to genetic invention between always changing parties in time-sensitive disputes involving the norms of business, healthcare innovators, and the law. Actions for patent infringement are brought to the federal court or superior court of any province and are heard by a judge alone. Although the patentability of genetic inventions directly related to health has not been considered, the Supreme Court of Canada ("SCC") decided in *Harvard College v. Canada*[76] that "higher life forms" are not patentable, rejecting the dissent's observations that "the massive investment of the private sector in biotechnical research [in Canada] is exactly the sort of research and innovation that the *Patent Act* was intended to promote."[77] The holding in *Harvard College* was modified by the SCC's subsequent decision in *Monsanto v. Schmeiser*,[78] which held that the fact that a claimed cell could form part of a higher life form does not mean that the claim to the cell should be equated to a claim to the higher life form.[79] As a result, genetic technologies remain patentable in Canada, but there is great ambiguity about the extent of their patentability given the conflicting SCC decisions and an unrevised MOPOP. That ambiguity is unlikely to be resolved soon by the courts because

76. Harvard College v. Canada (Commissioner of Patents), [2002] 4 S.C.R. 45, 2002 SCC 76 (Can.).

77. *Id.* at 18. Higher life forms are defined as: plants, seeds, animals at any stage of development including fertilized eggs and to tipotentstem cells, which have the inherent ability to develop into animals. *Id.* at 14. Embryonic, multipotent and pluripotentstem cells, which do not have the ability to develop into an animal, are considered to be lower life forms. *Id.* at 15.

78. Monsanto Canada Inc. v. Schmeiser [2004] 1 S.C.R. 902 (Can.).

79. *Id.* at 89.

patent litigation in Canada is of low volume, largely focuses on disputes between brand name and generic pharmaceutical companies over the implementation of the Patented Medicines (Notice of Compliance) Regulations, and rarely reaches the Supreme Court of Canada.[80] Thus patenting of genetic invention continues apace in Canada with some technical modifications to claims as a result of *Harvard Mouse* and *Monsanto* and with little litigation over those claims. This might be evidence that judge-made law leads more to the rent-seeking rather than rule-following behavior that an effective access regime would seek to avoid.

Administratively, directing reforms to the Canadian Intellectual Property Organization ("CIPO") could be a possible lever, but it has limited contact with the parties concerned with providing access to health innovation.[81] Instead, CIPO provides the security of a patent to international companies to market health innovations in Canada without introducing or embedding them further in the regulatory, legal, political, or socio-economic context of Canadian healthcare provision. In 2006 through 2007, CIPO received only 10,879 national patent applications, and 29,994 patent applications through the Patent Cooperation Treaty, for a total of 40,873 applications.[82] The vast majority of patents granted in Canada are to foreign patentees, mostly U.S. residents.[83] Biotechnology patents form a very small proportion

80. CANADIAN BIOTECHNOLOGY ADVISORY COMM., HUMAN GENETIC MATERIALS, INTELLECTUAL PROPERTY AND THE HEALTH SECTOR (2006), *available at* http://www.ic.gc.ca/eic/site/cbac-cccb.nsf/eng/ah00578.html. Taking a four-year period, in 2005 the Supreme Court of Canada heard one patent law case related to the interpretation of the notice of compliance regulations. In 2006 and 2007, the Supreme Court of Canada heard no patent law cases. In 2008 it is scheduled to hear one patent law case.

81. Note that CIPO does not take an active policy-making role, which is reserved to the Patent Policy Directorate. Intellectual Property Policy Directorate, http://www.ic.gc.ca/epic/site/ippd-dppi.nsf/en/h_ip00003e.html#ppd (last visited Apr. 10, 2009).

82. PCT applications originate outside the country as part of a bundle of patent applications to several states. Vaver, *supra* note 66. Combined European and PCT applications to the EPO in 2006 were 208, 502. EUROPEAN PATENT OFFICE, ANNUAL REPORT 2006, at 15, *available at* http://documents.epo.org/projects.babylon/eponet.nsf/0/3713591e285bdd02c12572ff003ca152/$FILE/Annual_Report_2006.pdf.

83. In 2006–2007, 1,617 patents were granted to residents of Canada; 14,413 patents were granted to residents of foreign countries, 7,560 (47% of the total) of which were to U.S. residents. CANADIAN INTELLECTUAL PROP. OFFICE, ANNUAL REPORT 2006–07: SUPPORTING CANADIAN INNOVATION 52, *available at* http://www.cipo.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/vwapj/ar06-07-e.pdf/$FILE/ar06-07-3.pdf. Japan and Germany were distant

of the patents granted by CIPO.[84] Most Canadian patentees patent first in the United States and then, only if necessary, in Canada; in this respect, Canada's patent system and market resemble those of a developing rather than developed country.[85] Moreover, CIPO neither collects information nor regulates licensing of patented innovation even though licensing of patented technologies is widespread in Canada. This further limits CIPO's possible role as a source of information to mediate disputes over access concerns. These facts and figures[86] suggest no real role for CIPO in influencing access disputes over patents that it has granted. CIPO has reserved for itself the limited and technocratic job of granting patents to foreign innovation; how those patent tokens are received and used on the market is left to the patent holders. Patentees must mediate local realities, including the fact that a patent granted in Canada may have neither the strength nor the significance of a patent granted in the United States; anecdotal evidence from the private sector suggests that patents held by industry on diagnostic tests are so routinely ignored that private companies in Canada are unwilling to enter the business.[87]

The discussion thus far has analyzed various state institutions and instruments such as legislation and has concluded that none is an obviously effective lever for norm creation in ensuring access to genetic innovation in the health field. I will now present empirical research that has investigated public universities and the culture of research scientists to determine whether they effectively generate binding norms for ensuring access and, if so, why.

