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An Analysis of the Obstacles Faced

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Abstract

Legal challenges are an important element of the regulation of gene patents (e.g. *Consumer Watchdog v Wisconsin Animal Research Fund*), yet successful challenges are rare. The difficulties faced by the public, notably procedural and substantive legal barriers, when seeking to invalidate patents are understudied from a doctrinal and socio-legal perspective. The contribution of this thesis is to address this gap in knowledge by investigating those barriers through a theoretically informed doctrinal and empirical perspective. The doctrinal case study of the legal challenges to BRCA patents held by *Myriad* in the United States, Australia, and at the European Patent Organisation identifies initial procedural barriers to gene patent challenges, and substantive barriers resulting from judicial interpretations of patent eligibility criteria. The consequent empirical study, informed by 12 interviews with key actors involved in challenging the BRCA patents, identifies further substantive institutional, and cultural hurdles which limit the public's ability to identify, understand, and successfully challenge such patents. This raises questions about the effectiveness of previously identified mechanisms to increase public engagement with the patent system, including improving access to patent information and relaxing procedural rules; and identifies the difficulties in creating cohesive, consistent coalitions to represent the public interest in the patent system.

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Author's Declaration

I declare that the work in this dissertation was carried out in accordance with the requirements of the University's Regulations and Code of Practice for Research Degree Programmes and that it has not been submitted for any other academic award. Except where indicated by specific reference in the text, the work is the candidate's own work. Work done in collaboration with, or with the assistance of, others, is indicated as such. Any views expressed in the dissertation are those of the author.

SIGNED: DATE: 09/08/2021

Contents

List of Appendices

Commonly Used Acronyms

ACIP	Advisory Council of Intellectual Property
ACLU	American Civil Liberties Unions
ALRC	Australian Law Reform Commission
AMP	Association for Molecular Pathology
CRUK	Cancer Research UK
EBA	Enlarged Board of Appeal
EPC	European Patent Convention
EPO	European Patent Office
ESA	Endangered Species Act
GTG	Genetic Technologies Inc
IBC	International Bioethics Committee
IP	Intellectual Property
IPCRC	Intellectual Property and Competition Review Committee
OD	Opposition Division
PA 1990	Patents Act 1990 (Australia)
PR 1991	Patent Regulations 1990 (Australia)
TBA	Technical Boards of Appeal
USPTO	United States Patent and Trademark Office
USSC	United States Supreme Court
WIPO	World Intellectual Property Organisations

Key Patents cited

Europe

EP0705902	(17q Linked Breast and Ovarian Cancer Susceptibility Gene)
EP0705903	(In vivo mutations and polymorphisms in the 17q-linked breast and ovarian cancer susceptibility gene)
EP0699754	(Method for diagnosing a predisposition for breast and ovarian cancer)
EP0785216	(Chromosome 13 linked Breast Cancer Susceptibility Gene BRCA2)

United States

US5747282	(17Q-linked breast and ovarian cancer susceptibility gene)
US5837492	(Chromosome 13-linked breast cancer susceptibility gene)
US5693473	(Linked breast and ovarian cancer susceptibility gene)
US5709999	(Linked breast and ovarian cancer susceptibility gene)
US5710001	(17q-linked breast and ovarian cancer susceptibility gene)
US5753441	(170-linked breast and ovarian cancer susceptibility gene)
US6033857	(Chromosome 13-linked breast cancer susceptibility gene)

Australia

AU691,331	(Method for diagnosing a predisposition for breast and ovarian cancer)
AU691958	(17q-linked breast and ovarian cancer susceptibility gene)
AU686004	(In vivo mutations and polymorphisms in the 17q-linked breast and ovarian cancer susceptibility gene)
AU773601	(Chromosome 13-linked breast cancer susceptibility gene)

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Shell Oil Co v Amoco Corp 522 F.2d 33 (1975).

Universal Oil Products v Globe Oil & Refining 322 U.S. 471(1994).

Europe

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Case C-34/10, *Oliver Brüstle v Greenpeace*, ECLI:EU:C:2011:669

G0002/13 *Plant Bioscience Limited* of 25.03.2015, ECLI:EP:BA:2015:G000213.20150325

G0009/03 *(Opposition by Patent Proprietor)* of 6.7.1994 ECLI:EP:BA:1994:G000993.19940706

T0080/05 *(Method of diagnosis/UNIVERSITY OF UTAH)* of 19.11.2008 ECLI:EP:BA:2008:T008005.20081119

T0080/05 *Method of diagnosis/University of Utah*, of 19.11.2008 ECLI:EP:BA:2008:T008005.20081119

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T0356/93 *Plant Genetic Systems N.V., et al* (Plant cells), Board of Appeal (EPO) of 21.02.1995ECLI:EP:BA:1995:T035693.19950221

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UK

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*D'Arcy v Myriad Genetics Inc [*2014] FCAFC 115.

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Joos v Commissioner of Patents [1972] HCA 38.

Meat and Livestock Australia Limited v Cargill, Inc (2018) 354 ALR 95.

National Research Development Corporation v Commissioner of Patents [1959] HCA 67.

Smith Kline & French Laboratories (Aust) Ltd v The Commonwealth [1991] HCA 43.

