Chicago-Kent Law Review

Volume 84
Issue 1 *Symposium: Who Owns Your Body?*

Article 7

December 2008

Human Gene Patents: Proof of Problems?

Timothy Caulfield

HUMAN GENE PATENTS: PROOF OF PROBLEMS?

TIMOTHY CAULFIELD*

INTRODUCTION

Despite being common practice since the 1980s,[1] the idea of patenting human genes continues to stir controversy. It has been the subject not only of innumerable policy reports but also, in some jurisdictions, of intense media scrutiny, most of it negative.[2] And, if you believe the opinion research, the general public is not crazy about the idea of gene patenting either. Indeed, it would appear that the more people learn about biotechnology patents, the less fond they grow of them.[3]

Is this skepticism justified? What are the social issues associated with human gene patents and is there evidence to support purported concerns? In this paper, I explore two of the most commonly stated worries associated with gene patents. While the patenting of biological material has long caused ethical angst, the suggestions that patents will hurt scientific progress and limit access to useful health technologies have had the greatest policy traction.[4] Moral questions about the acceptability of patenting "life" remain,[5] and there are still debates about the legal patentability of

* Canada Research Chair in Health Law and Policy, Professor, Faculty of Law and School of Public Health, Research Director, Health Law Institute, University of Alberta. Thanks to Laura Geddes and Ubaka Ogbogu for their assistance. A special thanks to the wonderful and insightful research support provided by CJ Murdoch and Julie Burger. The research was funded by the Stem Cell Network and Genome Canada.

1. The first human gene patent was issued in 1982, U.S. Patent No. 4,322,499. Stephen Petrina et al., *Technology and Rights*, 14 INT'L J. TECH. & DESIGN EDUC. 181, 199 (2004); STEPHEN PETRINA, CHANGE AND TECHNOLOGY IN THE UNITED STATES: A RESOURCE BOOK FOR STUDYING THE GEOGRAPHY AND HISTORY OF TECHNOLOGY 49 (2004), *available at* http://teched.vt.edu/ctte/ ImagesPDFs/Petrina.Change.TechInUS.pdf.

2. *See, e.g.*, Robert Benzie, *Ontario to Defy U.S. Patents on Cancer Genes*, NAT'L POST (Can.), Sept. 20, 2001, at A15; Scott Foster, *Gene Patent Fight Imperils Health-Care System*, EDMONTON J., Aug. 24, 2001, at A1. For an analysis of the media coverage of human gene patents, see Timothy Caulfield et al., *Myriad and the Mass Media: The Covering of a Gene Patent Controversy*, 9 GENETICS MED. 850 (2007).

3. Edna F. Einsiedel, *Patents in the Public Sphere: Public Perceptions and Biotechnology Patents*, *in* EMERGING TECHNOLOGIES: FROM HINDSIGHT TO FORESIGHT 102 (Edna F. Einsidel ed., 2009).

4. *See e.g.*, Timothy Caulfield et al., *Patenting Human Genetic Material: Refocusing the Debate*, 1 NATURE REVIEWS: GENETICS 227 (2000).

5. *See, e.g.*, DAVID B. RESNIK, OWNING THE GENOME: A MORAL ANALYSIS OF DNA PATENTING (2004); Timothy Caulfield & Roger Brownsword, *Human Dignity: A Guide to Policy Making in the*

genes,[6] but these two practical concerns are the most effective issues in actually mobilizing policy makers.[7] For example, the recently proposed Genomic Research and Accessibility Act,[8] a law that seeks to ban gene patents, is justified by one of its sponsors, Congressman Weldon, on the grounds that "[t]he practice of gene patenting is preventing critical research from advancing because scientists are wary of trespassing patent laws."[9]

Although recognizing that there are myriad other social concerns associated with gene patents,[10] this brief comment will focus on these two policy issues, the ideas that patents hurt basic research and limit access to useful technologies. Specifically, I am interested in what the available empirical data can tell us. Does the evidence, which is mounting but remains less than robust, support the speculation about the undesirable social repercussions of gene patenting? Is the evidence clear enough to support policy action?

This paper starts with a review of the specific social concerns and the most salient evidence presently available. We will see that, particularly for concerns regarding an adverse impact on research, the evidence is, at best, equivocal.[11] Given this reality, what is the role of evidence in the context

Biotechnology Era?, 7 NATURE REV. GENETICS 72 (2006); Gerald Dworkin, *Should There Be Property Rights in Genes?*, 352 PHIL. TRANSACTIONS ROYAL SOC'Y B 1077 (1997); David B. Resnik, *DNA Patents and Human Dignity*, 29 J.L. MED. & ETHICS 152 (2001) [hereinafter Resnik, *DNA Patents*]. *See also* DANISH COUNCIL OF ETHICS, PATENTING HUMAN GENES AND STEM CELLS: A REPORT 69 (2004), *available at* http://www.etiskraad.dk/graphics/03_udgivelser/engelske_publikationer/patenting_human_genes/patents04/patenting_human_genes.pdf (suggesting that treating the human body or parts of it as a mere commodity promotes a lack of respect for human life, or as stated by The Danish Council on Ethics, amounts to the "impermissible reduction of something vested with its own sovereign integrity.").

