Gene Patents and the Marginalisation of Ethical Issues.

Dr Aisling McMahon*

Forthcoming *European Intellectual Property Review* (2019)

Abstract

In 2013 and 2015, the Supreme Court of the United States (US)[1] and Australian High Court,[2] respectively, rejected the patentability of isolated genes.[3] Subsequently, in March 2016 a case in the Federal Court of Canada involving the Children's Hospital of Eastern Ontario's (CHEO) challenge to patents on genes related to Long QT syndrome was settled. The settlement provided a licence to CHEO to test for the syndrome. A primary driver of the litigation in all three jurisdictions, was the broader ethical issues posed by such patents, including, the potential healthcare implications of such patents. The European Union adopted tailored legislation to deal with biotechnology patents in 1998, including gene patents. Again, in Europe, a primary concern underlying the drafting of the Directive was the ethical issues posed by biotechnological patents.[4]

Nonetheless, despite ethical issues driving challenges to, and debates on changes of patent law in such contexts, in practice ethical issues are given limited consideration within patent law cases in each of these jurisdictions. Using gene patents as a case study, this article argues patent law in these jurisdictions, has failed to engage with the broader ethical issues (including potential healthcare implications) of biotechnological patents in any meaningful way. In effect, a marginalisation of ethical issues is evident within patent law. The only exception to this is Canada, where solutions outside patent law, via licensing, have been devised to deliver access to technologies under patent, focusing on the public health issues at stake.

The article argues that unless and until we adopt fundamental institutional change within patent law to address broader ethical issues inherent in the grant of patents, it behoves us to take seriously and devise appropriately, solutions outside patent law to address such ethical issues including potential healthcare implications posed by patent use. For such reasons, at a practical level, the solution offered by tailored licensing approaches in the Canadian context, although not without some potential shortcomings, is arguably a preferable solution in the short term. Such licensing approaches should be taken seriously in other jurisdictions.

** Lecturer, Department of Law, Maynooth University. Email: aisling.mcmahon@mu.ie

The author would like to thank and acknowledge the support of British Academy/Leverhulme Small Grant (SG163006'Gene Patentability: A comparative institutional analysis of the US, Canadian and European Approaches') which supported this research including funding empirical interviews informing the background research for the paper. The author is also very grateful to anonymous interviewees for participating in this project. An earlier version of this paper was presented at the: Oxford Intellectual Property Research Centre Invited Speaker Series, the Ethox Centre Oxford, and the Hastings Centre where it received valuable feedback. Finally, the author would like to thank Prof TT Arvind, Dr David Doyle and Dr Bríd Ni Ghráinne for their helpful comments on earlier versions of the paper.

[1] *Association for Molecular Pathology v. Myriad Genetics Inc*. (2013) 569 U.S. 576.

[2] *D'Arcy v Myriad Genetics Inc.* [2015] HCA 35.

[3] These are genes which have been isolated or removed from the human body.

[4] Directive 98/44EC

Introduction

In 2013 and 2015, the Supreme Court of the United States (US)[5] and Australian High Court,[6] respectively, rejected the patentability of isolated genes.[7] Subsequently, in March 2016 a case filed in the Federal Court of Canada involving the Children's Hospital of Eastern Ontario's (CHEO) challenge to patents on genes related to Long QT syndrome (a condition involving irregular heart rhythms) was settled. The settlement provided a licence to CHEO to test for the syndrome.[8] A primary driver of the litigation in all three jurisdictions, was the broader ethical issues posed by such patents, including, specifically the potential healthcare implications of such patents. The European Union adopted tailored legislation to deal with biotechnology patents in 1998, including gene patents. Again, a primary concern underlying the drafting of the Directive was the ethical issues, including healthcare implications, posed by biotechnological patents.[9]

However, despite ethical issues driving challenges to and debates on changes of patent law, in practice ethical issues are given limited consideration within patent law cases in each jurisdiction. To demonstrate this marginalisation of ethical issues, including healthcare implications, posed by patents, this article uses gene patents as a case study focusing on approaches adopted in Europe,[10] Australia and the US, and Canada. These jurisdictions were chosen as they offer examples of three differing legal approaches to gene patentability, namely: a tailored legislative approach to biotechnological patents, including gene patentability (EU); jurisdictions with no tailored legislative approach where questions on patentability are decided by judicial interpretation (United States and Australia); and an approach using tailored licensing agreements between patent holders and public hospitals (Canada). Through these case studies, the article demonstrates that despite differences in the legal approaches adopted to gene patenting a marginalisation of ethical issues is evident in all contexts *within patent law*, the only exception being Canada where a solution to address the public health issues is devised outside of patent law through a contractual licensing approach. This in turn implies that the marginalisation of ethical issues is a broader feature of the interpretative framework of patent law.[11]

These arguments have important practical significance. They demonstrate that in the absence of institutional change within patent law to give greater teeth to ethical

[5] *Association for Molecular Pathology v. Myriad Genetics Inc*. (2013) 569 U.S. 576.
[6] *D'Arcy v Myriad Genetics Inc.* [2015] HCA 35.
[7] These are genes which have been isolated or removed from the human body.
[8] This was a challenged by Children's Hospital of Eastern Ontario against Transgenomic. For further details, see *http://www.cheo.on.ca/en/challenge-gene-patents*
[9] Directive 98/44EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions (hereafter the Biotechnology Directive).
[10] In this context, Europe, can be taken to mean the countries where the European Patent Convention 1973 (EPC) applies, where patents can be applied for via the European Patent Office (EPO). The EPC is applicable in 38 States including all EU states. The Biotechnology Directive, as discussed below, has been adopted as supplementary interpretation for the EPC. For a detailed discussion of the European patent system, see: Aisling McMahon, "An Institutional Examination of the Implications of the Unitary Patent Package for the Morality Provisions: A Fragmented future too Far?" (2017) 48(1) *International Review of Intellectual Property and Competition Law*, 42-70.
[11] Aisling McMahon, *The Morality Provisions in the European Patent System: An Institutional Examination* (PhD Thesis, University of Edinburgh 2016). For a discussion of the interpretative community within patent law, see: Peter Drahos, "Biotechnology Patents, Markets and Morality" (1999) 21(9) *European Intellectual Property Review* 441, 441-442.

provisions law to exclude or limit patents, solutions *outside of* patent law, such as via licensing, are needed to address ethical issues, including the potential healthcare implications of patents. Such approaches are likely to be a quicker and more cost-effective mechanism to address healthcare implications than solutions within patent law. There are two elements to this argument. First, the article demonstrates there is a marginalisation of ethical issues within patent law, due primarily to either a failure to engage with such issues or because when such issues are raised often via provisions allowing for exclusions from patentability,[12] the judicial bodies/quasi-judicial bodies interpreting such exclusions tend to do so in a narrow technical manner which water down the effects of exclusions. Second, to compound this, the article demonstrates that it is likely to be difficult to bring successful patent challenges in such contexts, given the asymmetry between those who hold patents on genes (typically large companies) and those who may be affected by such patents (such as individual patients and hospitals), in terms of their resources and capacity to take and sustain legal action. This asymmetry reduces the likelihood of patents being successfully challenged even where there are potential healthcare implications. Shedding light on such issues suggests that once granted, patentability is likely to be maintained, because challenges are likely to be rare and even when taken likely to be unsuccessful in addressing broader ethical issues. Hence, it is argued that solutions outside patent law are a more effective means to achieve health related goals in the short term.

Importantly, in making such arguments, the article is not suggesting that patent law *should* not engage with ethical issues, instead, it is demonstrating how it currently *does not* do so, using gene patents as a case-study. For it to do so effectively, a fundamental institutional change would be needed within patent law in the way patent criteria and exclusions from patentability are interpreted. This is unlikely to be achieved in the short term, given that it would require a bottom up change to patent law, to fundamentally reconfigure how exclusions against patentability are applied in practice.[13] Hence, particularly in cases of health-related biotechnologies, where potential risks to health and/or life are posed by patents, solutions outside patent law are needed.

Furthermore, the ethical issues posed by gene patents and other biotechnologies from a healthcare perspective, can be distinguished from debates around patents and medicines. Whilst patents pose healthcare implications in both contexts, the concerns are heightened and arguably, of a different order in the gene patent sphere. Within gene patenting, the patent relates directly to an element, albeit isolated, from the human body. The potential for using such patents to limit genetic testing and isolation of a gene, also directly impacts on what samples can be taken from the body, and on what tests can be performed on samples taken from the human body. In other words, gene patents can be used to place limits on what can be done with biological specimens, and hence can be seen as a broader interference with human autonomy or bodily integrity.