Chapter 1: Setting the Scene

1.1 Introduction

"You, or someone you love, may die because of a gene patent…Gene patents are now used to halt research [and] prevent medical testing…"[1]

This thesis asks: what are the barriers faced by the public in seeking to challenge the validity of gene patents which stand in the way of public access to diagnosis and treatment? Gene patents – and the legal challenges against their grant - have attracted a significant amount of discussion and debate following an explosion in patenting activity in the 1980s.[2] This chapter outlines what this research adds to this discussion. The first part of this chapter sets out the background, and outlines the research questions. The second part describes the methodological approach and the socio-legal approach to the study. The third part sets out the scope and limitations of this research, along with the contribution of the thesis. This chapter concludes with an outline of the thesis.

1.2 Background to the Research

Before discussing the background to this research, it is worth briefly defining what is meant by a gene patent. The term gene patent can be used to refer to a wide range of patent claims.[3] Here, the term is used to refer to any patented invention which claims isolated DNA. Mutations in DNA sequences are responsible for genetic diseases, such as Alzheimer's and certain forms of cancer. Research into these genetic diseases for diagnosis and treatment are costly, and patents can provide an important economic incentive to invite investment.[4] Patents, which grant a twenty-year exclusionary right, provide this incentive by granting a temporary monopoly over a

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1 Crichton, M. 'Patenting Life' New York Times: (Feb 13th, 2007) available at https://www.nytimes.com/2007/02/13/opinion/13crichton.html (accessed April 2018).

2 Cook-Deegan, R. and Heaney, C. 'Patents in Genomics and Human Genetics' (2010) Annual Review of Human Genetics 11: 283–425.

3 "The term "gene patent" has been used to refer to a wide range of different patent claims. A single gene can have multiple patents. And a single patent can have dozens of claims….the controversy around gene patenting has centred primarily on composition claims on isolated, but otherwise unaltered, human genomic DNA, because these claims have the effect of covering any and all uses of the isolated DNA molecule (Simoncelli, T. and Park, S. 'Making the Case Against Gene Patents' (2015) Perspectives on Science 23(1): 106 – 145 at 111). See also Merz, J. and Cho, M.K. 'What Are Gene Patents and Why Are People Worried About Them?' (2005) Public Health Genomics 8(4): 203–208. To be awarded a patent, inventions need to meet patentability criteria which include that a patent is new (or novel), inventive (or not obvious), and has industrial application. There is significant variance in how these criteria are interpreted in different jurisdictions. See Sections 3.3 (Europe); 4.4.1 (US) and 5.3 (Australia). The use of the term 'gene patent' in this research refers to patents which claim the isolated DNA.

4 Section 2.2.1.

claimed invention. In the 1980s and 1990s there was a "land rush" of research, spurred on by technological advancements in computing and bioinformatics which led to significant breakthroughs in the diagnosis and treatment of such genetic diseases. But, linked with these breakthroughs, were concerns over the commercialisation of science and the adverse impact of patents on access to data, research and genetic tests. Concerns about the implications of the monopolies fuelled several attempts to legally challenge the validity of gene patents by NGOs and public interest groups. As Plomer states:

> *"Some of the most significant legal cases this century have centred on controversial patents granted to individual scientists, university spin-offs, and for-profit organizations over scientific breakthroughs that have the potential to revolutionise the diagnosis and treatment of crippling diseases".*[5]

Perhaps the most well-known example of these cases are the challenges to Myriad's patents in the US, Australia, and Europe. A more detailed history of the BRCA challenges is provided in Chapters 3 – 5 to provide context to the analysis of the decisions made in each jurisdiction. This section therefore only briefly describes the history of Myriad's BRCA patents and its challenges. This provides context to identify the gap in the literature this research fills.

1.3 Why Study the Challenges to the BRCA Patents?

There have been several public interest challenges to patents.[6]This research uses the legal challenges to Myriad's BRCA patents to investigate the barriers faced when challenging gene patents. This begs the question: why study these challenges? This section answers this question by discussing the background to the grant of the BRCA patents and explains the justification for their use as a lens through which to analyse barriers to public interest challenges.

Ground breaking familial studies in the late 1980s discovered that mutations within the BRCA gene are responsible for hereditary breast and ovarian cancers.[7] In 1990 Dr Mary Claire King and her team at the University of California found that mutations within chromosome 17q21 of the human genome were responsible for this genetically inherited risk of breast cancer.[8] Carriers of this gene are at a significantly increased risk of developing breast or ovarian cancer,

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5 Plomer, A. *Patents, Human Rights and Access to Science* (Edward Elgar, 2015) at 1.

6 For example, Consumer Watchdog v Wisconsin Animal Research Foundation 753 F.3d 1258 (2014); Organic Seed Growers and Trade Association et al. v Monsanto 718 F.3d 1350 (2014); T0019/90 Onco-Mouse/Harvard (EPO) of 03.10.1990 ECLI:EP:BA:1990:T001990.19901003. The conceptualising of the public interest in patents is explored further in Chapter 2.