6. *See, e.g.*, Dianne Nicol, *On the Legality of Gene Patents*, 29 Melb. U. L. Rev. 809 (2005). While this patentability debate will likely continue, it has never had a serious impact on the issuance of patents on human genes. *See, e.g.*, Linda J. Demaine & Aaron X. Fellmeth, *Patent Law: Natural Substances and Patentable Inventions*, 300 SCIENCE 1375, 1375 (2003) ("The [United States] Patent and Trademark Office and federal courts now routinely hold discovered natural substances patentable if they are 'isolated and purified' or otherwise insubstantially modified. Naturally occurring DNA and protein biomolecules have, consequently, become the subject of patent applications.").

7. Numerous commentators have noted the dominance of these two issues. *See, e.g.*, Birgit Verbeure et al., *Analysing DNA Patents in Relation with Diagnostic Genetic Testing*, 14 EUR. J. HUM. GENETICS 26 (2006) at 26–27. See generally Timothy Caulfield et al., *Evidence and Anecdotes: An Analysis of Human Gene Patenting Controversies*, 24 NATURE BIOTECH. 1091, 1092–93 (2006) (for a discussion of the issues which have mobilized policy makers).

8. H.R. 977, 110th Cong. (2007).

9. Press Release, Xavier Becerra, Reps. Becerra & Weldon Introduce Bill to Ban the Practice of Gene Patenting (Feb. 9, 2007), *available at* http://becerra.house.gov/HoR/CA31/News/Press+Releases/2007/02-09-07+REPS+BECERRA+WELDON+INTRODUCE+BILL+TO+BAN+THE+PRACTICE+OF+GENE+PATENTING.htm.

10. *See e.g.*, Pilar N. Ossorio, *The Human Genome As Common Heritage: Common Sense Or Legal Nonsense?*, 35 J.L. MED. & ETHICS 425 (2007) (providing a discussion and critique of the idea that the human genome is common heritage of humanity, and thus should not be patentable).

11. Indeed, it has been noted that although policy reports often report the existence of these prob-

of patent policy? The paper concludes with a discussion of several issues relevant to the interpretation of existing and emerging data.

I. PATENTS HURT GENETIC RESEARCH

There are thousands of human gene patents in existence[12] and many more applications pending. Might this sea of intellectual property make it more difficult and costly to do basic research? Might patents hurt the innovation process? From a science policy perspective, this concern is particularly problematic. If true, it cuts against one of the explicit rationales of patents: the stimulation of innovation.

From the early days of patent law, the stated goal of awarding a state-imposed monopoly was to encourage innovation for the benefit of society. Throughout his career, Thomas Jefferson, often viewed as one the fathers of the American patent system, continually questioned the social utility of patents, believing that ideas and invention "should freely spread from one to another over the globe, for the moral and mutual instruction of man . . . ."[13] Ultimately, he came to believe that patents could stimulate innovation and, therefore, in the aggregate, they were socially beneficial. But, as Thomas Jewett points out, for Jefferson, "the purpose of the patent office was to promulgate invention, not protect them."[14]

When evaluating the impact and value of patents, we should not lose sight of this perceived foundational social purpose. However, against this historical justification for the patent system, it must also be recognized that there is, in fact, little empirical data to support the idea that patents are

lems, the assertions are rarely based on hard evidence. *See*, Verbeure et al., *supra* note 7, at 27 (noting that "no in-depth data are available yet on the scope and effective characteristics of the problem described. Most of the reports contain only anecdotal evidence to support their conclusions, probably because broadly based evidence is not readily available."). *See also* Timothy Caulfield et al., *Evidence and Anecdotes: An Analysis of Human Gene Patenting Controversies*, 24 NATURE BIOTECH. 1091, 1092–93 (2006).

12. Over 40,000 patents have been issued, covering more than 20% of the extant human genome. NAT'L RESEARCH COUNCIL, REAPING THE BENEFITS OF GENOMIC AND PROTEOMIC RESEARCH: INTELLECTUAL PROPERTY RIGHTS, INNOVATION, AND PUBLIC HEALTH 101–02 (Stephen A. Merrill & Anne-Marie Mazza eds., 2006); Fiona Murray & Scott Stern, *Do Formal Intellectual Property Rights Hinder the Free Flow of Scientific Knowledge? An Empirical Test of the Anti-Commons Hypothesis*, 63 J. ECON. BEHAV. ORGAN. 648 (2007).

13. Letter to Isaac McPherson (Aug. 13, 1813) *in* THE LIFE AND SELECTED WRITINGS OF THOMAS JEFFERSON 629, 630 (Adrienne Koch & William Peden eds., 1944).