[12] For example, in the European context, Art 53, EPC which provides for listed exceptions from patentability.

[13] See discussion in: Aisling McMahon, *The Morality Provisions in the European Patent System: An Institutional Examination* (PhD Thesis, University of Edinburgh 2016) which argued that a presumption favouring patentability is evident within European patent law. The EPO has expressed reluctance to engage with ethical issues or refuse patents on the basis of the morality provisions unless such inventions are considered abhorrent. For a discussion of presumption of patentability in the US context, see Margo Bagley, "Patent First, Ask Questions Later: Morality and Biotechnology in Patent Law" (2004) 45(2) *William and Mary Law Review* 469.

These arguments are novel for three reasons: First, it is the first article to compare the judicial interpretative approaches (US and Australia), legislative approaches (Europe) and licensing avenues (Canada) related to gene patents. In doing so, it demonstrates the pervasive marginalisation of ethical issues within patent law for gene patents which is not confined to any one jurisdiction or legal approach. Second, and relatedly, although European law at first glance may appear more responsive to ethical issues due to the ethical provisions within the text of the Biotechnology Directive, the article illustrates that such ethical provisions have limited teeth in practice. They tend to be interpreted by the Boards of the European Patent Office in a narrow technical manner. Thirdly, it sheds light on some of the difficulties in challenging patents in such contexts making a case for why solutions outside patent law are needed.

In making these arguments, the paper is structured as follows: Part I sets the foundation for the analysis by providing a brief overview of what gene patents are, and the main ethical and legal objections raised against gene patents. Part II then examines the three legal approaches to gene patentability demonstrating the gap between the rationales driving such legal challenges to gene patents (based primarily on health-related objections), and the way these challenges are framed within patent law adjudication (focusing on narrow application of patent criteria). It highlights the Canadian approach as the only one which directly engages with the potential healthcare implications.

Part III then demonstrates why solutions outside patent law such as licensing agreements are needed by illuminating some of the main obstacles to mounting successful challenges to gene patents. It also highlights the needs for governmental intervention if such solutions are to be effective, in order to lend greater strength to stakeholders in negotiating such licenses in the healthcare context. Part IV concludes arguing that the current marginalisation of ethics within patent law, compounded by the obstacles for challenging patents needs urgent re-consideration. Such issues are only likely to be exacerbated as biotechnologies and areas such as personalised medicines continue to develop.

Part I: Gene Patents: The Legal and Ethical Objections

'Gene patent' is a general term which can include several types of inventions.[14] It is most commonly used to refer to any patent involving a claim over nucleic acids including deoxyribonucleic acid (DNA) or ribonucleic acid (RNA). Many products can use DNA sequences, such as, genetic testing which are diagnostic tests used to identify if a person has a genetic variant that may be indicative of a particular disease, or of a higher risk of developing a disease.[15] For example, certain mutations or changes on the BRCA1 or BRCA2 gene, considered below in further detail, can indicate a higher risk of developing breast or ovarian cancer. This article focuses primarily on patents related to isolated genes, but the arguments raised also have implications for patents on other health-related biotechnologies.

[14] See discussion in Robert Cook-Deegan, "Gene Patents" in Mary Crowley (ed) *From Birth to Death and Bench to Clinic: The Hastings Center Bioethics Briefing Book for Journalists, Policymakers, and Campaigns* (Garrison, New York: The Hastings Center, 2008) 69, 69; Robert Cook Deegan and Christopher Heaney, "Patents in Genomics and Human Genetics" (2010) 11 *Annu Rev Genomics Hum Genet* 383.

[15] See discussion in: Nuffield Council, *The Ethics of Patenting DNA* (London, 2002) at 25.

This section focuses on briefly mapping the main types of objections which have been raised to gene patents. It does so in order to set the foundation for Part II, which argues that although the main driving objections to gene patents often focuses on the ethical implications, and particularly, the healthcare implications of such patents, however, gene patent challenges tend to focus instead on the objections based on technical patent criteria. For this reason, the arguments in favour of gene patents, which tend to focus primarily on the (albeit contested) need for patents to incentivise innovation in this context, are beyond the scope of this analysis, but have been examined in detail elsewhere.[16]

Objections against gene patents can be divided into three main categories. The first category are objections are raised against the *consequences for healthcare and research*. Patents allow the patent holder to exclude others from using the invention, unless they have the express permission (usually via a licence on the patented technology) from the patent holder. Therefore, granting a patent gives control over the invention to the patent holder, and a potential monopoly over the use of an invention. This creates five main issues for healthcare and research.

Firstly, gene patents can influence the price of products containing isolated genes, such as genetic tests which has potential implications for *access to genetic testing.* If the patent holder refuses to license the invention or only licences for a high cost, this has the potential to reduce competition in an area and in turn to drive up the price of an invention. For example, in the United States, Myriad Genetics Inc. (hereafter Myriad) held patents on isolated BRCA1 and BRCA2 genes – as noted mutations on these genes indicate a higher risk of breast and ovarian cancers[17] - to become the sole provider of BRCA1/2 testing in the US. Prior to the recent US decision in Myriad which rejected the patentability of isolated genes in the US, including Myriad's patents on BRCA1 and BRCA2, it was reported that BRCA1 and BRCA2 tests cost approximately $2,200, whereas after the ruling a competitor company DNATraits announced the availability of competing BRCA tests at $995.[18] This example is returned to in Part II below. It is conceded that pricing issues are complex and other factors aside from patenting contribute to the pricing of genetic testing.[19] However, patents are at the very least a contributory influence as they

[16] For example, for a discussion on the gene patent incentives, and critiques in this context, see: Daniel K. Yarbrough, "After Myriad: Reconsidering the Incentives for Innovation in the Biotech Industry" (2014) 21 *Michigan Telecommunications & Technology Law Review* 141.

[17] The overall lifetime risk of developing breast or ovarian cancers is between 2.7 and 6.4 times greater for those with mutations on BRCA1 and BRCA2 in comparison to other women. See Robert Cook Deegan, "Impact of Gene Patents and Licensing Practices on Access to Genetic Testing for Inherited Susceptibility to Cancer: Comparing Breast and Ovarian Cancers to Colon Cancers" (2014) 12(4) *Genetic Medicine* 15-38. A recent study estimated that in the general population approximately 12% of women will develop breast cancer, in contrast around "72% of women who inherit a harmful BRCA1 mutation and about 69% of women who inherit a harmful BRCA2 mutation will develop breast cancer by the age of 80". There is also a higher risk of ovarian cancers, 1.3% risk in the general population for women to contract ovarian cancer in their lifetime, compared to "44% of women who inherit a harmful *BRCA1* mutation and about 17% of women who inherit a harmful *BRCA2* mutation will develop ovarian cancer by the age of 80." See KB Kuchenbaecker, JL Hopper, DR Barnes et al, "Risks of breast, ovarian, and contralateral breast cancer for BRCA1 and BRCA2 mutation carriers" (2017) 317(23) *JAMA* 2402.

[18] Robert Cook Deegan and Anne Niehaus, "After Myriad: Genetic Testing in the Wake of Recent Supreme Court Decisions about Gene Patents" (2014) 2(4) *Curr Genet Med Rep*. 223, Table 1.

[19] See, discussion of other factors in Naomi Hawkins, "A red herring – Invalidity of human gene sequence patents" (2016) 38(2) *European Intellectual Property Review* 83, who cites the following: A Colaianni, S Chandrasekharan and R Cook-Deegan, "Impact of Gene Patents and Licensing Practices on Access to Genetic Testing and Carrier

allow the patent holder to exclude others from using an invention. Hence, patents have the potential to be used to limit competition of providers creating a monopoly of provision.

Secondly, if there is only one provider of genetic testing - for example, if the patent holder refuses to license the technology – then there could be shortages in the *availability of testing*.[20] This could result in longer waiting times for instance for diagnostic screening if only one provider is licenced to perform this, or delays if the material must be sent away to the genetic test provider for screening.

Thirdly, there may also be potential issues with the *quality of an invention*.[21] However, one argument is that if there are no competitors or a reduction in competitors providing testing,[22] there will be no rivals to provide genetic testing and hence limited scope for the market to ensure the best quality tests are being offered.