7 The term BRCA is an initialisation of "Breast Cancer".

8 Hall, J.M. *et al.* 'Linkage of Early-Onset Familial Breast Cancer to Chromosome 17q21' (1990) Science 21 (250): 1684-1689.

and face serious decisions about whether to undergo life changing medical procedures to avoid, or survive, a cancer diagnosis. Dr King's findings spurred an international race to locate and isolate the BRCA genes. In 1994 Dr Mark Skolnick's team at the University of Utah announced in *Science* that they had won this race.[9] An application for a US patent claiming the isolated gene was filed shortly before publication.[10] In the following years, Myriad Genetics – Dr Skolnick's spin-off biotechnology company – filed for a number of other US patents claiming the isolated BRCA1 and BRCA2 genes, methods for diagnosing an inherited risk of breast cancer, and a synthetic form of DNA called cDNA. Similar patents were granted in other jurisdictions, including Europe and Australia. Myriad enforced its rights aggressively and became the sole provider of BRCA testing in the US; a position they sought to replicate in other jurisdictions.[11]

Whilst the isolation and patenting of genes responsible for inherited disease is not unique to Myriad, the backlash against the company for BRCA patents was particularly intense.[12] Scientists were surprised and angry that Myriad had been able to obtain a patent over the isolated BRCA gene. Finding the location of the gene had been an international collaborative effort with several laboratories, and many argued that a private company should not have exclusive rights to that knowledge.[13] Myriad's patents also raised significant concerns about access to the BRCA gene for patients and researchers. There was evidence that women were denied access to testing, that the available tests were inaccurate, and that Myriad's patents blocked ongoing research into the BRCA genes.[14]

These concerns eventually drove a series of legal challenges to the validity of Myriad's patents in Europe, the US, and Australia. The challenges were driven by groups of patients, NGOs,

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9 Miki, Y. *et al.* 'A Strong Candidate for the Breast and Ovarian Cancer Susceptibility Gene BRCA1' (1994) Science 7 (266): 66-71.

10 US Patent 5710001A. The reason for this timing is due to the legal criteria that an invention must be new or novel to be granted patent protection. This standard includes information about the invention not being published prior to the patent application.

11 Parthasarathy, S. 'The Patent Is Political: The Consequences of Patenting the BRCA Genes in Britain' (2005) Public Health Genomics 8(4): 235–242.

12 Other biotechnological companies had also patented genes responsible for diseases including Alzheimer's, Long QT Syndrome, colon cancer, and deafness. See in Secretary's Advisory Committee on Genetics, Health and Society, *Report on Gene Patents, Licencing Practices and Their Impact on Patient Access to Genetic Tests* (2010) for a review of patents over genes in the US. Myriad were not the only company to hold patents over the BRCA genes. OncorMed were initially granted patents claiming some BRCA1 mutations, which were given to Myriad in the settlement of an infringement dispute. See Van Zimmeren, E. *et al.* 'The BRCA Patent Controversies: An International Review of Patent Disputes' in Gibbon, S. *et al. Breast Cancer Gene Research and Medical Practices* (Routledge 2014) at 160.

13 Myriad had initially worked closely with Cancer Research UK, although the collaboration ceased following a dispute over whether or not to patent the BRCA gene.

14 For a discussion see Sections 3.2; 4.2.1; and 5.2.

professional organisations, scientists, researchers, and advocates who believed that the effects of the BRCA patents were harmful to the public. These were significant. Through litigation in the US and Australia, the challenges were successful not only in invalidating the BRCA patents, but also in overturning a 30-year practice of granting patents over genes. In Europe, through the European Patent Office (EPO) opposition procedure, the challenges significantly narrowed the scope and application of the BRCA patents. In doing so, the importance of the public interest in the grant of patents was asserted. As Simoncelli, a member of the ACLU bringing the US litigation notes:

> "*The case succeeded in bringing to the forefront a more holistic understanding of how improperly issued patents can harm people and innovation by giving voice to the full range of legal and policy arguments against gene patenting*."[15]

Such successful challenges are rare. Various groups have attempted to bring challenges against other controversial patents but were unsuccessful, often due to legal procedural barriers.[16] The challenges to Myriad's patents were almost similarly fated.[17] This research is therefore inspired by understanding and analysing the challenges faced by public interest groups to bringing gene patent challenges. The legal challenges provide the lens through which the research question is answered.

1.4 Relationship To Existing Literature

There is voluminous literature in this area. Both gene patents and the Myriad challenges have been extensively discussed, debated and analysed. Given the breadth of literature, this section addresses the question: what does this research contribute to the field? This section outlines the existing literature in three areas: existing literature on gene patents, the impact of the Myriad challenges, and the existing literature on the challenges themselves.

The grant of gene patents is controversial. There have been several national and regulatory reports into whether gene patents inhibit innovation and patient access.[18] These reports have

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15 Simoncelli and Park *supra* n.3 at 141.

16 See, e.g. *Consumer Watchdog v Wisconsin Animal Research Fund* 753 F. 3d 1258 (Fed. Cir. 2014).

17 The US challenge, for example, was nearly prevented from progressing due to procedural limits to standing. See Section 4.3.