14. Thomas O. Jewett, *Thomas Jefferson: The Father of Invention*, EARLY AM. REV., Winter 2000, http://www.earlyamerica.com/review/winter2000/jefferson.html. However, it must be noted that Jefferson's philosophy with respect to and personal impact on patent law were both complex. For an intricate examination of the Jeffersonian perspective, see Adam Mossoff, *Who Cares What Thomas Jefferson Thought About Patents? Reevaluating the Patent "Privilege" in Historical Context*, 92 CORNELL L. REV. 953 (2007).

required for the innovation process. As noted by Richard Gold, "despite the assumption within intellectual property systems that they are necessary to encourage research and development, there is only a modest body of empirical evidence to support this in the biotechnology industry."[15]

However, for the purposes of this paper, let us assume that patents are an asset to the innovation process. At a minimum, this is certainly the view held by the industry and many within the scientific community,[16] and regardless of the evidence on their positive social influence, if patents stifle innovation, this would cut against the core justification for the existence of the patent regime.[17] A 1998 paper by Heller and Eisenberg crystallized this concern by suggesting that gene patents hurt research by making it difficult to acquire the rights to all necessary research inputs. This difficulty could, in turn, result in underuse of valuable technologies or even the obstruction of potentially important research. They called this policy dilemma the "tragedy of the anti-commons."[18] Since the publication of the Heller and Eisenberg paper, this concern has appeared in some form in almost every relevant policy document.[19]

But what does the evidence tell us? Do human gene patents hurt upstream innovation? While most research on point is not tremendously robust (for example, much of it consists in survey data on the perceptions of the scientific community), there is at present no strong evidence that the "anti-commons" concern has had a major impact on the research communi-

15. E. Richard Gold et al., *Needed: Models of Biotechnology Intellectual Property*, 20 TRENDS BIOTECH. 327, 327 (2002); E. Richard Gold, *Finding Common Cause in the Patent Debate*, 18 NATURE BIOTECH. 1217, 1218 (2000).

16. *See, e.g.*, Robert M. Cook-Deegan & Stephen J. McCormack, *Intellectual Property: Patents, Secrecy and DNA*, 293 SCIENCE 217 (2001); Joseph Straus, *Bargaining Around the TRIPS Agreement: The Case for Ongoing Public-Private Initiatives to Facilitate Worldwide Intellectual Property Transactions*, 9 DUKE J. COMP. INT'L L. 91 (1998). This also seems to be the perception of researchers. In a recent survey of the Canadian stem cell research community, almost all of those surveyed identified the development of beneficial products and services for society as a very important or important social goal and approximately three-quarters considered the role of patents in facilitating research translation to be important or very important. Timothy Caulfield et al., *Patents, Commercialization and the Canadian Stem Cell Research Community*, 3 REGENERATIVE MED. 483, 485 (2008).

17. While gene patenting is the focus of this piece, this concern is not restricted to this context. *See, e.g.*, Lori B. Andrews et al., *When Patents Threaten Science*, 314 SCIENCE 1395 (2006).

18. Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698, 698 (1998).

19. See, for example, NAT'L RESEARCH COUNCIL OF THE NAT'L ACAD., A PATENT SYSTEM FOR THE 21ST CENTURY 71 (Stephen A. Merrill et al. eds., 2004) stating that:

> In a 1998 *Science* article, attorney Michael Heller and legal scholar Rebecca Eisenberg hypothesized the emergence of what they termed an "anticommons" in biotechnology, which could result if assembling the rights to use the numerous separate patented building blocks necessary to pursue a particular line of research or product development proved to be prohibitively costly and time consuming or simply impossible, causing a promising prospect to be avoided or abandoned.

Id.

ty. In 2006, our research team conducted a systematic review of all available data, with particular emphasis on the data and studies used in policy reports. We concluded that the effects predicted by the anti-commons hypothesis are not borne out in the available data.[20] For example, a 2005 study by Walsh, et al. for the National Academy of Sciences found that only 1% of the scientists surveyed reported suffering a project delay of more than 1 month due to patents.[21]

Shortly after the publication of our paper, the American Association for the Advancement of Science released a major study surveying the international research community that came to a similar conclusion.[22] The report notes explicitly that the data "offer very little evidence of an 'anticommons problem.'"[23] The authors conclude that research results suggest, at least for the United States, the United Kingdom, and Germany, that:

> IP-protected technologies remain relatively accessible to the broad scientific community, and not as constrained by IP protections as many have cautioned. In the case of research tools, the majority were transferred rather quickly, taking less than a month to obtain. Most research tools were licensed nonexclusively in all employment sectors, allowing them to remain accessible to multiple parties.[24]

Emerging research continues to buttress these findings—often by using a variety of methodologies.[25] For example, a 2005 study by Murray and

20. Caulfield et al., *supra* note 11, at 1092.

21. JOHN P. WALSH ET AL., PATENTS, MATERIAL TRANSFERS AND ACCESS TO RESEARCH INPUTS IN BIOMEDICAL RESEARCH 2 (2005). Another one of our more recent studies involved a survey of the Canadian stem cell research community. We found very similar results to the Walsh study. Though the sample size was small, and it was in the context of stem cell research, the results are worth mentioning as the study captured leading Canadian researchers and fits well with the other data in the area. Of the twenty-seven investigators that responded, only two had been refused a license. Both of these investigators proceeded with the work without obtaining a license. *See* Caulfield et al., *supra* note 16, at 486.