Fourthly, if an individual or healthcare practitioner is not satisfied with the test, if the patent is being enforced strictly, there may be only one test provider, and in such cases there will be no option to get a *second opinion* on a diagnostic test from an alternative provider.[23] Fifthly, gene patents have the potential to hamper or restrict *research* if researchers divert attention away from working on patented inventions due to the fear of patent infringement claims.[24] Tests may not be developed further, if competitors fear patent infringement litigation. These issues are the core, often-cited, 'health-related' implications of gene patents as denoted in this article; however, this is not an exhaustive list.

Turning back to the core objections to gene patents, a second category of objection is based on *the special status of DNA* which claims DNA is special in nature and should not be patented. This argument can be extended to the idea that patenting is a form of commodification of the body which should be prohibited. Such arguments are encompassed by the 'No Patents on Life' slogans used in protesting against patents on biotechnology.[25] Relatedly, it has been argued that the human genome should be part of the 'common heritage of mankind' and should not be subject to patent protection.[26]

Screening for Tay-Sachs and Canavan Disease" (2010) 12 *Genetics in Medicine* S5; Secretary's Advisory Committee on Genetics Health and Society, "Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests" (2010).

[20] Naomi Hawkins, "A red herring – Invalidity of human gene sequence patents" (2016) 38(2) *European Intellectual Property Review* 83.

[21] Such issues are contested, see discussion in Hawkins, ibid.

[22] This was raised by the plaintiffs at District Court level in *Association for Molecular Pathology v. Myriad Genetics Inc*. 569 U.S. 576 (2013).

[23] Naomi Hawkins, "A red herring: invalidity of human gene sequence patents" (2016) 38(2) *European Intellectual Property Law Review* 83 who notes this as being a concern cited in the context of Myriad's patents on BRCA1/BRCA2 and for patients whose test results suggested there was a variant of uncertain significance. Secretary's Advisory Committee on Genetics Health and Society, "Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests" (2010).

[24] Naomi Hawkins, "A red herring: invalidity of human gene sequence patents" (2016) 38(2*) European Intellectual Property Law Review* 83-91 raises some interesting counter-arguments to the above concerns.

[25]See Nicholas Hildyard, & Sarah Sexton, "No Patents on Life" (2000) 15(1) *Forum for Applied Research and Public Policy*; Knoxville 75-79; Rogeer Hoedemaekers, "Commercialization, Patents and Moral Assessment of Biotechnology Products" (2001) 26(3) *Journal of Medicine and Philosophy* 273; G Dutfield, *Intellectual Property Rights and the Life Science Industries: A Twentieth Century History* (Taylor and Francis 2003) chapter 6.

[26]Bartha Maria Knoppers, "Status, sale and patenting of human genetic material: An international survey" (1999) 22 *Nature Genetics* 23-25; M.L. Sturges, "Who should hold property rights to the human genome? An application

Thirdly, objections are based on whether *isolated genes meet or fit within with technical patentability criteria*.[27]Inventions must fulfil three basic criteria to be patentable - they must demonstrate: novelty, inventive step and industrial applicability.[28] Arguments against gene patents under this category have tended to focus on three aspects: 1) Genes, even when isolated, are naturally occurring substances and thus, patent ineligible subject-matter. The argument is that genes are discoveries or products of nature, rather than technical man-made creations or inventions. A discovery is an acquisition of knowledge about an existing fact whereas an invention is something that someone creates or develops which did not previously exist. Therefore, some argue that genes which exist in our bodies (and so in the world) are natural substances and not an invention. 2) Relatedly, it is questioned whether identifying and isolating a gene, and/or its function, is sufficiently novel to warrant patent protection. The genes are not created as a new substance, even isolated genes mirror what already exists in the human body. 3) Arguments can be raised around whether isolated genes fulfil the inventive step criteria according to which inventions should be non-obvious to the person skilled in the art. For instance, several teams of researchers may be working separately on a particular scientific development at the same time, for example to sequence and locate a gene, or to develop a similar technology.[29] In such circumstances, if multiple teams are working on the same thing, often using similar techniques, can this truly be said that this was an inventive or non-obvious development?[30]

Part II: Differing Legal Approaches & Common Marginalisation of Healthcare Implications

Turning to the legal approaches to gene patents, this section demonstrates a chasm between the primary objections tending to drive and underpin legal challenges to gene patents (which often relate to the potential healthcare implications of patents) and the focus within such patent law challenges, both in the courts and patent offices, where a marginalisation of ethical issues is evident, and where cases instead, focus on narrow technical patentability criteria. The only exception is the Canadian public health licensing approach, which is tailored specifically towards public health issues, and is a solution devised *outside patent* law.

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of the common heritage of humankind" (2017) 13 *Am. Univ. Intl Law Rev*. 219; Lori B Andrews, "Genes and patent policy: rethinking intellectual property rights" (2002) *Nature Genetics* 803; Jasper A Bovenberg, "Mining the Common Heritage of our DNA: Lessons Learned from Grotius and Pardo" (2006) 8 *Duke Law and Technology Review* 1.

[27] See discussion in Naomi Hawkins, "Human Gene Patents and Genetic Testing in Europe: A Reappraisal" (2010) 7(3) *SCRIPTed* 453, 455.

[28] Art 52-57 EPC in Europe. The terminology differs on the criteria across jurisdictions. However, this is also the terminology used in the TRIPS Agreement, Article 27.

[29] The CRISPR-Cas9 patent litigation provides a recent example of this, see the discussion of the race to patent in: Arti K. Rai & Robert Cook-Deegan, "Racing for academic glory and patents: Lessons from CRISPR" (2017) *Science* 874.

[30] For a discussion of the scientific race to isolate BRCA1 see: Mary Claire King, "The race to clone BRCA1" (2014) 343(6178) *Science* 1462; Mark Skolnick, "Winning the race to find BRCA1" (Interview, DNA Learning Center) *https://www.dnalc.org/view/15246-Winning-the-race-to-find-BRCA1-Mark-Skolnick.html*

(a) Judicial Challenges to Gene Patents

Patents on isolated genes, specifically related to BRCA1 and BRCA2, were successfully challenged in 2013 in the United States in *Association for Molecular Pathology v. Myriad Genetics Inc,*[31] and in October 2015 in Australia in *D'Arcy v. Myriad Genetics Inc*.[32] Both cases demonstrate a similar pattern where health-related objections against gene patents formed the impetus for challenges, however, when the cases were litigated the focus shifted to objections based on narrow patentability criteria. There was no engagement by the courts in either jurisdiction with the underlying healthcare issues posed by the patents. The section analyses both contexts and reflects on the implications of these cases.

At the outset, it is conceded that courts are confined by the legal arguments presented to them. However, the healthcare implications were expressly referenced in plaintiff statements in the US District Court context of Myriad case leaving scope for the court to engage further with these. Instead, they were dismissed at District Court stage with limited analysis by the court, which merely stated they were issues of factual dispute which could not be resolved by the court.[33] Arguably, even if the court found it could not engage directly with such issues, given that the potential healthcare implications of such patents were a central driver of such cases, obiter comments could have been made on the patents potential for health-implications. It is also accepted that legal teams will present their strongest arguments in litigation and the analysis which follows is not a criticism of the choice of focus on patentability criteria *per se*. Instead, this very focus on patentability criteria to challenge such patents demonstrates the perceived limited scope for ethical considerations within patent law. By highlighting the gap between the ethical objections driving such challenges and the way arguments are framed within the case law as issues involving narrow technical patentability criteria, the article aims to highlight the disjoint between patent law and health contexts. It demonstrates the disconnected nature of patent law and calls for a deeper consideration of this disconnect.