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runners up. *Id.* To compare, 23.63% of patents granted at the EPO were to U.S. residents, closely followed by Japan (19.18%). EUROPEAN PATENT OFFICE, *supra* note 82, at 94–95. Of the top ten patent applicants in Canada in 2006–2007, only one could be considered a Canadian company, and of the top ten patentees in Canada in 2006–2007, none could be considered a Canadian company or a genetic invention company.

84. Only 3% of patents granted in 2006–2007 were for biotechnology patents. CANADIAN INTELLECTUAL PROP. OFFICE, *supra* note 83, at 50.

85. Manuel Trajtenberg, Is Canada Missing the "Technology Boat"? Evidence from Patent Data 15, Address Before the CSLS-Industry Canada Conference on Canada in the 21st Century (transcript available at http://www.tau.ac.il/~manuel/pdfs/Is%20Canada%20Missing%20Tech%20Boat.pdf); Phillip McCalman, *Reaping What You Sow: An Empirical Analysis of International Patent Harmonization*, 55 J. INT'L ECON. 161 (2001).

86. CANADIAN INTELLECTUAL PROP. OFFICE, *supra* note 83, at 51.

87. PIPER & GOLD, *supra* note 41, at 9–10.

D. Canadian Innovation

Norm generation in Canada in this area is affected by the public nature of universities and the research culture of scientists. State-based law appears to have little relevance to their work. Thus the courts, CIPO, and legislation do not reflect the vibrant biotechnology research and development ("R&D") community in Canada. Unlike the standard developing country profile, biotechnology R&D in Canada is significant ranking it as one of the top five countries for biotechnology R&D in the world, the majority of which is human-health related.[88] Universities are the second largest performers of R&D in Canada.[89] The federal government is by far the largest single funder of scientific research in Canada[90] and in 2004–05 spent $760 million on biotechnology R&D.[91] Thus universities are key to access in Canada as they direct and produce much of the important Canadian innovation in this area.

Understanding university research is critical when considering Canadian innovation and access to technology issues, and its importance is likely to grow. The Canadian government has made a priority of closing the "innovation gap" between itself and other industrialized nations as the key to long-term prosperity, and biotechnology is a priority sector.[92] Canada does not perform well on markers of innovation: It ranks fourteenth in the OECD in private sector R&D investment as a percentage of GDP and sixteenth in the

88. Biotechnology—Invest in Canada, http://www.investiraucanada.gc.ca/eng/industry-sectors/biotechnology.aspx (last visited Apr. 10, 2009).

89. Wulong Gu & Lori Whewell, *University Research and the Commercialization of Intellectual Property in Canada* (Industry Canada Research Publications Program, Occasional Paper Series No. 21, 1999), *available at* http://www.ic.gc.ca/eic/site/eas-aes.nsf/vwapj/op21e.pdf/$FILE/9021e.pdf); Janet Thompson, *Estimates of Canadian Research and Development Expenditures (GERD) Canada, 1994 to 2005, and by Province 1994 to 2003* 9–12, 24 (Statistics Canada, Working Paper No. 88F0006XIE2005020, 2005), *available at* http://www.statcan.gc.ca/pub/88f0006x88f0006x2005020-eng.pdf.

90. Donald Fisher & Janet Atkinson-Grosjean, *Brokers on the Boundary: Academy-Industry Liaison in Canadian Universities*, 44 HIGHER EDUC. 449 (2002).

91. Biotechnology—Invest in Canada, *supra* note 88.

92. INDUS. CANADA, MOBILIZING SCIENCE AND TECHNOLOGY TO CANADA'S ADVANTAGE 24, 94 (2007), *available at* http://www.ic.gc.ca/eic/site/ic1.nsf/vwapj/S&T strategy.pdf/$file/S&Tstrategy.pdf. The 2007 Science & Technology strategy states that is "the OECD has estimated that every percentage point increase in business R&D as a proportion of GDP leads to a 12-per-cent increase in income per person in the long run." *Id.* at 24.

OECD for high-quality patents per million of population.[93] Closing the gap, however, has proven challenging: government research has identified few policy levers other than tax credits for scientific R&D to stimulate innovation and commercialization in the private sector.[94] This research further confirms the conclusions thus far that the levers for managing innovation in the health technology sector in Canada are likely both state and non-state tools. Given the volume and importance of research conducted in universities and on policy levers to encourage innovation there, universities remain an important area of focus in ensuring access to health-related innovation.[95]

E. Research and Development: The Importance of Universities

Canadian universities are critical non-state institutions whose own norms are rarely examined but are important to effect access to valuable health innovation. Universities are major participants in research and hold IP or incubate innovation for many valuable health technologies. Two factors determine more than others the types of non-state norms that are generated. First, most major Canadian research universities are public and share the same mandates of education, research, and community service.[96] Thus a high degree of concurrence exists among the research objectives of the various universities and translates into publicly minded goals for their research outputs. Second, the goals of the universities are reflected in the attitudes of faculty members. Empirical research has found no link between financial incentives for university researchers and technology transfer outcomes in Canada.[97] Researchers have been found instead to be motivated to participate in technology transfer by

93. *Id.* at 25.

94. David B. Audretsch et al., *The Economics of Science and Technology*, 27 J. TECH. TRANSFER 155 (2002). Encouraging high levels of transfer of university technology based on public sector funded research remains a top priority as part of a broader strategy to increase the R&D integrated into Canadian innovation. *See* INDUS. CANADA, *supra* note 92.

95. Katherine A. Hoye, University Intellectual Property Policies and University-Industry Technology Transfer in Canada (2006) (unpublished Ph.D. thesis, University of Waterloo), *available at* http://uwspace.uwaterloo.ca/bitstream/10012/2855/1/kahoye2006.pdf.