18 Secretary's Advisory Committee on Genetics, Health and Society, *Report on Gene Patents, Licencing Practices and Their Impact on Patient Access to Genetic Tests* (2010); Community Affairs References Committee for the Commonwealth of Australia, *Gene Patents* (2010); Nuffield Council on Bioethics, *Ethics of Patenting DNA*; 2); International Bioethics Committee "Report of the IBC on Ethics, Intellectual Property and Genomics" July 2002; Nicol, D. and Nielsen, J. 'Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing The Australian Industry' (2003) Centre for

resulted in recommendations but have had limited policy impact.[19] There are also a broad range of academic studies including: empirical assessments analysing whether gene patents have impacted the development of diagnostic testing and patient access;[20] the ethical and moral implications of granting gene patents[21]; studies analysing gene patents and the right to health[22]; and doctrinal analyses of the patentability of gene patents.[23]

The Myriad decisions have similarly been extensively studied. Such studies have focused on: the doctrinal significance of the Myriad decisions for gene patents[24]; the impact of the decisions on the grant of patents and patenting behaviour[25]; analyses of whether the decisions have alleviated the access concerns which drove the challenges; [26] and the international divergence in

Law and Genetics Occasion Paper No.6; Intellectual Property and Competition Review Committee, 'Review of intellectual property legislation under the Competition Principles Agreement' (2000); Advisory Council on Intellectual Property, 'Patentable Subject Matter' (2010).

19 For example, the Secretary's Advisory Committee on Genetics, Health and Society, *Report on Gene Patents, Licencing Practices and Their Impact on Patient Access to Genetic Tests* in 2010 had several recommendations, including statutory exemptions to infringement for the development therapeutic applications for genetic disease and additional expert support to the USPTO. None of these recommendations brought about any significant policy change, despite the broad public interest issues, and the SACGHs committee were disbanded soon after. SACGHS was disbanded in 2011, see National Institute of Health Website, available https://osp.od.nih.gov/scientific-sharing/secretarys-advisory-committee-on-genetics-health-and-society-archives/ (accessed April 2018).

20 Section 6.2.

21 For example, Constand, S. 'Patently a Problem – Recent Developments in Human Gene Patenting and Their Wider Ethical and Practical Implications' (2013) QUT Law Review 13(1) 100-125; Soini, S. et al 'Patenting and Licensing in Genetic Testing: Ethical, Legal, and Social Issues' (2008) European Journal of Human Genetics 16: 10-50.

22 Aurora Plomer, *Patents, Human Rights and Access to Science* (Edward Elgar, 2015); Donders, Y 'The Right to Enjoy the Benefits of Scientific Progress: In Search of State Obligations In Relation To Health' (2011) Medicine, Health Care and Philosophy 14(4): 371-381.

23 See sections 3.3 (EPO); 4.4 (US) and 5.4 (Australia).

24 For example, see: Gay, R. and Gumley, T. 'Patents: D'Arcy v Myriad Genetics: What Next for Gene Patents in Australia' (2015) 18 Law Society of NSW Journal 70–72; Nicol, D. 'Myriad Genetics and the Remaining Uncertainty for Biotechnology Inventions' in Charles Lawson and Berris Charnley (eds), *Intellectual Property and Genetically Modified Organisms: A Convergence in Laws* (Ashgate 2015) Shikora, M. '*Mayo* and *Myriad*, and a muddled Analysis: Do Recent Changes to the Patentable Subject Matter Doctrine Threaten Patent Protections for Epigenetic Based Inventions?' (2018) Minnesota Law Review 102(5): 2229-2264.

25 See, for example, Aboy, M. et al. 'How Does Emerging Patent Case Law in The US and Europe affect Precision Medicine?' (2019) Nature Biotechnology 37: 1118-1126; Aboy, M. et al. 'Myriad's Impact on Gene Patents' (2016) Nature Biotechnology 34(11): 1119-1123; Evans, J. B. 'Mining the human genome after Association for Molecular Pathology v. Myriad Genetics.' (2014) Genetics in Medicine 16(7): 504.

26 Nicol, D. Nielsen, J. and Dawkins, V. 'D'Arcy v Myriad Genetics: The Impact of the High Court's Decision on The Cost of Genetic Testing in Australia' (2018) Centre for Law and Genetics Occasion Paper 9 : 1-101.

the patentability of genes as a result of the decisions.[27] There are also a number of studies which explore the challenges themselves, including: case studies outlining the challenges and the social and political context which drove them;[28] and commentary from the challengers themselves.[29] These discussions focus on why the challenges were brought, the strategies for bringing the claims, and the experiences in doing so.

Notwithstanding the breadth of the above, the legal challenges to Myriad's patents are under studied from an empirical and socio-legal perspective. Specifically missing from the current literature is a study of the barriers faced by the challengers in attempting to invalidate Myriad's patents. Some studies do identify some of the difficulties faced by the challengers – such as those arising from standing. However, there is not a systematic consideration of the barriers faced. This research aims to fill this gap.

1.5 Research Questions and Methodology

Given the current literature outlined above, the overarching research question of this thesis is: what are the barriers faced by the public in seeking to challenge the validity of gene patents which stand in the way of public access to diagnosis and treatment? This question is divided into several sub-questions:

- What, if any, are the procedural barriers to bringing gene patent challenges?
- What, if any, are the substantive barriers to bringing gene patent challenges? Are there any barriers as a result of the judicial interpretation of the patentability criteria and exceptions?
- What, if any, are the institutional and cultural barriers?