(i) United States: Association for Molecular Pathology v Myriad Genetics

On 13th June 2013, Justice Thomas delivered the Supreme Court judgment in the *Myriad* case which found "naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated, but that cDNA is patent eligible because it is not naturally occurring".[34] The case was originally brought by twenty plaintiffs[35] - including medical doctors, patient groups, individual patients, professional medical associations, and scientists - whose objections to gene patents were based primarily around concerns related to the potential healthcare implications of gene patents,

[31] (2013) 569 U.S. 576.
[32] [2015] HCA 35.
[33] Association for Molecular Pathology v USPTO (2010) 702 F.Supp.2d at 207 Justice Sweetman stated: "Whether the patents at issue impact the testing for BRCA1/2 mutations favorably or unfavorably is an issue of factual dispute not resolvable in the context of the instant motions."
[34] 569 U.S. 576 (2013), 1.
[35] The original plaintiffs in the District Court case were: Association for Molecular Pathology; American College of Medical Genetics; American Society for Clinical Pathology; College of American Pathologists; Haig Kazazian; Arupa Ganguly; Wendy Chung; Harry Ostrer; David Ledbetter; Stephen Warren; Ellen Matloff; Elsa Reich; Breast cancer Action; Boston's Women's Health Book Collective; Lisbeth Ceriani; Runi Limary, Genae Girard; Patrice Fortune; Vicky Thomason; Kathleen Raker.

including issues of access to genetic testing, the quality of the testing, the availability of second medical opinions, and the potential restrictions on research as a result of the patents.[36]

The Court's finding that isolated genes were not patentable was significant because it meant Myriad's patents on BRCA1 and BRCA2 were no longer valid.[37] Importantly, if Myriad's claims were upheld as valid by the Court the patents would have given Myriad an exclusive right to isolate BRCA1 and BRCA2 DNA in the US,[38] for the duration of the patents. This would have had significant healthcare implications because isolation of the BRCA1 and BRCA2 genes is needed to conduct genetic testing,[39] and prior to the US Supreme Court decision, Myriad had used its patent to issue cease and desist letters to other laboratories providing genetic testing on BRCA1 and BRCA2, claiming patent infringement because testing involved the isolation of these genes.[40] Accordingly, such laboratories ceased the testing and this enabled Myriad to solidify its role as the only BRCA testing provider in the US.[41] Importantly, if the patents were valid, this would have set a precedent for other patent holders to enforce patents on isolated DNA in other contexts, and potentially to use patents in a similar manner for other genes, and genetic testing.

However, when one examines the Supreme Court's reasoning, the decision's effect is more limited than it may initially seem. This is because the Court's reasoning for finding patents on isolated DNA invalid, was based on narrow technical grounds rather than based on broader ethical concerns, including the healthcare implications of such patents. This is significant because it limits the application of the case for future technologies.

In assessing validity of the patent, the Court focused on s. 101 of the Patents Act, the operable provision in the US patent law. This states that:

> "Whoever invents or discovers any new and useful…composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."

The Court stated that an exception to this principle is that "laws of nature, natural phenomena and abstract ideas are not patentable", and the reason for this exclusion is that patent "[p]rotection strikes a delicate balance between creating "incentives that lead to creation, invention and discovery" and "imped[ing] the flow of information that might permit, indeed spur, invention".[42] This was the closest the Supreme Court came to alluding to the underlying ethical issues involved in gene patenting, and even here the discussion of 'impeding the flow of information' is framed around the innovation context, not around the potential implications for health or research. This lack of reference to broader ethical issues is disappointing given the origins of the challenge. Moreover,

[36]The plaintiff statements are available at *https://www.aclu.org/other/brca-plaintiff-statements?redirect=free-speech_womens-rights/brca-plaintiff-statements#warren*
[37] 569 U.S. 576 (2013), See discussion of claims p. 5-6.
[38] Ibid, 6, C.
[39] Ibid, 7.
[40] Ibid, 7.
[41] Ibid, 7.
[42]Ibid, 11.

nowhere in the Supreme Court judgment did it directly highlight the healthcare implications of gene patents.

The Court found that Myriad's "principal contribution was uncovering the precise location and genetic sequence of the BRCA1 and BRCA2 genes".[43] However, in doing so, Myriad did not create anything,[44] instead, it "found an important and useful gene, but separating that gene from its surrounding genetic material is not an act of invention."[45] In the Court's view "[g]round-breaking, innovative or even brilliant discovery does not by itself satisfy the s. 101 inquiry."[46] Accordingly, although Myriad located the BRCA1 and BRCA2 genes this discovery did not mean the BRCA genes were a new composition of matter required for patentability under s.101.[47] Instead, the value in Myriad's patent claim was in the Court's view the information contained within the genes not with the "specific chemical composition of a particular molecule."[48] Thus, isolated genes were not patent eligible.

A technical distinction was also drawn by the Court relating to cDNA (an exons only molecule that is not naturally occurring),[49] which it held was patentable because it differs from the DNA molecule itself and is therefore not "a "product of nature".[50] The Court did not give guidance on how to define whether something is 'naturally occurring' or not, and this could also create uncertainty in the context of future patent challenges.[51]

In short, the decision focused primarily on whether a substance is a 'product of nature' or 'man made' to determine patentability and this will be the key question asked in future cases concerning similar patents. The finding that isolated genes are not patentable had positive implications for genetic testing in the US. However, the decision does not have direct implications for patents on other biotechnologies which pose similar healthcare implications given that such healthcare implications were not material to the court's decision. Thus, should similar healthcare implications arise in the context of patents related to other types of future biotechnologies which are not isolated genes, further litigation would be required – which is both costly and time consuming. Technologies have already significantly developed since the filing of the Myriad patents, but given the narrow grounds of the reasoning it is confined to isolated genes, and does not have broader implications for more recent technologies such as, for example, CRISPR techniques which have the potential to modify human genes and could also have healthcare implications. Hence, the benefits of the case do not have the breadth or potential longevity, they might have had were the court to engage directly with the underlying healthcare and broader ethical implications of such patents.

(ii) Australia: D'Arcy v Myriad Genetics Inc

[43]Ibid, 12.
[44]Ibid, 12.
[45]Ibid, 12.
[46]Ibid, 12.
[47]Ibid, 13.
[48] Ibid, 15.
[49]Ibid, 16, section C.
[50] Ibid, 17.
[51] Jessica C. Lai, "Myriad Genetics and the BRCA Patents in Europe: The Implications of the U.S. Supreme Court Decision" (2015) 5 *U.C. Irvine L. Rev.* 1041.

A similar challenge was brought in Australia against Myriad's patents on the BRCA1 gene by Yvonne D'Arcy. Ms D'Arcy was a breast cancer survivor and stated that she wished to challenge Myriad's patent in order to ensure that women would not be denied access to genetic testing as a result of the patents. She stated that she had '"met a lot of women with genetic cancer and if I can help them in any way stop having to have chemo and radiation therapy then I will have done my job."[52] It must be noted, that although Myriad had patents over BRCA1 in Australia, unlike in the US context, it did not enforce these patents as aggressively there.[53]

In 2010, Ms D'Arcy's case commenced,[54] the challenge failed in both the Federal Court and Full Federal Court stages, but she was successful in the Australian High Court. However, like the US, the case and Australian High Court's reasoning is framed entirely around technical patent criteria with no reference to the broader healthcare context.

The High Court was asked to consider whether the isolated gene was patentable within s. 18(1)(a) of the Patents Act 1990. Section 18(1)(a) states that a patentable invention is one which is a: "manner of manufacture within the meaning of section 6 of the Statute of Monopolies".[55] The court found that DNA was not a manner of manufacture and hence unpatentable subject matter. According to the court, to be patentable an invention must be created by human action, and isolated DNA is not created by human action. The court stated that the core substance of the claimed invention is the "information embodies in arrangements of nucleotides" and such information is "not "made" by human action" instead it is discerned.[56] Hence, it was not patentable subject matter.

Similarly, to the US context, the court made no reference to the health-related issues that motivated Ms D'Arcy to challenge the patent. Its only comment on the broader implications of such patents, was to say that if the patent was granted it:

[52]Tracey Bowden, "Brisbane grandmother in legal battle against US biotech company Myriad Genetics over human gene ownership" (*ABC News*, 16 June 2015) available at *https://www.abc.net.au/news/2015-06-16/grandmother-sues-biotech-company-over-gene-ownership/6550600*

[53]Instead, Myriad granted an exclusive licence to Genetic Technologies for these patents in Australia – see Reema Rattan, "Australian federal court upholds gene patents" (*The Conversation*, 5th September, 2014) available at *https://www.bbc.com/news/world-australia-34461941*; Myriad also stated it would be willing to surrender its patents in Australia but highlighted this was not admitting patent invalidity. See Mark Summerfield, "Myriad Offers BRCA Gene Patent as "Gift" to the Australian People" (7th September 2010) available at *https://blog.patentology.com.au/2010/09/myriad-offers-brca-gene-patent-as-gift.html*

[54] *https://www.mauriceblackburn.com.au/about/media-centre/media-statements/2015/high-court-to-hear-breast-cancer-gene-patent-case/* Her case was joined by Cancer Voices Australia, whilst she also re-mortgaged her house to help fund the challenge. See *https://www.codea.com.au/publication/darcy-v-myriad-genetics-a-grandmother-goliath-case-highlighting-broad-legal-standing-in-patent-opposition-and-public-interest-litigation/*

[55] Section 6, Statute of Monopolies 1623 states that : "Provided also and be it declared and enacted that any declaration before mentioned shall not extend to any letters patent and grants of privilege, for the term of 14 years or under hereafter to be made of the sole working or making of any manner of new manufacture within this realm to the true and first inventor and inventors of such manufactures which others, at the time of making such letters or grant, shall not use, so as also they be not contrary to the law, nor mischievous to the state, by raising prices of commodities at home or hurt of trade or generally inconvenient."