96. *Id.* at 4.

97. *Id.* at 101, 108. Canadian researchers distinguish themselves from their U.S. counterparts in this regard.

its positive effects on scholarship, mentoring of graduate students, teaching performance, effects on the local or national community, and even the fact that researchers find creating spin-offs fun.[98] Thus universities and their researchers produce and disseminate health-related technologies with little leverage from extrinsic state-based factors such as revenues from IP rights; instead, their rules reflect the broader public purposes that govern researchers and their institutions.

Technology transfer from researchers to the public is conducted by Technology Transfer Offices ("TTOs") at most Canadian universities that are direct levers to access innovation in Canada. TTOs are governed by their own distinct institutional norms. TTO officers, like the universities that house them, embody a mandate to act in the public good, but what that "public good" looks like is often ill-defined.[99] TTOs have effected this public good in a variety of ways, most strikingly to non-Canadian observers by allowing researchers in many cases to retain total or joint control of IP arising from their inventions at 61 out of 121 universities in Canada.[100] TTOs have appreciated that what is most important in marketing invention in the Canadian context is unity of invention (i.e., one entity or person holds the IP), not who holds it.[101] Canadian universities are not nearly as influenced by state-based norms as their U.S. counterparts, who are subject to the requirements of the Bayh-Dole Act,[102] mandating commercialization of federally funded research.[103] Further, Bayh-Dole's lessons for Canada are of limited import to norm development at Canadian TTOs given Canada's distinct

98. *Id.* at 87, 101, 108.

99. Fisher & Atkinson-Grosjean, *supra* note 90, at 454.

100. Hoye, *supra* note 95, at 5. For purposes of comparison, "in the United States, all but three universities retain the rights to IP developed by their faculty." *Id.* (internal citation omitted).

101. TINA PIPER, E. RICHARD GOLD & OLIVER PLESSIS, A STUDY AND RECOMMENDATIONS REGARDING INTELLECTUAL PROPERTY POLICIES IN THE NOT-FOR-PROFIT CANCER RESEARCH SECTOR (2007); CHRIS RIDDELL, COMMERCIALIZATION STRATEGIES OF CANADIAN UNIVERSITIES AND COLLEGES: A STUDY FOR THE ADVISORY COUNCIL ON SCIENCE AND TECHNOLOGY 26 (2004); Hoye, *supra* note 95, at 50, 112.

102. 35 U.S.C. §§ 200–211 (2000).

103. *Id.* Bayh-Dole's value as a policy model export is unclear. Researchers doubt that a Bayh-Dole-type model would have a similar effect on Canadian research, given the very different research contexts, histories, and structure of public research. Hoye, *supra* note 95, at 7–8.

technology transfer context.[104] TTOs initiate and maintain relationships with private-sector partners through licensing and other business development arrangements. Thus TTOs are critical to leveraging a commitment to access to innovation. Although encouraging industry to enable access to health-related genetic inventions is important, and qualitative empirical research shows industry claims to support access goals, there are fewer direct levers to do so.[105] University TTOs are a direct lever, informed by rules developed in light of their research institutions and the TTO's own internal norm-generating structure.

The institutional priorities and rules governing TTOs are further influenced by their unique situation in the Canadian health innovation landscape and their efforts to develop a professional identity. TTOs traditionally have been organized to commercialize university innovation through patenting, promising innovations, and then licensing those innovations, mostly through exclusive licenses with industry.[106] TTOs thus derive their main income from licensing, and most aim to be financially self-sufficient. Licensing university technologies is not generally lucrative for Canadian TTOs, and most Canadian TTOs are not self-supporting.[107] Compared to counterparts in the United States, TTOs at universities are also relatively new: Although a number of universities founded "Research Offices" in the 1970s, modern TTOs did not develop until the mid-1980s.[108] TTO

104. 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 (2005).

105. PIPER & GOLD, *supra* note 41, at 9–10, 19–23.

106. ASS'N OF UNIV. TECH. MANAGERS, AUTM CANADIAN LICENSING ACTIVITY SURVEY FY 2006, *available at* http://www.autm.net/about/dsp.Detail.cfm?pid=216. TTOs also are responsible for in-licensing technologies to be used by their members. TTOs engage in a range of activities in addition to licensing, including fostering spin-offs, maintaining links with industry, nurturing collaborations with external partners, and otherwise managing IP on university technologies.

107. Although thirty-eight Canadian TTOs reported receiving $65,863,816 in licensing income in 2006, when TTO costs are considered, those numbers are very low. *Id.* The detailed results suggest that rather than providing a consistent income, commercialization acts more as a lottery ticket with high income generated from a few particular innovations.

108. Fisher & Atkinson-Grosjean, *supra* note 90. Compare this to U.S. counterparts that have been in operation since the early 20th century. Rima D. Apple, *Patenting University Research: Harry Steenbock and the Wisconsin Alumni Research Foundation*, 80 ISIS 375, 377–78 (1989).

officers are involved in actively defining a professional identity that involves creating a mission distinct and independent from oversight and control by home institutions and government.[109] As part of this initiative, Canadian TTO officers have been integrated into the U.S. Association of University Technology Managers network ("AUTM") and attend annual meetings.[110] Further, TTOs are seeking to develop more subtle measures of their own performance than revenue generation, in accordance with their vision of the public good and a more coherent sense of their professional mandate.[111] The success of a TTO has traditionally been measured by the number of licenses it concludes and the revenue it has generated.[112] Thus TTOs are norm-generating institutions with a sense of public service; given their important role in the ecology of technology development and transfer in Canada, they are critical levers for managing access to health technologies.