22. AM. ASS'N. FOR THE ADVANCEMENT OF SCI., INTERNATIONAL INTELLECTUAL PROPERTY EXPERIENCES: A REPORT OF FOUR COUNTRIES 23 (2007).

23. *Id.* at 12. Specifically, the report related the following regarding the US and Japan data:

> Of those 107 respondents to the question about difficulties with technology acquisition, [2%] reported that their research was delayed, [6%] reported that they had to change a research project, and one respondent ([1%] of those who acquired technology—or 0.1% of the whole sample) reported abandoning a research project. Thus, although there is some concern that the cost of patented technologies might be too high, the vast majority of researchers largely have been unaffected by others' patented technologies.

Id. The data from the UK was somewhat less clear, but still the authors concluded that "respondents who reported acquiring IP were most likely to report that they did not experience any problems during that process as well." *Id.* In Germany, the numbers reporting possible anti-commons problems were the highest, but still were only listed at 23%. *Id.* at 13.

24. *Id.* at 15 (footnote omitted). For Japan, the conclusions were even stronger. "For the Japan survey results indicated that despite the increasingly pro-IP environment for Japanese university and public sector researchers, there is little evidence that patents are interfering with research." *Id.* at 14.

25. See, for example, a news report on a recent conference where Robert Cook-Deegan reports on research by his team concerning the lack of evidence regarding the impact of gene patents in this re-

Stern explored the relationship between patents and associated publications. Specifically, they were looking to see if patents influenced publication. Interestingly, they did find an "anti-commons" effect, such that the number of publications decline slightly after the granting of a patent (suggesting that the patents have an impact on knowledge distribution), but the effect was small enough to ameliorate at least some public policy concerns.[26]

To be fair, all of these studies can be critiqued on various grounds, such as sample size, using an inappropriate comparator technology, and the exploration of perceptions rather than actual, objectively determined, effects.[27] However, taken as a whole, they paint a fairly consistent picture. And, at a minimum, given the vast number of gene patents the effects are much less prevalent than would be expected if the hypothesized mechanisms of the anticommons were in fact operating. Surely, if patents caused a problem warranting immediate policy action, there would be some clear, discernable, effect. Naturally, this absence of evidence has been noted by other scholars, such as Holman: "The paucity of documented examples in which the fears surrounding gene patents have manifested themselves is striking, particularly when one considers the high level of public concern and the extraordinary nature of the proposed legislative fix."[28]

In sum, "despite the large number of patents and numerous, heterogeneous actors—including large pharmaceutical firms, biotech startups, universities and governments—studies that have examined the incidence of anticommons problems find them relatively uncommon."[29] It should be noted, however, that there has been some speculation that gene patenting

spect:

> Comparing the number of literature citations for three 'seminal technologies' commonly used in molecular biology laboratories—one patented, two unpatented—Cook-Deegan said, 'The thing to notice here is you can't really tell the difference too much in the adoption of these technologies. So if your theory is, "if something's patented, nobody gets to use it"—wrong.'

Shawna Williams, *Genetics Perspectives on Policy Seminar - Who Owns Your Genes? Intellectual Property and the Human Genome*, GENETICS AND PUB. POL'Y CENTER, July 10, 2007, http://www.dnapolicy.org/news.past.php?action=detail&past_event_id=41.

26. Murray & Stern, *supra* note 12 at, 648.

27. In addition, much of the referenced data does not address the impact of patents on down stream research, such as the development of new diagnostic approaches. *See, e.g.*, Fabienne Orsi & Benjamin Coriat, *Are 'Strong Patents' Beneficial to Innovative Activities? Lessons from the Genetic Testing for Breast Cancer Controversies*, 14 INDUS. & CORP. CHANGE 1205, 1206 (2005).

28. Christopher M. Holman, *The Impact of Human Gene Patents on Innovation and Access: A Survey of Human Gene Patent Litigation*, 76 UMKC L. REV. 295, 300 (2007). *See also* Verbeure et al., *supra* note 7, at 27 and accompanying quote, *supra* note 11. For a discussion of the anti-commons phenomenon in the context of nutrigenomics, see David Castle, *Intellectual Property and Nutrigenomics*. 16 HEALTH L. REV. 58 (2008). Castle concludes that while it is early, there is no evidence that gene patents have impeded nutrigenomic research. *Id.* at 62.

29. Caulfield et al., *supra* note 11.

strategies are starting to become more targeted on "inventions" that are more likely to have certain market value—in other words, on patents with a clear utility and commercial potential. As noted by Pressman et al.: "Patent prosecution, maintenance and management costs—estimated by respondents at between $20,000 and $30,000 per patent—militate against patenting inventions that are unlikely to recover those costs, and encourage greater selectivity in what gets patented."[30] This change in strategy may result in more aggressive protection of patents (if they are viewed as more valuable, they may be viewed as worth protecting), thus raising the possibility of an increase in the anticommons effect.[31] There is, as of now, no evidence to support this interesting speculation.