[56] *D'Arcy v Myriad Genetics Inc.* [2015] HCA 35, Para 6.

> "…raises the risk of a chilling effect upon legitimate innovative activity outside the formal boundaries of the monopoly and risks creating a penumbral de facto monopoly impeding the activities of legitimate improvers and inventors."[57]

This offers a recognition of a potential chilling effect of the patent on other technologies or improvement of these but again it is framed in terms of innovation, and fails to question or engage with the potential implications for human health.

(iii) Interim Reflections: Judicial approaches and marginalisation of healthcare implications

The US and Australia decisions in Myriad display no engagement with the potential healthcare implications of patents on isolated genes, despite this being the primary motivating factor for the individuals challenging such patents.[58] As noted, it is conceded that courts are confined by arguments put to them and this may explain why this was not their core focus. However, this is also problematic, as the fact that such legal arguments, were premised on technical narrow patent criteria suggests these were deemed the strongest arguments by legal teams to put forward. This article is not questioning whether this is the case, rather it argues that this focus on narrow technical criteria demonstrates the gap between the core underlying issues at stake i.e. the potential healthcare implications of such patents, and how patent law frames such issues. In effect, patent law is not engaging with the underlying objections to such patents. Rather, the court in each case when arguments are framed within patent law terms, treats the claimed invention, the isolated gene, as fungible or interchangeable with any other inventions, which in turn leads to a lack of engagement with the broader issues such as the effects of patents on health and human life.[59]Once an invention is deemed patentable, the content of that particular invention, and the ramifications of patentability stemming from what the object of the invention is, is not questioned. Moving patent law beyond this, arguably blinkered view, although not impossible, would require a serious re-calibration of patent law. This would include a fundamental institutional shift in patent law towards examining whether the nature of the invention should be considered in terms of how the patent is used, for example, if healthcare implications at stake.

This is not a trivial point, because deciding such cases on narrow patent criteria rather than broader public-health reasons has significant implications as it reduces the potential impact of these decisions. In both the US and Australia, isolated genes are no longer patentable, but as noted, such findings do not have broader application for future patented biotechnologies which pose similar healthcare implications but are not isolated genes. Instead, such future inventions would need to be fully litigated. This takes considerable time and financial resources and this in turn helps to perpetuate the presumption of patentability in such cases, a point returned to in part III.

(b) Tailored Legislative Approach: Europe

[57] Ibid, para 93.

[58] As evident from what Yvonne D'Arcy stated in her discussions in the case, and also the plaintiff's statements in the US Myriad case.

[59] For a discussion of the de-relationising effects of patents on technologies which are premised on a fungible framing of technologies under patent, see TT Arvind and A McMahon, "Commodification, control, and the contractualisation of the human body" (Working Paper 2019).

Moreover, a marginalisation of ethical issues is not confined to where there is no tailored legislation dealing with patents and biotechnology. Instead, the European context shows, that even where there are tailored legislative provisions which have the potential to limit patents based on ethical issues, much will depend on how these provisions are interpreted within patent law and what teeth, if any, they are given to such provisions by patent offices or courts who apply them. To date, European patent law has shown strong reluctance to engage with the healthcare implications of inventions through such provisions. Instead, as in other jurisdictions, a disjoint is evident between the concerns as framed within patent law, and the underlying objections motivating legal challenges to gene patents. This lends further weight to the disjoint evident between patent law and health, as even where laws are drafted in a way which takes account of ethical issues, such provisions appear to be interpreted within patent law in narrow technical manner which waters down their potential effect.

Briefly, by way of background, within Europe, the European Patent Convention 1973 (EPC) applies to 38 States including all EU states. Patent grant is assessed either at a national level in each jurisdiction, or applicants can apply to the European Patent Office (EPO) for a patent in multiple EPC States. If the EPO grants this application, it will give the applicant a bundle of national patents, applicable in the States where the patents were applied for. The EU adopted the Biotechnology Directive 1998 (hereafter the Directive) to deal specifically with the patentability of biotechnological inventions. The Directive was subsequently adopted as supplementary interpretation for the EPC, and the implementing provisions to the EPC were updated to include provisions from the Directive.[60]

The Directive's main purpose was to clarify the patentability of biotechnological inventions,[61] its drafting involved over ten years of debate. Much of the debate focused on the ethical issues posed by biotechnological patents,[62] and the Directive was only adopted following its amendment to include specific provisions dealing with the ethical issues.[63] Hence, the European approach at least on paper is underpinned by an emphasis on addressing ethical issues posed by biotechnological patents. However, in practice, the provisions contained therein are interpreted in a technical manner demonstrated by the gene patentability context.

For instance, Article 5 of the Directive states that:

[60] Rule 28 was adopted to incorporate Art 6, Biotechnology Directive into the EPC framework.
[61] Gerard Porter, "The Drafting History of the European Biotechnology Directive" in Aurora Plomer and Paul Torremans, *Embryonic Stem Cell Patents: European Patent Law and Ethics* (Oxford University Press, 2009) at 10. For a discussion of the legal basis of the Directive, see Case C-377/98 *The Kingdom of the Netherlands v European Parliament and Council* [2001] ECR I-07079.
[62] Gerard Porter, "The Drafting History of the European Biotechnology Directive" in Aurora Plomer and Paul Torremans, *Embryonic Stem Cell Patents: European Patent Law and Ethics* (Oxford University Press, 2009), 10.
[63] The first draft was introduced by the Commission on 17th October, 1988; EC, Proposal for a Council directive on the legal protection of biotechnological Inventions' COM (88) 496 final/EYN 159 of 17 October 1988, OJ C10/3. This was subsequently amended and rejected by Parliament and the Council several times and finally adopted in May 1998. Gerard Porter, "The Drafting History of the European Biotechnology Directive" in Aurora Plomer and Paul Torremans, *Embryonic Stem Cell Patents: European Patent Law and Ethics* (Oxford University Press, 2009), 7.

> ‘The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.’

Based on this provision alone one might think isolated genes as parts of the human body would not be patentable. However, its effect is watered down by Art 5(2) which states:

> “An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.

Art 5(2) of the Directive is an express acknowledgment that isolated genes *may* be patentable. It is mirrored in the EPC where, although Article 52 of the EPC provides that “mere discoveries are unpatentable”, the EPO Guidelines for Examination[64] provide that a substance found in nature may be patentable if it can be shown to produce a technical effect and gives gene patents as a specific example. Limitations have been placed on this provision, for example to be patentable, one must disclose the function of the gene in the patent application.[65] However, this requirement of disclosure of function has also been eroded in some European States.[66]

Moreover, and more troubling, a similar watering down is evident in relation to potential exclusions against patentability in Europe. Three main exclusions could in theory be applied to limit gene patents, but all of these have been interpreted by the EPO in a way which limits their potential effect on gene patents.