F. How to Influence Access: TTO Practice, Researchers, and Universities

Based on the conclusions above, TTOs, researchers, and universities can be influenced by a range of tools to facilitate access to health innovation in Canada. The most common tools include drafting IP policies, providing voluntary guidance to TTO officers, changing metrics of TTO performance, implementing measures targeting researchers, encouraging license-bundling initiatives, creating an independent third body to mediate access disputes, and encouraging dialogue and information sharing between TTOs and others in the ecosystem of Canadian innovation. I argue that the most likely tools to influence norm generation in the TTO context are

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109. MAGALI SARFATTI LARSON, THE RISE OF PROFESSIONALISM: A SOCIOLOGICAL ANALYSIS (1977).

110. ACCT Canada, Our Partners, http://www.acctcanada.ca/index.php?option=com_content&view=article&id=6:our-partners&catid=5:our-partners&Itemid=2 (last visited Apr. 10, 2009).

111. For a recent example, see ASS'N OF UNIV. TECH. MANAGERS, AUTM U.S. LICENSING ACTIVITY SURVEY FY 2007, at 4, 10–11, *available at* http://www.autm.net/content/NavigationMenu/surveys/LicensingSurveysAUTM/FY2007LicensingActivitySurvey/AUTMUSLS07FINAL.pdf.

112. *See* ASS'N OF UNIV. TECH. MANAGERS, *supra* note 106.

those that account for the TTOs' institutional characteristics, the characteristics of Canadian innovation in the field, and other cultural and local factors.

First, revising the IP policy that governs the university research and its TTO is one possible lever for implementing commercialization practices that encourage access. IP policies, however, are not guaranteed means of effecting changes in licensing behavior. IP policies have a broad signaling function, and their content (for example, university- or faculty-owned IP policies) may affect faculty support for technology transfer.[113] There is, however, no observed relationship between the content of IP policies and technology transfer outcomes.[114] Interview-based research we conducted into this question confirms that a TTO's IP policy does not structure its daily behavior and in many cases is out-of-date. The policy's over-arching principles, however, do seem to play some role in the organization's function.[115] We observed that there remains a strong perception that an institutional IP policy has a great impact on how technology transfer is conducted.[116] Similar results have been observed in studies of legislation in the criminal law area, where criminal codes, rarely read by the general public, play a role in creating an environment of order, confidence, and direction.[117] The motivating power of IP policies seems to depend entirely on how members of the university interpret them, and this will vary institution by institution and depend on the organizational history of the institution including its group norms, leadership, and culture.[118] Ultimately, the IP policy is likely to have greatest effect on behavior when it is seen as a document produced in consultation with important stakeholders that reflects the institution's policies, practices, culture, and mission, rather than minutely dictating practice.

TTO practices and behavior are not much influenced by changes in IP policies where those changes do not acknowledge the

113. Hoye, *supra* note 95, at 18–21, 27–30.
114. *Id.*
115. PIPER, GOLD & PLESSIS, *supra* note 101.
116. Hoye, *supra* note 95, at 115.
117. Robinson, *supra* note 52, at 196.
118. Hoye, *supra* note 95, at iii, 109.

institutional norms and culture of the TTO. Research by Herder and Johnston[119] on Canadian and some U.S. TTOs indicates that any type of policy guidance to TTOs has to preserve their discretion to decide on a case-by-case basis.[120] Herder and Johnston's research found that from the perspective of TTO officers, guidance and advice were more likely to change behavior than mandatory requirements.[121] TTOs operate on rules of thumb in a complex policy environment, and a range of factors influence whether and how to license an innovation.[122] Mandatory requirements, such as adhering to the OECD Guidelines, and interventionist oversight processes, such as commercialization committees imposed by funding agencies, threaten to slow down or even forestall decisions to commercialize an innovation.[123] Thus a second lever is voluntary measures adopted by the community of practice (here, the TTO) and could include circulating examples of how other IP professionals have resolved problems, sharing fora for TTO officers and others to discuss problems, and providing model language for agreements.[124] This model was supported by TTOs as a key means of influencing norm generation by TTOs. All the TTO officers in the Herder and Johnston study reserve educational and research rights in licensing agreements for the home institution and were willing to accept direction on those types of terms, but were less willing to cede authority for the decision of whether to exclusively or non-exclusively license their innovation.[125]

Third, norm generation in the community of practice of TTO officers is a reflexive process; the norms adapt based on the success or failure of a particular strategy. The most common means of measuring success or failure thus far have been measurements of licensing revenue. Changing these metrics emerges from our

119. Matthew Herder & Josephine Johnston, Licensing for Knowledge Transfer in Human Genetics Research: A Study of Business Models for Licensing and Technology Transfer in Human Genetics Patents (Mar. 23, 2007), http://www.theinnovationpartnership.org/data/documents/00000015-2.doc.

120. *Id.* at 37–38.

121. *Id.*

122. *Id.* at 38–39.

123. PIPER, GOLD & PLESSIS, *supra* note 101.

124. Herder & Johnston, *supra* note 119, at 38.

125. *Id.* at 45–49.

empirical research as the most promising lever for influencing TTO behavior on the theory that what you measure is what you get.[126] Existing metrics of disclosures, patents filed/issued, licenses, spin-off companies, license income, and sponsored research tend to skew TTO behavior toward maximizing those markers. TTOs have expressed a desire for broader metrics that they could use readily. For example, if an organization's goal is broad dissemination of knowledge and the development of useful clinical tools, it could measure the number of students trained, disclosures, and/or clinical applications developed or implemented (regardless of patent status). These metrics should comprise criteria such as a TTO's contribution to the public benefit, to public health, or to more specific health-access markers. The change in metrics could and should be initiated at a university-wide level, spearheaded by leaders within the university (such as the VP research), and could be integrated as part of a broader vision of TTO practice that includes making university publications and other materials accessible. Government could also play a role in creating funding opportunities for research that studies and proposes new metrics. TTOs, the private sector, public healthcare providers, and government-funded laboratories could then discuss and share local information about promising innovation, licensing practices, and strategies to ensure access. This type of initiative is already underway in the annual meetings of TTO officers and has led to creative suggestions such as encouraging TTOs to specialize by technology area rather than based on geographical location.[127] Information collection and sharing initiatives hold promise in improving access to health-related innovation.