In line with the socio-legal approach to this research, the definition of 'barriers' is a broad one. This research does not seek to identify only legal barriers, but the socio-economic, cultural, institutional, and structural obstacles to challenging patents. Whilst the challenges to gene patents have received a significant amount of scholarly attention, they are understudied from an

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27 Nicol, D. et al. 'International Divergence in Gene Patenting' (2019) Annual Review of Genomics and Human Genetics (2019) 20: 519 – 541. See also Liddell, K. *et al.* 'Should We Change EU Law to Disallow DNA Patents?' (2016) Available at SSRN: https://ssrn.com/abstract=3102238 or http://dx.doi.org/10.2139/ssrn.3102238

28 These studies feed into the contextual discussions of each chapter. See Sections 3.2 (EPO); 4.2.1 (US) and 5.2.1 (Australia).

29 *Ibid.*

empirical and socio-legal perspective. Socio-legal studies is not easily defined,[30] however can be viewed as:

> "*the examination of how law, legal phenomena, and/or phenomena affected by law and legal system occur in the world, interact with each other and impact those who are touched by them. The 'socio' is about the societal context or impact of law and legal phenomena, rather than law in books. The 'legal' is more broadly defined than the text of law*."[31]

In combining a doctrinal analysis and empirical interviews, this research aims to examine the barriers faced by the challenges beyond that which is written in the statutes and treaties which create and regulate patent systems. In doing so, it aims to gain a deeper understanding of how the challengers experienced the function of patent law.

To answer these research questions, a hybrid method is used, combining comparative doctrinal legal analysis and semi-structured interviews with the participants who were involved in challenging gene patents.[32] The overall approach is theoretically informed by the socio-legal perspective articulated in Drahos' extensive empirical study into the global governance of patent offices.[33]

Given the above, to answer this question, this research aims to

- Complete a doctrinal analysis of the legal challenges to Myriad's BRCA patents to identify procedural barriers, or barriers arising from the judicial interpretation of the patentability criteria and exceptions;
- Critically analyse the findings from interviews with those involved in the BRCA challenges to understand what barriers they experienced and identify extra-legal barriers to patent challenges;
- If there are barriers, identify areas for reform to facilitate future public interest challenges to patents.

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30 Creutzfeld, N. 'Traditions of Studying the Social and The Law' Project' in Creutzfeld, N., Masson, M., and McConnachie, K. *Routledge Handbook of Socio-Legal Theory and Methods* (Taylor & Francis 2019).

31 Webley, L. 'The Why and How to Of Conducting A Socio-Legal Empirical Research Project' in Creutzfeld, N., Masson, M., and McConnachie, K. *Routledge Handbook of Socio-Legal Theory and Methods* (Taylor & Francis 2019). Although this chapter focuses on empirical research, socio-legal studies does not necessarily have to be empirically driven. See Creutzfeld, N. 'Traditions of Studying the Social and The Law' in the same collection.

32 The theoretical framework of the thesis is outlined in Chapter 2. The empirical methodology is outlined in Chapter 6.

33 Drahos, P. *The Global Governance of Knowledge: Patent Offices and Their Clients* (2010) Cambridge University Press.

1.6 Original Contribution

As the discussion of the existing literature shows, there are studies carried out in a number of related areas. However, none of these studies have conducted a systematic review into the barriers faced by public challenges to patents. This thesis therefore offers an original contribution to the field, particularly in the generation of empirical interview data. Where barriers to patent challenges have been identified, these tend to be doctrinal in nature. As such, the combination of comparative doctrinal research with an empirical arm to identify and analyse the barriers to patent challenges is also original.

1.7 Outline of the Thesis

This research is split into four parts:

Part I (Chapter 2) outlines the most commonly used justifications for the grant of patents, focusing on the social-contract justification. The social contract argues that patents spur socio-economic benefits through the incentivising of innovation and the disclosure of inventions which would otherwise be kept secret. These benefits are intended to balance the public interest and the powerful exclusionary rights granted to patent holders. This chapter will show, however, that there is unclear evidence to support either of these claims. An analysis of the research into the innovation incentive of the patent system will demonstrate that there is not a definitive conclusion on whether patents achieve this aim. The chapter will also show that poor enforcement of the disclosure standard has tilted the balance of the social contract in favour of the patent holder, thus obscuring the public interest in the patent system. Drahos' empirical work into the global governance of patent offices is discussed as a jumping off point for the doctrinal and empirical research into barriers to gene patent challenges.