First, under Art 53(c) EPC patents are not available on methods for treatment of the human body or diagnostic methods.[67] However, this exclusion for treatment methods has been interpreted as only for those practiced *on or in the human body*, and would not exclude the isolation of a gene from the body, because the treatment of fluids removed from the body is not excluded.[68] Moreover, the diagnostic methods exclusion only applies to methods practiced *on or in* the human body, and not to methods performed outside the body such as the analysis of blood or biological material which genetic testing involves. The exclusion been further watered down by the *Diagnostic methods* case,[69] where the EPO stated that to fall within the exclusion the invention would need to involve all four stages of diagnosis, namely, examination, comparison, identification and the diagnosis stage. In other words, patents are only excluded for inventions which make it “immediately possible to decide on a particular course of medical treatment.”[70] As Bently and Sherman, acknowledge, this interpretation means that only an invention leading to a complete diagnosis would fall within the exclusion. This waters down any limiting effect

[64] Part G – 3.1.
[65] Art 5(3), Biotechnology Directive.
[66] For instance, the UK Supreme Court in *Human Genome Sciences v Eli Lily and Co* [2011] UKSC51 found it was sufficient to disclose the proposed function only, whilst in some cases an educated guess would be sufficient.
[67] This article states: “methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods.”
[68]EPO Guidelines C-IV, 4.3’ in Bently and Sherman, *Intellectual Property Law* (OUP, 2014) at 450.
[69] *Cygnus/Diagnostic methods*, G 1/04 [2006] OJ EPO 334 (EBA), 352.
[70] Bently and Sherman, *Intellectual Property Law* (OUP, 2014) at 449.

on patents related to genetic testing which the provision may otherwise have had. Indeed, as they also acknowledge the interpretation may 'reopen concerns about the negative impact that patent law has upon health care and delivery".[71]

Second, the European system provides that patents shall not be granted on inventions the commercial exploitation of which are against morality or *ordre public*.[72] This provision pre-dated the Biotechnology Directive and was reiterated in Art 6 of the Directive. It was invoked to challenge gene patents prior to the Directive in *Howard Florey/Relaxin.*[73] However, the EPO demonstrated its acute reluctance to engage with the ethical issues, stating that whether:

> "…human genes should be patented is a controversial issue on which many persons have strong opinions… [T]he EPO is not the right institution to decide on fundamental ethical questions."

The EPO Opposition Division (OD) in this case dismissed any claims that patenting of a human gene was contrary to the morality provisions with short shrift. One argument raised in this context was that patenting genes was akin to patenting a living substance, the EPO rejected this with limited substantive analysis of the claim by simply stating that 'DNA as such was not life but one of the chemical entities participating in biological processes'.[74] It did not provide a justification for why patenting of genes amounted to patenting a chemical entity as opposed to living substance, nor did it delve into the broader implications of the claim. The OD also stated that gene patents did not infringe upon human dignity, and hence did not fall foul of the morality provisions in this way. It held that:

> "no offence to human dignity had occurred as the woman who donated tissue was asked for her consent and her self-determination was not affected by the exploitation of the claimed molecules".[75]

However, this statement looked only at the dignity of the person donating her biological sample used to isolate the DNA - in the circumstances of the case - which was then subsequently patented. It did not consider the potential impact of gene patents for third parties, including the restrictions imposed by gene patents on the isolation of samples from third parties, and what could be done with such samples as a result of gene patents. Arguably, these issues also amount to interferences with dignity, albeit of third parties, as they impact on individuals' control over their biological specimens, which becomes contingent upon whether gene patents are applicable and how these are enforced. Such broader interferences with dignity were not alluded to by the OD.[76] Moreover, although, four main EPO cases involved challenges to the patents owned by Myriad on BRCA1 and BRCA2, each of these cases, similarly to the Australian and US contexts, focused on technical elements of patent law. The patents were narrowed based on novelty or

[71] Ibid, 450.
[72] Art 53(a) EPC, and Art 6(1) Biotechnology Directive.
[73] [1995] EPOR 541.
[74] OJ EPO, 1995, 388 as cited in para IV of Case T 0272/95 (*Relaxin/Howard Florey Institute) of* 23.10.2002.
[75] Ibid.
[76] On the de-relationising effect of patents see: TT Arvind and A McMahon, 'Commodification, control, and the contractualisation of the human body' (Working Paper 2019).

other technical patentability concerns, but not because of broader ethical considerations.[77] Thus, despite ethical provisions underpinning European patent law, there has been limited engagement with the ethical issues posed by gene patents within cases involving gene patentability in Europe.

Third, the experimental use or research exemption exists in Europe which could in theory assist those concerned about impacts of gene patents on research. However, its interpretation differs across European States, [78] and the exemption is often narrowly interpreted.[79]

Hence, despite European patent laws sometimes being perceived as more ethically grounded or underpinned than other jurisdictions, in practice, the provisions which could allow consideration of ethical issues are interpreted with little practical force. Moreover, ironically, whilst patents are now not available on isolated genes in the US and Australia, the text of the Directive means they continue to be available in Europe. Hence, European patent law poses greater potential for negative healthcare implications arising from gene patents in this context than the US or Australia.

On this point, it is conceded that Myriad did not enforce its patents as aggressively in Europe as it did in the US. Furthermore, even where patents were applicable there was evidence in some countries of 'wilful blindness' where the patents were ignored in practice.[80] Nonetheless, just because patents on genes have not been enforced strongly in the past in Europe does not mean they could not be in future – the potential remains for these to be interpreted and applied in a way which poses restrictions on healthcare. This potential is particularly concerning as we move towards, for example, whole genome sequencing or personalised medicine which will require the screening of multiple genes which may be under patent.[81]

77 These were: EP0705902 "17q-Linked Breast and Ovarian Cancer Susceptibility Gene" (Case T 1213/05); EP0705903 "Mutations in the 17q-Linked Breast and Ovarian Cancer Susceptibility Gene" (Case T 0666/05); EP0699754 "Method for Diagnosing a Predisposition for Breast and Ovarian Cancer" (Case T 0080/05); EP0785216 "Chromosome 13–Linked Breast Cancer Susceptibility Gene BRCA2". See discussion in: Jessica C. Lai, "Myriad Genetics and the BRCA Patents in Europe: The Implications of the U.S. Supreme Court Decision" (2015) 5 *U.C. Irvine L. Rev.* 1041.

78 *See* OECD, Research Use of Patented Knowledge: A Review (2006) STI Working Paper No 6, ch II *http://www.oecd.org/science/sci-tech/36311146.pdf*

79 A McMahon, ''Patents, Human Biobanks and Access to Health Benefits: Bridging the Public–Private Divide'' in Jessica Lai and Antoinette Maget Dominicé (eds) *Intellectual Property and Access to Im/Material Goods* (Edward Elgar 2016). For example, in the UK s 60(5)(b) of the Patents Act 1977, as amended, offers an experimental use exemption, but this only applies if the purpose of the research was to discover something unknown about the particular invention or to test a hypothesis about the invention. If the research is related to a commercial purpose the exemption is less likely to apply. This means that even research to create improvements on the invention for commercial purposes would not be covered, if they involved the use of a patented invention. See: Bently and Sherman, *Intellectual Property Law* (OUP, 2014 4th Edition) 636

80 Naomi Hawkins, "The Impact of Human Gene Patents on Genetic Testing in the UK" (2011) 13(4) *Genet Med.* 320–324 which discusses the UK context. On non-compliance in the European context, see: S Gaisser, MM Hopkins, K Liddell, E Zika, D Ibarreta, "The phantom menace of gene patents" (2009) 458(7237) *Nature* 407.

81 See similar discussions in Sarah Khan and Richard Gold, "Contracting to counter gene patents – a 21st Century solution to access and innovation" (*Petrie Flom Blog*, 22nd May 2017) *http://blog.petrieflom.law.harvard.edu/2017/05/22/contracting-to-counter-gene-patents-a-21st-century-solution-to-access-and-innovation/*

(c) Solutions outside Patent Law: Canadian Public Health Licensing Agreement

Finally, turning to Canada, and specifically the Children's Hospital of Eastern Ontario (CHEO) case where solutions outside of patent law have been devised and provide useful lessons in terms of managing potential healthcare implications of gene patents. In March 2016, the CHEO's case which challenged Transgenomic's patents on genes associated with Long QT syndrome,[82] was settled. The settlements provided that Transgenomic would sign a licence to CHEO to allow it to test for the syndrome.[83] Long QT syndrome is a rare genetic condition involving a disorder in the heart's electrical activity which can cause irregular heartbeats that may be fatal.[84] Testing for the mutation on genes associated with the disease is particularly important, given that sometimes the first symptom can be sudden adult death.[85] In its challenge to these patents, CHEO sought: a declaration that processes to diagnose Long QT were not an infringement of the patent under s. 60(2) of the Patents Act (PA); a declaration that the isolated nucleic acid claims described would be invalid under s. 60(1) PA; and alternatively, a compulsory license claiming that the proposed tests constituted a public non-commercial use of the Long QT patents under s. 19 PA.