Fourth, given the strength of self-generated norms in the TTO community of practice, it is unrealistic to impose Guidelines and other policy direction. These documents are not a dead letter, however. External documents, particularly Guidelines, can be used in an unpredictable manner by TTOs to obtain desired outcomes by, for example, using them as a foil in negotiations.[128] Further, TTOs may support requiring researchers to explain how proposed

126. PIPER, GOLD & PLESSIS, *supra* note 101.
127. *Id.*
128. Herder & Johnston, *supra* note 119, at 46.

commercialization of a federally funded project accords with the OECD Guidelines or other access goals as a means of informing broader communities of their role in ensuring access to their innovation. Given the conclusions about researcher motivations highlighted above, it is realistic to think that this may be an effective lever in Canada.

Finally, given the importance of TTO discretion and self-identity, collective measures that bring TTOs into dialogue with one another may be effective levers to ensure access to health innovation. One measure could be a collaborative bundling or pooling approach to licensing with standard terms of access to technologies that may in the end generate valuable collective norms across TTOs. Bundling and pooling may lead to explicit model contracting terms that facilitate or provide access. Further, a quasi-governmental third-party body could mediate access disputes across interested parties as those disputes arise, serving as a forum for neutral dialogue in resolving particular access disputes. This non-state entity could mediate the norms that govern the TTO community of practice, providing binding or non-binding results. Without this organization, parties currently (as in the Myriad and Warnex examples above) tend to resort to the language of the law when other attempts to communicate break down. As has been demonstrated, formal legal mechanisms are unlikely to effectively alter behavior and are perceived as illegitimate and irrelevant given their poor comprehension of the informal rules that govern the practice of access to health innovation in Canada. Formalizing arbitration based on the interested parties and their relevant rules of practice could lead to more mutually acceptable resolution of access disputes.

III. WHAT IS ACTUALLY HAPPENING

The failure of state law to provide solutions to the access debate has helped foster initiatives to influence the practice of TTOs through non-state mechanisms. I will examine three types of initiatives (licensing, international standard-setting, and information gathering) and examine why they have been more or less successful. The examples posed support my thesis that the initiatives that have been most successful or seem to be most promising are those that have

accounted for contextual formal and informal features of the rule-making culture.

A. Private Ordering Through Open Source Licenses

The first initiative I will consider is the development of open source licensing communities for health innovation to facilitate access. Patent holders may consent to grant others rights under their patent through the voluntary mechanism of a license negotiated between the patentee and a second party, subject to the general law on contracts.[129] Information about licenses should ideally be collected at the national level, as in Japan, for example, but it is not.[130] As a result, very little is known about who is licensing what to whom, and under what terms.[131] Further, there is no obligation to make the terms of licensing agreements public, even when they cover important technologies such as medicines essential to treating serious diseases.[132] Licensing practice thus remains embedded within a regime of private ordering and is regarded as a trade secret by some industries. What information does exist suggests that licensing is common and widespread. In Germany, for example, about half of patented inventions held by research institutions and biotechnology companies are licensed.[133]

The commercial development of a patented product is often determined by how it has been licensed (exclusively, solely, or non-exclusively). An exclusive license permits only the licensee (and whomever she authorizes) to exploit the patent, barring even the

129. Licenses are sometimes created unilaterally without consideration. The distinction between a contract and a license is significant in U.S. law, for it determines whether the federal (license) or the state (contract) government will regulate the innovation.

130. Letter from E.R. Gold to author (Oct. 26, 2007) (on file with author).

131. ORG. FOR ECON. CO-OPERATION AND DEV. (OECD), GENETIC INVENTIONS, INTELLECTUAL PROPERTY RIGHTS AND LICENSING PRACTICES: EVIDENCE AND POLICIES 45, 48 (2002), http://www.oecd.org/dataoecd/42/21/2491084.pdf; *see also* Mark A. Lemley & Nathan Myhrvold, *How to Make a Patent Market* (Stanford Law & Economics Olin Working Paper Series, Working Paper No. 347, 2007), *available at* http://ssrn.com/abstract=1012726.

132. *See* Luke Eric Peterson, *More Anti-Virals in the Hands of Politicians*, EMBASSY, OCT. 19, 2005, at 1, 11, *available at* http://embassymag.ca/pdf/view/2005-10-19.

133. ORG. FOR ECON. CO-OPERATION AND DEV. (OECD), *supra* note 131, at 46. The data are unclear, however, as to whether licensing statistics covered multiple licenses on a single patent, and there are no data available for pharmaceutical companies. *Id.*

patent-holder from the rights.[134] A non-exclusive license allows the patent holder to retain rights to exploit the patented invention and also to license the invention to others on any terms it likes. Patent licenses are rarely stand-alone documents; they fit into a much broader commercial strategy.[135] Thus licenses have traditionally been used to circumscribe access to a particular innovation in pursuit of market exclusivity.