Part II (Chapters 3 – 5) presents the comparative doctrinal study of the challenges to Myriad's BRCA patents in Europe, the United States (US) and Australia. Chapter 3 critically analyses the opposition proceedings at the European Patent Office (EPO) against Myriad's patents. This chapter describes the quasi-judicial procedure through which a coalition of researchers, scientists, and professional organisations challenged three of the European BRCA patents and analyses the decisions by the Technical Board of Appeals (TBA) – a body within the EPO itself. This chapter will show that, whilst there are relatively low procedural bars to bringing oppositions at the EPO, there remain significant barriers to public challenges to patents as a result of the substantive interpretation of the patentability criteria and exceptions. Chapter 4 analyses the American Civil Liberties Union (ACLU) led litigation against the BRCA patents in the US. This will show that the invalidation proceedings were nearly prevented from

progressing as a result of the substantive interpretation of the harm required to demonstrate standing. This chapter also demonstrates how the courts applied the judicially created exceptions under s.101 USC 35 to find Myriad's BRCA1 patent invalid as a "product of nature" and thus not patentable subject matter. Chapter 5 analyses the litigation against Myriad's patents in Australia. This chapter describes how *D'Arcy v Myriad* was led by activists, patients, and a patient organisation and analyses the barriers in doing so. This chapter shows that, even where there are low procedural barriers with fewer legally substantive restrictions, challengers continued to face barriers to bringing litigation. This analysis will demonstrate how courts can facilitate a consideration of the public interest, and the difficulties faced in the subsequent enforcement of this consideration.

The context provided in Chapters Three to Five demonstrate that there are procedural and substantive barriers to public interest challenges to gene patents which would benefit from further empirical exploration. Part III (Chapters 6 – 7) details the empirical arm of this research. Chapter 6 sets out the methodology used in the empirical arm of the study including the benefits of semi-structured interviews, the limitations faced by the methodological approach, the sampling technique, and the interview schedule. Chapter 7 presents the data from the interviews and a discussion of the key findings. One such finding is that there are formidable barriers to a member of the public bringing gene patent challenges. The findings indicate that such barriers stem from an epistemic network of patent holders, patent professions, and the judiciary which shape the application and interpretation of the legal rules and standards of patents. The implications of these findings and recommendations are discussed in Chapter 8. The final part (Chapter 9) concludes this thesis, highlighting the main themes of this research and suggesting areas for further research.

This thesis makes a significant and original contribution to knowledge surrounding patent challenges by, for the first time, systematically interrogating the barriers faced by public interest challenges to patents. It does by using a theoretically informed mixed doctrinal and empirical study.

Chapter 2: Justifying the Grant of Patents

2.1 Introduction

This chapter reviews the most common justifications for IP rights and sets out the theoretical framework underpinning the comparative and empirical research in the second part of the thesis. The first section examines economic justifications whereby patents are claimed to create social and economic benefits through the incentivising of innovation and the disclosure of the invention. The chapter questions whether the patent system achieves these benefits, by reviewing the research into whether patents incentivise innovation.

The next section examines the idea of the "patent bargain" wherein patents are purported to be a *quid-pro-quo* between inventor and the public in which the former receives exclusionary rights in return for the public disclosure of the invention. The review highlights various problems with the standards of disclosure, indicating that the current system is tilted in favour of the patent holder, obscuring the public interest supposedly central to the justification of granting such powerful economic rights. The next section illustrates this patent holder tilt in the controversies over gene patents and their resolution in the 1990s. It examines how public, moral and ethical arguments against gene patents struggled to gain legitimacy against the private interests of patent holders and companies.

The second part draws on Drahos' social contract theory and empirical research to explain the tension between public and private interests in the patent system and open the way for an alternative normative approach to patent governance. Drahos empirical survey of patent offices' practices suggests that patent offices have abdicated their responsibilities to the public in patent governance. Drahos' findings explain how the functioning of patent offices and the 'insider' relationship with their clients results in the balance being tipped too far in favour of the patent holder. Drahos' social contract theory presents an alternative framework to resolve the tension between public and private interests in the governance of the patent system. The last section outlines how Drahos' research could be taken further, beyond patent offices to analyse the role played by courts in addressing the balance between private and public interests in the patent system.

2.2 Social and economic justifications for patents

The dominant justification for patents today is economic.[34] Patent advocates argue that patents incentivize innovation and in so doing produce social and economic benefits which outweigh the costs of temporary monopolies. The incentive to innovate was stated by Lord Neuberger in *Eli Lilly and Company v Human Genome Sciences Inc* when, in determining the validity of a patent covering gene sequences, held that "it is worth remembering the purpose of the patent system, namely to provide a temporary monopoly as an incentive to innovation" as a justification for validity of the patent in question.[35] Patents encourage innovation by offering a protection against the risks of inventing. Inventions require investing time, money, and effort which may not be recouped if the subsequent product was free for anyone to copy and sell, potentially undercutting the initial inventor. The lack of ability to recoup investment could act as a disincentive to invent or could result in companies keeping their products confidential, choosing instead to utilise trade secret protections to prevent competitors from being able to 'work around' their invention.[36]

Large pharmaceutical corporations claim these risks are most strikingly seen in the development of pharmaceuticals.[37] Bringing new medicines to the market is not only expensive – a recent study placed the average cost of developing a new therapeutic treatment at $986