The CHEO stated that the main impetus for the challenge was that their "physicians and scientists felt passionately it was the right thing to do for our patients and families".[86] Specifically, there were concerns that gene patents reduced "access, innovation and affordability"[87] of genetic testing. At the time, testing of samples was being conducted in the US, and not by CHEO itself due to fears in relation to patent infringement. This meant potential delays for the test, increased costs due to having to send samples to the US, and a disconnect between the clinical and genetic data of patients.[88] Arguably, a further issue was that as CHEO was not conducting testing it was not gaining any institutional knowledge (such as a database of results, training in conducting the test) which it would have gained were testing being performed by it.[89]

The main purpose of the settlement was that CHEO could provide genetic testing for Long QT genes on a not-for-profit basis specifically to 'persons entitled to healthcare under the Canadian healthcare system, and to carry out not-for-profit patient care and

[82] This condition involves irregular electrical impulses in the heart and can lead to sudden death in young adults.
[83] See generally, 'CHEO reaches 'historic' settlement with gene patent owner' *CBC News Ottawa*, 9th March 2016 available at ***http://www.cbc.ca/news/canada/ottawa/cheo-gene-patent-lawsuit-settlement-1.3483433*** . The challenge to such patents commenced on 3rd November 2014.
[84] See National Heart, Lung and Blood Institute, "Long QT Syndrome" ***https://www.nhlbi.nih.gov/health-topics/long-qt-syndrome***
[85] Behr ER, et al., 'Sudden arrhythmic death syndrome: familial evaluation identifies inheritable heart disease in the majority of families' (2008) 19 *Eur Heart J* 1670-80.
[86] ***http://www.cheo.on.ca/en/gene-patents***
[87] Sarah E. Ali Khan and Richard Gold, "Gene patents still alive and kicking: their impact on provision of genetic testing for long QT syndrome in the Canadian public health-care system" (2017) 19 *Genetics in Medicine* 1253.
[88] Sarah Khan and Richard Gold, ibid. The authors discuss in detail the difficulties posed by lack of testing in Canada prior to the CHEO case, and views of clinicians on the reasons behind the desire for local LQTS testing in Canada.
[89] See discussion of broader issues in the context of gene patenting generally in Richard Gold, Timothy Caulfield and Peter N Ray, "Gene Patents and the Standard of Care" (2002) 167(3) *Canadian Medical Association Journal* 256-7.

research'.[90] Transgenomic offered it a personal, non-exclusive, non-transferable licence to Long QT patents, for CHEO to:

(i) "Undertake or make but not to have undertaken or made Long QT Tests in the Territory;
(ii) To use the Long QT Tests undertaken or manufactured… to
    a. Conduct internal, not-for-profit research concerning Long QT Genes or their associated RNS and Polypeptides (provided that, for clarity, such research may not be carried out for commercial purposes or carried out on behalf of or for the benefit of any third party other than the patient …;
    b. Screen for mutations …
    c. Carry out diagnoses based on the screening
(iii) Advertise the screening and diagnosis services;"[91]

Three main conditions attached to the licence, in terms of what could be provided, namely: (i) the tests had to be performed and sold by CHEO at or below cost price;[92] (ii) screening services provided on research participants or patients could only be provided for residents or citizens of Canada, refugees in Canada, or those present in Canada other than for the purposes of obtaining medical treatment. This provision limits the potential for 'medical tourism' i.e. people travelling to Canada specifically to obtain cheaper genetic testing for Long QT syndrome. (iii) Tests of Long QT could only be provided following a direction or recommendation of a healthcare professional.[93] No royalty or fee was payable by CHEO for the use of the license.[94]

As noted, a further condition of the settlement was that CHEO would discontinue the legal proceedings against Transgenomic, and that it would not commence legal proceedings challenging the validity or enforceability of Long QT patents or Transgenomic's exclusive ownership of the Long QT patents or assist others in making such challenges. If CHEO commenced such legal proceedings or assisted third parties to do so, Transgenomic could terminate the licence immediately on giving notice to CHEO.[95] This clause meant that the challenge against gene patents in Canada had to be dropped as a result of their acceptance of the settlement and therefore whether isolated genes are patentable in Canada has not been resolved.

Thus, patents are still technically available on isolated genes in Canada, and there is no court decision to say patents on isolated gene are not possible. The CHEO challenge arose soon after the two successful challenges in the US and Australia, and although each jurisdiction is free to differ on whether genes are patentable, arguably given the similar nature of the arguments raised by CHEO to the Myriad cases in the US and Australia, and the similar wording of the relevant patent law statutes in Canada, it had a good chance of success. Thus, settling the case was of strategic benefit to

[90] S. 2.1.2 Settlement Agreement available at *http://www.cheo.on.ca/uploads/genetics/Gene%20patent/CHEO-Transgenomic-Settlement-Agreement-Signed-2016-03-08.PDF*
[91] Ibid, 3.1.1.
[92] Ibid, 3.2.
[93] Ibid, 3.1.1.
[94] Ibid, 3.1.3.
[95] Ibid, 3.1.4.

Transgenomic, as it prevented a definitive answer being given on gene patentability in Canada.

However, on a more pragmatic level, the agreement reached has significant benefits and it may be more, or at least as, advantageous than had the case been litigated fully even if gene patents were held invalid. Firstly, the settlement resulted in CHEO being able to test and screen for Long QT syndrome and genes for Long QT syndrome, which was the outcome it had desired. The settlement achieved this outcome without having to engage in full litigation of the claim which would have taken considerable time and financial resources. Furthermore, although it was arguably a strong case, there is no guarantee it would have succeeded. Secondly, the tailored licensing solution has broader benefits than might initially be appreciated. Alongside the licence provided between CHEO and Transgenomic, a standard licence template was also made available on CHEO's website which could be used by public hospitals and Transgenomic. This could also be rolled out for use for other genes, and the statement on CHEO's website notes that:

> "The deal defines a pathway for all public Canadian hospitals and labs to conduct genetic testing without legal roadblocks from gene patents."

Arguably, this could also be used for other genes, [96] and equally has potential as a model for use for other patentable health-related technologies. This could result in a quicker and likely less costly solution to patent issues if similar healthcare implications arise related to future technologies, where public healthcare facilities could seek to negotiate similar licences with patent holders rather than engaging in full litigation. Thus, unlike the narrowly framed judicial approaches in Myriad in the US/Australia which are confined to isolated genes, the tailored licensing approach has the potential to have generalisable benefits. It also has the potential to achieve public health outcomes in a quicker and more cost-effective manner.

However, the main downside to such licences, is that it is entirely dependent on buy-in from the patent holders and for applicants (such as public health hospitals) to seek to negotiate these types of licences. Without governmental intervention encouraging or incentivising such licensing approaches, it would be up to the patent holder to decide whether to agree to such licences and on what terms. Patent holders could place onerous burdens on hospitals or others seeking to use patented technology. Moreover, much would also depend on the terms of the licences, as for example, patent holders could draft them in ways which would allow them to revoke the licence. Furthermore, in cases like Long QT which involve rare disease, the reputational damage a patent holder might suffer for not agreeing to a licence may be greater than any potential profits it may make given the limited number of tests likely to be carried out. However, this may not be true for other genes or other patented technologies which may reduce the likelihood of patent holders voluntarily agreeing to such licences. Issues might also arise in terms of research, as depending on the terms of the licence, if it excluded use for research for commercial purposes, this may still restrict research on the patented invention or related

[96] Khan and Gold note that: "The CHEO agreement offers the potential to alter this landscape, but only if governments are proactive in their support of public health-care-system stakeholders." Sarah Khan and Richard Gold, "Gene patents still alive and kicking: their impact on provision of genetic testing for long QT syndrome in the Canadian public health-care system" (2017) 19 *Genetics in Medicine* 1253.

inventions. This is because if the intention is to produce a follow-on or improved healthcare product for commercial market, researchers arguably would fall foul of such conditions, or may not wish to risk this.