Licenses, however, also can be used just as easily to broaden access to innovation. The open source software movement demonstrated that licenses could in fact specify that the right-holder was only reserving some of her IP rights. The open source movement was founded by computer programmers who shared computer code using standardized open source licenses, creating new norms of sharing, re-use, and adaptation that stood in contrast to state-based IP law. These licenses allowed programmers, who often never met, to share and redistribute code by permitting creators to choose which aspects of copyright protection such as use, reproduction, modification, or distribution of the product they wished to allow third parties to exploit, and in what circumstances. The licenses helped create the rules that supported a complex community of practice that added, edited, patched, and modified software, which was very successful in producing a high-quality product.[136] The popularity of open source licenses in programming has demonstrated a high level of acceptance of shared non-commercial uses in some communities for certain products, destabilizing prevailing narratives about the importance of ever-stronger IP rights to ensuring productivity and disclosure.[137] Open source licenses also empirically support the

134. Exclusive licenses may be limited to a particular country, for a specific period of time, or for a specific use, thus allowing potentially several exclusive licenses on one patent.

135. Licenses are frequently involved in the creation of a spin-off company, a strategic alliance, or a joint venture, and licenses may be implicated in manufacture and collaboration agreements. Licenses may allow companies to exchange information and resources or provide a company with access to a new market by providing access to manufacturing or distribution networks. AUSTRALIAN LAW REFORM COMM'N, *supra* note 49.

136. ERIC RAYMOND, THE CATHEDRAL & THE BAZAAR: MUSINGS ON LINUX AND OPEN SOURCE BY AN ACCIDENTAL REVOLUTIONARY 72–78 (Tim O'Reilly ed., rev. ed. 2001).

137. LAWRENCE LESSIG, FREE CULTURE: HOW BIG MEDIA USES TECHNOLOGY AND THE LAW TO LOCK DOWN CULTURE AND CONTROL CREATIVITY (2004); RAYMOND, *supra* note 136.

proposition that property rights and economic reward are only one of many types of incentives (including altruism and reputation) encouraging people both to innovate and also to disclose their innovation.[138]

Initiatives built on the open source insight to apply standardized licensing and "copyleft" type terms to medical and genetic innovation in the hopes of similarly providing access to valuable public health products. An international NGO, the Public Intellectual Property Resource for Agriculture ("PIPRA"),[139] has been developing a humanitarian clause for material transfer licenses that would create royalty-free material transfers from developed to developing countries, but the status of this project is unclear.[140] The Bios initiative aimed to establish an open source community of genetics researchers subscribing to licenses with copyleft-type provisions. This project has found that patents are ill-suited to open source, and it is difficult to mimic the open source effect to broaden access to patented innovation.[141]

The reason why an open source research community has not spontaneously developed or been nurtured in the area of health innovation (particularly genetics) may lie in the conflict between normative orders and a failure to account for contextual rule-generating and rule-following characteristics. Scientific research is norm-dependent and relies on practices that both mimic and differ from formal IP law.[142] Open source initiatives standardize norms

138. YOCHAI BENKLER, THE WEALTH OF NETWORKS: HOW SOCIAL PRODUCTION TRANSFORMS MARKETS AND FREEDOMS 79, 82–83 (2006); Samuel Trosow, *The Illusive Search for Justificatory Theories: Copyright, Commodification and Capital*, 16 CAN. J.L. & JURISPRUDENCE 217 (2003). Open source showed that software developers as a community often were driven by goals of altruism, e.g., by creating a low-cost, high-quality operating system, and reputational rewards through being credited in software development and becoming known within the project community. RAYMOND, *supra* note 136, at 53; Nicholas Economides & Evangelos Katsamakas, *Linux vs. Windows: A Comparison of Application and Platform Innovation Incentives for Open Source and Proprietary Software Platforms* (NYU L. & Econ. Working Paper Group, Paper No. 05-21, 2005), *available at* http://ssrn.com/abstract=822894.

139. *See* Pipra—the Public Intellectual Property Resource for Agriculture, http://www.pipra.org (last visited Apr. 10, 2008).

140. *See id.*

141. Richard Jefferson, Freedom to Cooperate: Initiative for Open Innovation PatentLens & BiOSRJ, Presentation at the Washington University in St. Louis Conference on Open Source and Proprietary Models of Innovation: Beyond Ideology (Apr. 4–5, 2008).

142. Arti Kaur Rai, *Regulating Scientific Research: Intellectual Property Rights and the*

according to legal standards that may differ significantly from reality, thus making licensing projects unappealing. Tailoring copyright law through licenses functioned well for the way programmers programmed code, but it is unclear that it works for other communities of shared endeavour that labor in different contexts (for example, biochemistry researchers). Thus, modes of sharing scientific information in and between different scientific research disciplines are often not well reflected in standard form licenses that reflect the current state of the law.[143] Science Commons encountered this obstacle when it attempted to draft a license that would allow data-sharing between disciplines and settled instead on a protocol or certification system: The protocol would accredit indigenous data-sharing practices as open-access without requiring researchers to adopt a standardized legal definition of the term.[144] Similarly, WIPO and others are in the process of developing concordances that are effectively mutual non-assertion covenants, supervised by a central oversight party that respects the varying normative orders in heterogeneous research communities.[145] Thus attempts at ensuring open source licensing of health-related technologies stumble upon contextual factors such as the nature of the research community involved.

B. International Standard Setting

A further tool for effecting access to health-related genetic invention has been to develop multilateral international guidelines to influence behavior at the national level, as formal state-based rules have failed to appear to modify behavior. This type of law-making is characterized by its voluntariness, attempted normativity,[146] and limited or (in this case) non-existent enforcement mechanisms.[147] The

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Norms of Science, 94 NW. U. L. REV. 77 (1999); Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 LAW & CONTEMP. PROBS. 289 (2003).

143. Science Commons, Database Protocol, http://sciencecommons.org/resources/faq/database-protocol/ (last visited Apr. 10, 2009).