II. PATENTS HURT CLINICAL CARE AND HEALTH CARE SYSTEMS

The concern that patents hurt access to clinically useful technologies has also been around for over a decade.[32] Patents grant a limited monopoly, allowing the patent holder to decide the price and conditions of access. As noted above, this is the social trade-off inherent in the patent system. As such, it seems reasonable to predict that patents could result in restrictions on utilization, even utilization that is socially beneficial. This concern was amplified in the summer of 2001 when Myriad Genetics sought to aggressively enforce its patents on the BRCA1/2 gene mutations.[33] And survey research has shown that the public is especially concerned about the impact of patents on access.[34]

However, again, the empirical evidence exploring the access concern is less than ideal.[35] In fact, given the profile of the concern and the large amount of policy activity, there is surprisingly little research on point. And

30. Lori Pressman et al., *The Licensing of DNA Patents by US Academic Institutions: An Empirical Survey*, 24 NATURE BIOTECH. 31, 39 (2006). *See also* Michael M. Hopkins et al., *DNA Patenting: The End of an Era?* 25 NATURE BIOTECH. 185 (2007).

31. Ann E. Mills & Patti M. Tereskerz, *Changing Patent Strategies: What Will They Mean for the Industry?*, 25 NATURE BIOTECH. 867, 867 (2007).

32. For a general discussion of the issues, see Lori B. Andrews, *The Gene Patent Dilemma: Balancing Commercial Incentives with Health Needs*, 2 HOUS. J. HEALTH L. & POL'Y 65 (2002); Timothy Caulfield et al., *Genetic Technologies, Health Care Policy and the Patent Bargain*, 63 CLINICAL GENETICS 15 (2002).

33. Timothy Caulfield, *Policy Conflicts: Gene Patents and Health Care in Canada*, 8 COMMUNITY GENETICS 223, 224 (2005).

34. POLLARA RES. & EARNSCLIFFE RES. & COMM., PUBLIC OPINION RESEARCH INTO BIOTECHNOLOGY ISSUES: SEVENTH WAVE REPORT – EXECUTIVE REPORT (2002).

35. Given the limited scope of this paper, I do not touch here on the important research regarding the impact of patents on access in developing countries. *See, e.g.*, Amir Attaran, *How Do Patents and Economic Policies Affect Access to Essential Medicines in Developing Countries?*, 23 HEALTH AFFAIRS 155 (2004).

the data that is available is largely research on mere perceptions of impact and is limited to the specific context of diagnostic testing. Even so, this data does suggest that those providing genetic tests believe that patents are having an adverse impact on what is available. The oft-referenced study by Cho, et al. for instance, found that 25% of respondents (136 lab directors) reported having stopped offering a clinical genetic test because of a patent or license, while 53% reported deciding not to develop a new clinical genetic test for that reason.[36] Other studies have come to similar conclusions.[37] Likewise, some studies have suggested that the monopoly conferred by the patent creates significant cost inefficiencies for health care systems. A French study by Sevilla et al. for instance, concludes that "gene patents with a very broad scope, covering all potential medical applications, may prevent health care systems from identifying and adopting the most efficient genetic testing strategies due to the monopoly granted for the exploitation of the gene."[38]

III. REFLECTING ON THE EVIDENCE

Thus, while there is data suggesting that gene patents may affect access, utilization and costs, the studies available are relatively few in number and of limited methodological strength.[39] But even if we do accept the general themes emerging from this data (which, to me, makes intuitive sense), the fact that access/cost issues are a cause for concern at all raises some particularly challenging policy dilemmas. Arguably, enabling control of access and creating exclusive, specialized markets that result in premium prices is precisely what patents are *supposed* to do in a world of commercialized medicine, quite separately from whether this is held to be ethically praiseworthy or not.[40] It is this exclusivity that is intended to be the incen-

36. Mildred K. Cho et al., *Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services*, 5 J. MOLECULAR DIAGNOSTICS 3, 5 (2003).

37. *See, e.g.*, Jon Merz et al., *Diagnostic Testing Fails the Test: The Pitfalls of Patents are Illustrated by the Case of Haemocrhmatosis*, 415 NATURE 577, 577 (2002); Christine Sevilla et al., *Impact of Gene Patents on the Cost-Effective Delivery of Care: The Case of BRCA1 Genetic Testing*, 19 INT'L. J. TECH. ASSESSMENT HEALTH CARE 287, 289 (2003); Orsi & Coriat, *supra* note 27.