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34 Whilst economic justifications are the most commonly cited, there are other justifications for the grant of patents. Many theories have been advanced to justify patent rights see, e.g., Locke, J. 'Two Treatises of Government' (1764) (P. Laslett ed.) (CUP, 1988) for Locke's views on property as natural law and flowing from one's labour; Hegel, G.W.F. 'Philosophy of Right' (1821) (T.M. Knox trs.) (Clarendon Press, 1967) for a conception of property based on personality and a moral claim to one's talents; Stuart Mill, J. 'Utilitarianism' (1861), (CUP, 2014) and Bentham, J. 'An Introduction to the Principles of Morals and Legislation' (T Payne & Son,1780) for property based on ideas of utilitarianism. These justifications have attracted a substantial body of commentary and scholarly analysis, notably by Machlup and Penrose in their landmark article: Machlup, F. and Penrose, E. 'The Patent Controversy in the Nineteenth Century' (1950) The Journal of Economic History 10(1): 1-29. For a more recent review of the philosophical justifications of Intellectual Property Law, see Drahos, P. 'A Philosophy of Intellectual Property' (Australian National University Press, 1996, ANU EText Edition 2016). There are also multiple versions of the economic justification for patents. For an analysis of more recent economic justifications see Landes, W. and Posner, R. 'The Economic Structure of Intellectual Property' (Harvard University Press, 2003): Ch.1.

35 *Eli Lilly and Company v Human Genome Sciences Inc* [2011] UKSC 51 at para 99.

36 "Workarounds" refer to reverse engineering an invention. Workarounds are seen as problematic as they may undermine a company's competitive advantage gained by being the first to invent.

37 Ouellette describes the pharmaceutical industry as the "poster child" for a strong patent system, see Ouellette, L. 'How Many Patents Does It Take to Make A Drug? Follow On Pharmaceutical Patents and University Licencing' (2010) Michigan Telecommunications and Technology Law Review 17: 299 – 336; see also, Lord Neuberger in *Eli Lilly supra* n.30 where he stated that "it is worth remembering the purpose of the patent system, namely to provide a temporary monopoly as incentive to innovation…although this is true in any sector, it has particular force in the pharmaceutical field, where even many of those who are sceptical about the value of intellectual property rights accept there is a public interest in, and commercial need for, patent protection" at para. 99.

million[38] - but yield a very low success rate.[39] The argument from patent advocates is that patents act as a bulwark against these risks, granting the patent holder a limited period of monopoly in which they can exclude others from using the invention and recoup the value of their investment from the commercialisation of the invention.

In this justification for the grant of patents, innovation should lead to social and economic benefits. These benefits justify the grant of such powerful exclusionary rights by outweighing the temporary monopolies patents award. The 'social' *quid-pro quo* of the patent bargain is that the patent holder must disclose the technical details of the invention This disclosure, it is claimed, encourages innovation by both incentivising invention (flowing from the exclusionary monopoly) and by making available knowledge which others can build upon to develop new products. Patents also make innovation more efficient by avoiding the duplication of labour which can occur where two competitors independently work toward the same goal. The public benefits from products reaching the market sooner (or, at all), from efficient innovation, and through the diffusion of knowledge that may otherwise be kept secret.

Thus, it is claimed that patents are the outcome of a social contract between inventors and society, and the aim of patent law to strike a balance between the interests of inventors and those of society. Justice Thomas, in the US case *Association for Molecular Pathology v Myriad Genetics,* outlines this balance as:

> *"strik[ing] a delicate balance between creating "incentives that lead to creation, invention, discovery" and "impeding the flow of information that might permit, indeed spur invention."*[40]

In a similar vein, Lord Sumption in *Warner-Lambert v Generics Ltd* said that:

> *"it is worth reminding oneself at the outset of the juridical basis on which patents are granted, sometimes called the "patent bargain". The inventor obtains a monopoly in return for disclosing the invention and dedicating it to the public after the monopoly has expired."*[41]

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38 Wouters, O. et al 'Estimated Research and Development Investment Needed to Bring a New Medicine to Market 2009-2018' (2020) Journal of American Medical Association 323(9): 844-853 which examined 63 drugs approved by the US Food and Drug Administration. It is worth mentioning that this analysis suggests that other estimates have been vastly inflated, and highlights that in 2018 the cost of developing new drugs was placed at $2.8 billion.

39 A study by the Biotechnology Innovation Organization found that the probability of a new drug successfully progressing through the development phases and being approved by the US Federal Drug Agency is 9.6%: Thomas, D.W. *et al.* 'Clinical Development Success Rates 2006-2015' (BIO Industry Analysis, 2016).

40 569 U.S. 576 (2013)

41 *Warner-Lambert Company LLC v Generics (UK) Ltd t/a Mylan and another [2018]* UKSC 56 at para 17.

This bargain - or *quid pro quo*[42] - between the inventor and society is widely accepted as the modern justification for the grant of patents. The public benefit, in this justification, flows from innovation and from the disclosure within the patents. Unpacking these justifications is important to understand how the rights of the inventor and the rights of society are treated when decisions about patent policy are made. These decisions, in turn, shape how courts interpret aspects of challenging patents including procedural requirements, and the standards of patentability. They also shape how institutions are designed, framing who those institutions are for and what priorities will be pursued. This chapter now explore the incentive to innovation and the disclosure in turn to interrogate how the patent bargain works in practice.