144. *Id.*

145. Jefferson, *supra* note 141.

146. They purport to create standards of behavior and to influence behavior in those subject to it.

147. Simon B. Archer & S. Tina Piper, *Voluntary Governance or a Contradiction in*

OECD Guidelines for the Licensing of Genetic Inventions ("OECD Guidelines") were developed to focus on the licensing of patents over genetic inventions in member countries.[148] In addition, the U.S. National Institutes of Health ("NIH") prepared voluntary Research Tools Guidelines[149] and Best Practices for the Licensing of Genomic Inventions.[150] All set out best practices and guidelines for the licensing of genetic and genomic inventions as appropriate, but I focus on the OECD Guidelines in the discussion as directly applicable to Canadian policy-makers.[151]

The OECD Guidelines are intended to assist both OECD and non-OECD governments in developing governmental policies and influencing licensing behavior.[152] Thus the OECD Guidelines are neither directive nor binding; they merely "provide a framework within which to conceive of voluntary, market-oriented licensing arrangements with respect to genetic inventions."[153] The first part of the document sets out a number of principles and then a series of best practices that should govern each of licensing, health and genetic inventions, research freedom, commercial development, and

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Terms: Are Voluntary Codes Accountable and Transparent Governance Tools?, *in* SOMETHING TO BELIEVE IN: CREATING TRUST AND HOPE IN ORGANISATIONS STORIES OF TRANSPARENCY, ACCOUNTABILITY AND GOVERNANCE (Rupesh A. Shat et al. eds., 2003); Owen E. Herrnstadt, *Voluntary Corporate Codes of Conduct: What's Missing?*, 16 LAB. LAW. 349 (2001).

148. ORG. FOR ECON. CO-OPERATION & DEV., GUIDELINES FOR LICENSING OF GENETIC INVENTIONS (2006), *available at* http://www.oecd.org/dataoed/39/38/36198812.pdf. The Guidelines were based on earlier research (pre-dating the Myriad controversy) into the effect of human gene patents on research and access to medical products.

149. Principles and Guidelines for Recipients of NIH Research Grants and Contracts, 64 Fed. Reg. 72090 (proposed Dec. 23, 1999), *available at* http://ott.od.nih.gov/pdfs/64FR72090.pdf.

150. Best Practices for the Licensing of Genomic Inventions: Final Notice, 70 Fed. Reg. 18413 (Apr. 11, 2005), *available at* http://ott.od.nih.gov/pdfs/70FR18413.pdf.

151. Although I will not discuss the NIH Guidelines in great detail, they are significant in that along with the OECD's Guidelines, they encourage non-exclusive licensing of genetic and genomic inventions whenever practicable, especially in respect of foundational inventions. Further, they target licensing practices that threaten to limit researcher access to genetic and genomic knowledge. The NIH Guidelines are significant in that they are the governing policy of one of the world's most influential funding agencies, presiding over grants to major genomic and genetic research projects, and they may apply to Canadian commercialization agreements. Herder & Johnston, *supra* note 119.

152. The OECD is a forum that brings together the governments of its thirty member countries to support economic growth and development. It also compiles statistics, economic data, and social data, and it monitors economic trends.

153. ORG. FOR ECON. CO-OPERATION & DEV., *supra* note 148, at 5.

competition.[154] Several pages of annotations at the end of the document clarify the intended meaning of each of the general provisions.[155] The most important best practices encourage rights holders to broadly license genetic inventions for research and investigation purposes[156] and state that health-related inventions should be licensed to ensure the broadest public access.[157] The best practices also stipulate that foundational genetic inventions should be licensed on a non-exclusive basis[158] and encourage limiting the use of exclusive licensing and reducing coordination problems through pooling and other arrangements to ensure that the best products and services are brought to market.[159]

By setting out standards through guidelines, the OECD encourages effective legal regimes relevant to the local context,[160] allowing national institutions an active role in developing understandings based on on-the-ground realities and particularities.[161] Parties are encouraged to adopt a holistic, cooperative, and creative approach adapted to local circumstances while staying as close to the international standard as possible.[162] The general and non-binding nature of the Guidelines, along with its explanatory comments, suggests that the OECD is engaging in a process of norm development rather than harmonization. The unenforceable, voluntary nature of the standard is its greatest strength and weakness.[163] The standard can be adapted and applied (and may even provide a regulatory advantage) in a local context, but its unenforceability means that it can be easily ignored.[164] Thus its success and influence will depend on the extent to which it is incorporated by domestic institutions, and this in turn will depend on

154. *Id.* at 5–6.
155. *Id.* at 13–22.
156. *Id.* at 9.
157. *Id.*
158. *Id.* at 12.
159. *Id.* at 20, 22.
160. Katharina Pistor, *The Standardization of Law and Its Effect on Developing Economies*, 50 AM. J. COMP. L. 97, 123–24 (2003).
161. *See id*. at 111 (discussing when rules can be understood only in the context of a free-standing legal order).
162. *Id.* at 100–02.
163. *Id.* at 102.
164. Archer & Piper, *supra* note 147.

the extent to which the norms expressed in the Guidelines cohere with the internal institutional objectives of TTOs and others. Thus a process will be necessary to ensure the appropriate translation of the Guidelines.

In Canada, the University of British Columbia ("UBC") has developed Global Access Principles[165] that express a commitment to building on the values of access and dissemination, promoting non-exclusive licensing based on the OECD Guidelines, and considering field-of-use and jurisdictional limitations in exclusive licenses to exclude developing countries.[166] UBC is also a member of the West Coast Licensing Partnership, an initiative to bundle technologies from nine West Coast research institutions in four areas: animal models, biomarkers, medical imaging, and medical devices. A single license covers all the research institutions, and all licenses issued are non-exclusive, with the goal of "increasing global access to research tools by promoting and enhancing non-exclusive licensing."[167] Federally, the Canadian Institutes of Health Research,[168] Genome Canada,[169] and the Social Sciences and Humanities Research Council[170] have developed, or are in the process of formulating, open access to research output policies that will affect all grantees in relation to publications, software, materials, and data. While limited data as yet are unavailable, existing nascent initiatives suggest that the voluntary approach of the Guidelines has been useful in bridging and influencing rule-making cultures.