38. Christine Sevilla et al., *supra* note 37, at 288. *See also*, Orsi & Coriat, *supra* note 27. As further evidence of this effect, a commentary accompanying a recent scientific study claims that some clinicians have chosen to pursue some applied research *because* of the impact of gene patents. If this is the case, their area of work would itself be evidence of the impact of gene patents on access. Brian Goldman, *HER2 Testing: The Patent "Genee" is Out of the Bottle*, 176 CANADIAN MED. ASS'N J. 1443, 1443 (2007) ("One can argue that the study by Dendukuri and colleagues in this issue of *CMAJ* [] is necessary only because patenting issues have made the drug so expensive."). The study to which Goldman refers is Nandini Dendukuri et al., *Testing for HER2-Positive Breast Cancer: A Systematic Review and Cost-Effectiveness Analysis*, 176 CANADIAN MED. ASS'N J. 1426 (2007).

39. *See generally* Verbeure et al., *supra* note 7.

40. I have, in several articles, been highly critical of the commercialization pressures that pervade

tive that stimulates and promotes innovation.[41]

It is certainly reasonable and appropriate for policy makers to revisit the social utility of the tradeoff, just as Thomas Jefferson did at the inception of the system.[42] However, such a critique should be placed in the context of the overall goals of the patent system and also within the context of the current, highly commercialized, state of biomedical research and the healthcare delivery apparatus.[43] One might argue that the policy question at hand here should not be whether gene patents have an impact on access—for it seems inevitable that they will, just as they do in other domains—but whether the tradeoff resulting from these limitations to access is, in the aggregate, acceptable, functional, and worthwhile.[44]

In this piece I take the easy way out and refrain from providing an opinion regarding these obviously complex policy questions, questions which engage not only issues concerning the sufficiency of evidence, but also a wholesale analysis of social values well beyond the scope of this short paper. But regardless of one's view on the worth of the patent system, it seems reasonable to conclude that the gene patent debate should be informed by the best evidence possible and, to date, the available evidence is substantially less than ideal. With this reality in mind, I consider several issues relevant to the interpretation of existing and emerging data.

A. The Role of the Myriad Genetics Controversy

A major conclusion from our 2006 study was that much of the international gene patent policy debate was catalyzed by the controversies sur-

the current research environment. *See, e.g.*, Timothy Caulfield, *Sustainability and the Balancing of the Health Care and Innovation Agendas: The Commercialization of Genetic Research*, 66 SASK. L. REV. 629 (2003); Caulfield, *supra* note 33.

41. One needs to be careful not to overstate the degree to which the rise of the patent regime maps a single clear, unified, social goal. Obviously, the story of patent law is historically and philosophically complex. Are patent rights the inevitable result of inventors' natural rights to "own" something of his/her own creation or are they a privilege conferred by the state to stimulate innovation? For the purposes of modern patent reform, the latter view has dominated. It is interesting to note that the type of legal right at play (a property right versus a privilege) might also play a role in determining the level of evidence needed to justify reform. For instance, if patents are an inherent right of inventors, the level of evidence required to justify reform might be higher than if patents are a privilege conferred by the state.

42. The social utility of the patent system has frequently been questioned since its inception. *See, e.g.*, Fritz Machlup & Edith Penrose, *The Patent Controversy in the Nineteenth Century*, 10 J. ECON. HIST. 1, 1 (1950).

43. This latter point is, I think, central. The contemporary biomedical researcher is increasingly encouraged to invent and commercialize. As such, concern about the impact of patents on access and cost could be viewed, in some ways, as a more general condemnation of the commercialization strategy and the role of patents in the innovation process.

44. There is, of course, a rich literature critiquing the value of intellectual property rights. *See, e.g.*, Birgitte Andersen, *If 'Intellectual Property Rights' Is the Answer, What Is the Question? Revisiting the Patent Controversies.* 13 ECON. INNOVATION & NEW TECH. 417, 418 (2004).

rounding the BRCA1/2 patents and, in particular, Myriad Genetics' sion to enforce their patent rights.[45] In the summer of 2001, Myriad ics, the small Utah based company that owns the patents for the BRCA1/2 mutations, sent "cease and desist" letters to laboratories throughout the world stating that all testing must be done through Myriad or one of riad's licensees.[46] The BRCA1/2 mutations predispose women to increased risk for breast and ovarian cancer and, at the time of the "cease and desist" letters, testing women in particular at-risks groups was common practice throughout the world. The Myriad testing procedure was, in general, much more expensive than that being offered in publicly funded laboratories.[47] Thus, the "cease and desist" letters were viewed as a threat to public health systems.[48]

Almost all of the international policy documents that came after the unfolding of the controversy were dominated by references to Myriad (as compared to other companies or gene patents), and Myriad's actions were often used as a justification for patent reform.[49] There is also the possibility that the profile of the Myriad controversy may have influenced the perceptions of clinicians regarding the potential problems regarding patents. For example, Nicol suggests that, in Australia, the negative perceptions of clinicians regarding the impact of patents on access were probably related "to the well-known patent enforcement actions of Myriad Genetics in other jurisdictions and the fear of similar actions in Australia."[50] The ubiquitous nature of the Myriad anecdote raises questions about the degree to which a single social controversy should be able to, on its own, inform major policy reform. Certainly, high profile cases can serve as motivators of constructive

45. Caulfield et al., *supra* note 11, at 1091.

46. Bryn Williams-Jones, *History of a Gene Patent: Tracing the Development and Application of Commercial BRCA Testing*, 10 HEALTH L. J. 123, 141–42 (2002).