Thus, whilst tailored licensing solutions offer potential to address healthcare implications of patents, much would depend on how they are drafted and implemented and on their uptake by patent holders in other contexts or other jurisdictions. For this reason, to offer an effective means to address health-related implications of patents on genes and other biotechnologies, a stronger voice or power to negotiate such licences must be given to stakeholders such as hospitals and patients likely to be affected by such patents.[97] One way to do this, as noted by Khan and Gold is to encourage greater governmental intervention in the field.[98] For example, governments could help encourage or where needed force patent holders, who are deemed to be unreasonably refusing patent licences or charging high prices for these, to engage with licensing similar to the CHEO approach within the public health context. This would help shifting the asymmetry of power currently evident between patent holders and those affected by patents. As Khan and Gold suggest, if patent holders unreasonably failed to negotiate a patent for use of the technology for a public health purpose, recourse could be given to applicant to seek compulsory licences.[99] To give further teeth to such provisions should they be considered in other jurisdictions, guidelines could also be provided in how to negotiate licences in such context and the circumstances where compulsory licensing would be granted by governments outside of Canada if licensing where refused. Standard form licenses detailing model terms for use in public health context could also be drafted, as examples for use by industry. Arguably, agreeing to voluntary licensing measures may be more appealing to patent holders than compulsory licensing as they still leave much control to patent holders, and for example, the CHEO model would still allow profit to be made in the private health context. Thus, they offer a useful middle ground solution.[100]

Part III: Moving outside Patent Law: Giving a Voice to Stakeholders

In terms of why such licensing approaches are likely more effective in the short term to addressing the potential healthcare implications posed by patents than legal challenges patents, as has been seen, in each jurisdiction, a presumption favouring the narrow technical application of patent criteria applies and cases are decided on this, rather than on health-related grounds. This means that as technologies develop posing similar health-related implications new challenges are needed each time to assess patentability. However, alongside the failure of patent law to substantively engage with the healthcare

[97] See Sarah E Khan and Richard Gold, "Contracting to counter gene patents – a 21st Century solution to access and innovation" (22 May 2017, *Petrie Flom Blog*) available at *http://blog.petrieflom.law.harvard.edu/2017/05/22/contracting-to-counter-gene-patents-a-21st-century-solution-to-access-and-innovation/*

[98] Ibid.

[99] This argument is put forward by Sarah Khan and Richard Gold who argue in favour of a role for provincial governments in Canada to take the first steps in this context. See Sarah E Khan and Richard Gold, "Contracting to counter gene patents – a 21st Century solution to access and innovation" (22 May 2017, *Petrie Flom Blog*).

[100] See also Naomi Hawkins, "A red herring: invalidity of human gene sequence patents" (2016) 38(2) *European Intellectual Property Law Review* 83 who discusses potential to using licensing as a more nuanced approach to denial of patents in such contexts.

implications of patents, another reason for looking outside patent law for solutions to such issues stems from the problems with the current approaches for challenging patents which makes successful patent challenges difficult, time consuming, and often unlikely to be sustained.

Three key issues arise in this context. First, patent law is extremely expensive litigation to take,[101] and can last a considerable amount of time. Notably, all of the judicial challenges to gene patents examined in this article, in Canada, United States and Australia were led by pro-bono legal teams.[102] This level of commitment to challenging the healthcare implications of patents is laudable.[103] However, it is may be difficult to find such groups or individuals who are willing and able to provide their time and skills on a pro-bono basis to object to such patents. Moreover, even when a group like this can be brought together, a further challenge is whether such groups can match the time and financial resources of patent holders, often large corporations with deep financial pockets to sustain patent litigation. This is also not just an issue for gene patents, it implicates patents on all health-related biotechnologies.

Second, and relatedly, even if patentability is questionable, patent holders may still try to enforce or to threaten patent infringement if others choose to ignore what they argue is covered by their patents. And because patent holders have deeper financial resources, a threat to litigate may be enough to stop others carrying out the 'alleged infringing activity' and patents may go unchallenged, or the patent holder may be able to delay proceedings or appeal, thereby extending the time for the patent, or driving up costs of litigation to the point that the challenger may have to settle or halt litigation.

Third, and mostly importantly, issues are exacerbated in the context of patents on health because actors likely to be affected by such patents and to challenge them are patients who may have limited resources, or hospitals. Hospitals have limited budgets which must be managed carefully to deal with patients' medical needs. Using a significant sum of money in patent litigation would reduce such overall hospital funds for other patients and arguably, this would be extremely difficult to justify for any public health facility. Hospitals may also be affiliated with universities, who themselves may have patents on similar technologies, and hence permission to initiate litigation may not be granted, if there is a conflict of interest.

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[101] For example, see: James Bessen; Michael J. Meurer, "The Private Costs of Patent Litigation" (2012) 9 J.*L. Econ. & Pol'y* 59; for a discussion on the European context see: K. Cremers, M. Ernicke, F. Gaessler, et al., "Patent Litigation in Europe" (2017) 44(1) *Eur J Law Econ* ; For a discussion of the UK see: Helmers, C., & McDonagh, L. "Patent litigation in England and Wales and the issue-based approach to costs" (2013) 32(3) *Civil Justice Quarterly* 369.

[102] In Canada by Gilberts LLP, Prof Richard Gold and his research team, and pro-bono scientific experts; in the US the challenge was led by ACLU and multiple scientific/healthcare practitioners challengers; and in Australia by Maurice Blackburn lawyers providing pro-bono assistance, together with financial support from Cancer Voices Australia and Yvonne D'Arcy's who used own personal finances.

[103]For example, in the CHEO case, the lawyers for CHEO acted on a pro-bono basis and devoted "their time, unpaid, to administer the case from beginning to end." The lawyers also secured commitment from scientists to provide expert testimony on a pro-bono basis, and the team worked on the case with Prof Richard Gold, McGill University and his research team, supported by a Genome Canada, Genome Alberta and Genome Quebec grant. Statement of 'Gilbert LLP: Breaking the Gene Patent Barrier' available at *http://www.cheo.on.ca/uploads/genetics/Gene%20patent/Lawsuit%20backgrounder_FINAL.pdf*

For these reasons, once granted, patents are difficult to challenge because such challenges are often highly time-consuming and resource intensive.[104] This in turn means that legal challenges have a limited correctional effect in such contexts.

Part IV. Conclusion

This article has sought to demonstrate that gene patent challenges in Canada, Australia, the US, and Europe, have been driven by concerns related to healthcare implications of such patents. Despite this, these jurisdictions, have failed to engage with such healthcare implications in a meaningful way when challenges are brought within patent law. The only exception to this is Canada, where solutions outside patent law, via licensing, have been devised specifically to deliver access to technologies under patent by focusing on the public health issues at stake, in a manner that could be used for other technologies, by other entities and in other jurisdictions.

Such licensing approaches arguably offer a more meaningful solution from a public health perspective than the technical patent law interpretations offered within the US and Australian in the Myriad cases. This is because in the US and Australia although patents are no longer available on isolated genes which is undoubtedly an important achievement, however, this does not have broader applicability for patents on future technologies raising healthcare concerns. Under such judicial approaches, new cases need to be taken for each new type patented technology which will be both time and resource intensive. Similarly, such licensing solutions are preferable to the current approach within European law. This is because although European law contains exclusions from patentability which could be used to limit patents on technologies with healthcare implications, these are interpreted narrowly in practice. A gap between patent law and health concerns is evident, and the two areas continue to speak past but not to each other. Hence, solutions outside patent law are warranted.

Put simply, at a substantive level patent law appears institutionally configured to adopt technical interpretations of exclusions from patentability, rather than engage with the broader health-related issue at stake. Moreover, power asymmetries within the current systems mean that stakeholders affected by patents on health-related technologies are likely to have less resources to challenge these than patent holders will have to defend them, which makes the likelihood of successful challenges rare. As technologies develop and we enter the fields of personalised medicines and whole genome sequencing, the potential healthcare implications of patents on biotechnologies are likely to increase. Patent law is failing to engage with such issues, and this lends further credence for the need to consider solutions outside patent law.

In short, unless and until we are not going to adopt fundamental institutional change within patent law, it behoves us to take seriously and devise appropriately, solutions outside patent law to address the potential healthcare implications of patents. For such reasons, at a practical level, the solution offered by tailored licensing approaches in the

[104] EPO Opposition Division proceedings in Europe are a useful alternative for anyone to raise an objection to European patents, however, such proceedings can only be brought within a limited time of the patent being granted which may not allow enough time for the health-related issues to come to light.

Canadian context, although not without shortcomings, is arguably a preferable solution in the short term. Such approaches should be taken seriously in other jurisdictions.