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165. The Univ. of British Columbia, Principles for Global Access to UBC Technologies, http://www.uilo.ubc.ca/global.asp (last visited Apr. 10, 2009).

166. *Id.*

167. W. Coast Licensing P'ship, The Benefits, http://www.westcoastlicensing.com/benefits.html (last visited Apr. 10, 2009).

168. Canadian Institutes of Health Research, Policy on Access to Research Outputs, http://www.cihr-irsc.gc.ca/e/34846.html (last visited Apr. 10, 2009).

169. Genome Canada, Data Release and Resource Sharing Policy, http://www.genomecanada.ca/medias/PDF/EN/DataReleaseandResourceSharingPolicy.pdf (last visited Apr. 10, 2009).

170. Soc. Sciences & Humanities Research Council of Can., Policy Focus: Open Access, http://www.sshrc.ca/site/about-crsh/policy-politiques/open_access-libre_acces/index-eng.asps (last visited Apr. 10, 2009).

C. Information

A third approach seeks to provide information about the nature and scope of existing patent rights in order to enable better rule-making by institutions seeking to secure access to innovation. In theory, patent law grants an exclusive monopoly in return for a public disclosure of the innovation to teach the public and other innovators. A potential downstream inventor can access the patent's claims and specifications in the public registry and understand the technical advance from that document, as well as the area in which she can safely innovate.[171] As the system has evolved in practice, however, the information provided by national patent offices is incomplete and poorly serves the underlying rationale. Although patent disclosures provide basic information about what has been invented and by whom, they supply limited information on the broader ecology of invention, e.g., how, by whom, where, and under what licensing terms the technology is being developed.[172] Further, the scope of a patent may be clear only upon litigation for infringement, and specifications are increasingly drafted to reveal as little as possible.[173] These factors mean that patent disclosure at the patent office is of limited use to innovators and the public. Thus, civil society, through groups such as PIPRA[174] and CAMBIA's Patent Lens,[175] has conducted technology landscape and freedom-to-operate analyses to understand the nature and breadth of existing patents and policies for specific diseases or crops.[176] These initiatives provide invaluable information about the patent ecosystem, including the breadth and strength of existing patents and terms of control, and they suggest gaps for research and innovation.[177] These projects provide critical

171. Vaver, *supra* note 2.

172. Except through studies of patent citation statistics.

173. Vaver, *supra* note 2.

174. About Pipra, http://www.pipra.org/en/about.en.html (last visited Apr. 10, 2009).

175. Patent Lens, Explore Technology Landscapes, http://www.patentlens.net/daisy/patentlens/landscapes-tools.html (last visited Apr. 10, 2009).

176. *See, e.g.*, Influenza Genome Executive Summary, http://www.patentlens.net/daisy/influenza/4132.html (last visited Apr. 10, 2009); Rice Genome Landscape: Table of Contents, http://www.patentlens.net/daisy/RiceGenome/3648.html (last visited Apr. 10, 2009).

177. *See, e.g.*, Mapping of Rice Patents and Patent Applications onto the Rice Genome, http://www.patentlens.net/daisy/RiceGenome/3909.html (last visited Apr. 10, 2009).

information to justify the exclusive monopoly granted by a patent; the groups involved arguably are generating norms that information must be aggregated or contextualized in order for it to be truly available or disclosed to the public.

Concretely, Agriculture and Agri-Food Canada and the University of Saskatchewan are both members of PIPRA.[178] UBC's TTO has undertaken to modify its metrics and in the process aggregate and disseminate different information about its technology processes, in collaboration with the NGO Universities Allied for Essential Medicines ("UAEM").[179] UBC's TTO reviewed its portfolio of 237 active license agreements and evaluated them based on academic, societal, economic, financial, and political impacts. The results included the conclusion that 68% of its licenses have a minor or negligible impact and that licenses with the most potential to gain impact as time progresses tend to be life science technologies. For those technologies where societal impact has the greatest potential, it takes ten to fifteen years for half of these technologies to reach their potential.[180] Information collection and aggregation initiatives are too early in development to determine whether they are successful at bridging the gap between state and non-state rule-making orders but provide promise for the future.

CONCLUSIONS

The proliferation of patent rights in recent years has resulted in real and predicted access problems to health-related genetic invention. This Article has examined situations where IP rights have ostensibly blocked access to health-related genetic innovation. Various tools have been proposed to remedy these access barriers, many of which envision top-down state-based rule-making processes; these initiatives have produced few results. I argue that unblocking access to innovation will be determined by non-state, rather than

178. About Pipra Members, http://www.pipra.org/en/about.en.html#members (last visited Apr. 10, 2009).

179. Universities Allied for Essential Medicines, http://www.essentialmedicine.org/ (last visited Apr. 10, 2009).

180. Angus Livingstone, New Metrics: Communicating the Value of Technology Transfer to Your Constituents, Presentation at Health Canada Workshop (Mar. 28, 2008).

state-based, rule-making regimes and norms in Canada because of the nature of the institutions that inhabit the ecology of Canadian innovation. The Article considered as a case study two access disputes in Canada and the state and non-state norms that could lever access to those technologies, concluding that university-based TTOs are the most likely lever. Initiatives that then give these TTOs room to develop rules and practices coherent with their institutional priorities, identity, and purposes will be most successful in providing access. These types of initiatives will include information aggregation projects and voluntary standard-setting initiatives. This Article suggests that research time and energy should be invested in both investigating local contexts and designing novel schemes and initiatives.