47. *See id.* at 135, 139.

48. Foster, *supra* note 2.

49. *See, e.g.*, Caulfield et al., *supra* note 11, at 1093 ("The survey of policy reports reveals that the Myriad Genetics controversy was used as a primary tool for justifying patent reform—thus highlighting the potential of a single high-profile controversy to mobilize both governmental and non-governmental policy makers."). Our research team also found that the Myriad story was a major news event and that almost all the stories were negative in tone. *See* Caulfield et al., *supra* note 2, at 850. It has been noted that:

> [T]he mass media comprise the principal arena where policy-relevant issues come to the attention of decisionmakers, interest groups, and the public. Not only do the media influence the attention of competing political actors and the public, but the media also powerfully shape how policy issues related to biotechnology are defined and symbolized.

Matthew Nisbet & Bruce Lewenstein, *Biotechnology and the American Media: The Policy Process and the Elite Press, 1970 to 1999*, 23 SCI. COMM. 359, 360 (2002).

50. Dianne Nicol, *Balancing Innovation and Access to Healthcare Through the Patent System—An Australian Perspective*, 8 COMMUNITY GENETICS 228, 230 (2005).

change, as we have seen in the realm of research ethics.[51] Ideally, however, the use of an illustrative controversy as evidence for policymakers should be supplemented by more systematically collected supporting data.

B The impact of existing social angst

Similarly, when reviewing the gene patent data, we need to be cognizant of how the strong moral and visceral reactions often registered against gene patents might influence interpretations.[52] Ethics-based arguments against gene patents, such as those informed by notions of human dignity,[53] are an important and necessary part of the dialogue, but they should not color our view of empirical evidence. For some, gene patents are intuitively morally reprehensible. For others, the campaign against human gene patenting debate fits well with an existing ideological agenda.[54] Indeed, in some jurisdictions, these concerns have even led to public demonstrations.[55]

For those who hold such views about gene patents, any data that reinforces the negative image of gene patents will, unsurprisingly, be given special attention.[56] But even if one has instinctive or ideological sympathies against gene patents, we must remember that policy development can only stand to benefit from a rigorous and dispassionate assessment of the value, relevance, and strength of data. This is not to say that philosophically based arguments cannot, on their own, serve as a rationale for patent reform. Indeed, in some jurisdictions they form the foundation of several

51. *See generally* LAW AND ETHICS IN BIOMEDICAL RESEARCH: REGULATION, CONFLICT OF INTEREST, AND LIABILITY 3 (Trudo Lemmens & Duff R. Waring eds., 2006).

52. *See, e.g.*, Mike Stott & Jill Valentine, *Impact of Gene Patenting on R&D and Commerce*, 21 NATURE BIOTECH. 729, 731 (2003) ("This is particularly relevant in the field of DNA patenting where an objective analysis of the impact of patent filings on research and commercial activities readily risks conceding ground to a subjective reaction to the whole question of gene patenting.").

53. *See generally* Resnik, *DNA Patents*, supra note 5.

54. To cite but two examples of this phenomenon: Greenpeace has argued against patenting genes and living organisms. *See, e.g.*, GREENPEACE, THE TRUE COST OF GENE PATENTS 4 (2004), *available at* http://weblog.greenpeace.org/ge/archives/1Study_True_Costs_Gene_Patents.pdf. This argument sits well with Greenpeace's well-established, multifaceted political ideology based around animal rights and anti-commercialization. Similarly, Jeremy Rifkin, an outspoken critic of gene patents, has broader views about globalization and the development of technology into which his thoughts on patenting nestle quite comfortably. *See* JEREMY RIFKIN, THE BIOTECH CENTURY (1998). Rifkin, for example, believes biotechnology patents will give a handful of global corporations "unprecedented power to dictate the terms by which we and future generations will live our lives.") *Id.* at 9.

55. For a sampling of powerful images from such protests, see Greenpeace Int'l., Patents on Life, http://www.greenpeace.org/international/campaigns/genetic-engineering/ge-agriculture-and-genetic-pol/ patents-on-life (last visited Sept. 12, 2009).

56. *See, e.g.*, GREENPEACE, *supra* note 54. This report focuses almost exclusively on the Myriad controversy, and the Cho et al. study discussed *supra* text accompanying note 36.

patent policies.[57] However, these arguments stand independent of what the empirical evidence tells us about the impact of gene patents on innovation and clinical access.

C. *How much evidence is needed to justify reform?*

The ambiguous nature of the available research raises the interesting question of how much data is necessary to justify patent reform. It seems unlikely that we will ever have enough data to definitively answer all of the questions concerning the true benefits and harms of human gene patents. Patent reform will never be perfectly informed. As such, some have suggested that, given the importance of science and health policy, it is appropriate to act on moderately informed speculation. Gold, et al. note as follows: "Policy makers must make their decisions here and now based on the evidence that does exist and the best hypotheses available. The healthcare system cannot wait, for example, for the true dimensions of the anti-commons problem to be clear before addressing pressing political and social issues."[58] While the authors make an important point about the realities of policy making activities, it seems axiomatic that there should be, at least, *some* evidence that purported problems are real. Speculation and anecdotes may stir constructive dialogue and highlight the need for further exploration and reflection, but they should not form the principal foundations of policy reform. To date, there is simply no good evidence that the anti-commons problem is a profound social problem worthy of policy attention.

That said, if the issue is socially important, the harms associated with policy inaction significant, the social norms implicated relatively malleable (i.e., the revision of a "privilege" rather than a "right"),[59] and there is sound speculation with at least some objective support, then policy action may be

57. *See, e.g.*, THE EUROPEAN GROUP ON ETHICS IN SCI. AND NEW TECH.TO THE EUROPEAN COMMISSION, OPINION ON THE ETHICAL ASPECTS OF PATENTING INVENTIONS INVOLVING HUMAN STEM CELLS, OPINION NO. 16, at 16 (2002) ("[I]solated cells are so close to the human body, to the foetus or to the embryo they have been isolated from, that their patenting may be considered as a form of commercialisation of the human body.").

58. E. Richard Gold et al., *Gene Patents—More Evidence Needed, but Policymakers Must Act*, 25 NATURE BIOTECH. 388, 388 (2007). *See also* JOSEPHINE JOHNSTON & ANGELA A. WASUNNA, PATENTS, BIOMEDICAL RESEARCH, AND TREATMENTS: EXAMINING CONCERNS, CANVASSING SOLUTIONS S14 (2007) ("Until better evidence of the actual impact of patents on research exists, and in light of the potential for patent infringement lawsuits, the risk that patents may slow or prevent research ought to be taken seriously.").

59. For instance, if a patent is a "right", rather than a privilege conferred by the State, perhaps a higher evidentiary standard would be required to justify any erosion of the "right". For a discussion of the right versus privilege debate, see Mossoff, *supra* note 14, at 953; Hans Morten Haugen, *Intellectual Property—Rights or Privileges?*, 8 J. WORLD INTELL. PROP. 445, 445 (2005).

warranted even when good evidence is absent. The problem in the context of gene patent reform, at least in response to the "anti-commons" concern, is that the evidence regarding all of these conditions is far from solid.[60] In addition, we do not have adequate evidence regarding the benefits of gene patents and the adverse implications of altering the existing system.[61] Would patent reform, in the aggregate, do more harm than good? At least some in the community, rightly or not, believe that patents have played a tremendously constructive and important role.[62] These views, and any evidence relevant to the perspective, must also be weighed in the policy process.

IV. CONCLUSION

The modest goal of this short comment is to question the degree to which existing evidence supports the calls for patent reform. Naturally, this is a tremendously complex topic and it would be naïve to assume that the concerns about gene patents turn only on the impact of patents on upstream research and downstream access. [63] However, these are two of the most commonly heard justifications for reform.[64] As such, it seems reasonable to analyze what the evidence tells us about them. Moreover, an exploration of the evidence reminds us to consider the degree to which initial speculation about social harm (or, for that matter, benefit) is playing out. This should, indeed, be a primary goal of ethical, legal and social issues (ELSI) research—that is, working with interdisciplinary teams to produce data about what is really going on.

60. While beyond the scope of this paper, it is worth noting that the evidence regarding the value of genetic technologies is far from overwhelming. Thus, even the importance of the issue, in a broad society sense, can also be contested. Though I believe genetic research is tremendously socially valuable, is it more so than other areas where traditional patent rules prevail. For a critique of emerging genetic technologies, see A. Cecile, J.W. Janssens et al., *A Critical Appraisal of the Scientific Basis of Commercial Genomic Profiles Used to Assess Health Risks and Personalize Health Interventions*, 82 AM. J. HUM. GENETICS 593 (2008).

61. *See* Holman, *supra* note 28, at 361 ("Without more compelling evidence of an overwhelming negative impact in contexts that are critical to the public good, there is no adequate justification for rushing into a radical legislative fix that might have substantial unintended negative consequences.").

62. *See, e.g.*, Martin Bobrow & Sandy Thomas, *Patents in a Genetic Age*, 409 NATURE 763, 763 (2001) ("In helping to develop many discoveries into clinically useful products, the patent system has been a force for good. It has encouraged innovation and sensible risk taking, stimulated investment in research and development, and delivered drugs and devices that have changed the face of modern medicine.").

63. As noted at the start of this paper, there are many other social concerns associated with gene patents. The evidence associated with each one of these concerns should also be considered. For example, there is at least some evidence that biotech patents are correlated with the withholding of scientific information. David Blumenthal et al., *Data Withholding in Genetics and the Other Life Sciences: Prevalances and Predictors*, 81 ACAD. MED. 137, 137 (2006).

64. *See, e.g.*, Caulfield et al., *supra* note 11, at 1092; Verbeure et al., *supra* note 7, at 29, 32, 33.