2.2.1 Patents as Incentives

According to the patent bargain justification, one of the ways in which the public benefits is from increased innovation. Whether patents do, in fact, incentivise innovation is therefore vital to determine whether the public receive their side of the patent bargain. Whether patents incentivise innovation can be considered from two perspectives: does the availability of patents incentivise commercial innovative activities and do patents motivate individuals to be innovative?

In terms of commercial incentives, there is evidence that patents are necessary to attract private investment in research and development, particularly in high- risk areas of development such as biotechnology and pharmaceuticals.[43] But the picture in terms of driving innovative behaviour is less clear. The question of whether patents spur innovation has been empirically tested, with mixed results. Eisenberg, in her research into the experimental use exception in the US, highlights that companies may be driven instead to innovate by the competitive advantages awarded from being the first to market with a new product.[44] Other factors also play a role in driving innovation. Market demand has also been found to rank highly as a factor which influences innovation.[45] There is also evidence that innovation would occur regardless of any potential to patent the invention. Mansfield's empirical study exploring the impact of patent protection on the research and development of US manufacturing firms, found that 10 – 30% of inventions would not have been developed without patent protection. However, this number

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42 This is also referred to as the patent bargain. The term *quid pro quo* is often also used in US cases to mean the same exchange, see *Universal Oil Products v Globe Oil & Refining (1994)* 322 U.S. 471.

43 Ouellette *supra* n.37; Landes and Posner *supra* n.34 (which argues that "the strongest case for patents in something like their present form is said to be found in a subset of the drug industry" at 316.)

44 Eisenberg, R. 'Patents and the Progress of Science: Exclusive Rights and Experimental Use' (1989) University of Chicago Law Review 56: 1017-86.

45 *Ibid* at 1025-1026.

varied significantly according to industry: pharmaceutical companies relied on patents to encourage innovation more than industries involved in developing electrical equipment and textiles.[46] Whether patents incentivise individuals to engage in innovative activities is also unclear. Goktepe-Hulten and Mahagaonkar's study of 2500 scientists at 67 universities in Germany found that scientists were driven by acclaim and professional recognition to innovate, rather than because of the potential of patents.[47]

Despite concerns that patents fail to directly incentivise either commercial or individual innovation, the rate of patents granted around the world continues to climb.[48] Some critics argue that this is because the patent system does not incentivise innovation, but instead encourages invention. The OECD policy roundtable highlighted the distinction between innovation and invention in its report into competition, defining innovation as "the successful development and application of new knowledge" requiring more than just invention.[49] Such a distinction is important because in the patent bargain the public benefits from increased innovation, not from a proliferation of inventions. Boldrin and Levine argue that, despite an explosion in patenting since the 1980s, there has been no corresponding growth in productivity, improved research and development, or innovation.[50] As such, increases in invention have not resulted in increased *socially valuable* innovation. Rather, strengthened patent systems tend to only increase patenting itself.[51] A 2018 meta-analysis exploring the empirical evidence on patents and innovation reached a similar conclusion, finding that "strengthening of patent protection leads to changes in patenting behaviour and patent propensity, but this is not necessarily correlated with more innovation."[52]

This increased rate of patenting can also stunt innovation, rather than incentivise it. This may happen when a so-called anticommons develops, which can limit ongoing research and

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46 Mansfield, E. 'Patents and Innovation: An Empirical Study' (1986) Management Science 32(2): 173-181.

47 Goktepe-Hulten, D. and Mahagaonkar, P. 'Inventing and patenting activities of scientists: in the expectation of money or reputation?' (2010) Journal of Technology Transfer 35(4): 401-423

48 The 2020 World Intellectual Property (WIPO) report 'World Intellectual Property Indicators'(2020) shows that the grant of patents has continued to increase up to 2019. However, the report does also show that there was a 3% drop in global patent applications in 2020.

49 OECD Policy Roundtable 'Competition, Patents, Innovation' (2006) DAF/COMP(2007) 40 at 17.

50 Boldrin, M. and Levine, D. 'The Case Against Patents' (2013) Journal of Economic Perspectives 27(1): 3-22.

51 *Ibid.*

52 Sampat, B. 'A Survey of Empirical Evidence on Patents and Innovation' (2018) National Bureau of Economic Research; Working Paper 25383; Boldrin and Levine's meta study of empirical work in 2008 examining whether the introduction or strengthening of patent protection increased innovation also reached similar conclusions. They found that there was limited evidence to support the idea that introducing or strengthening patent regimes increased innovation. Rather, it increased patenting. Boldrin, M and Levine, D. *Against Intellectual Monopoly* (CUP, 2008).

development and restrict the public's access to innovative products. An anticommons occurs where "multiple owners each have a right to exclude others from a scarce resource and no one has an effective privilege of use."[53] With patents, this effect can occur where too many patents are granted over previous discoveries, creating obstacles to further research.[54] Heller and Eisenberg highlight that this is a particular issue in biomedical research. They argue that patents over upstream research can cause blocks to ongoing product development because of multiple and overlapping patent rights, each of which requires different negotiation before a product can be developed.[55] They use gene patents as an example. In the 1980s a multitude of patents were granted over gene fragments. Future products – such as genetic diagnostic tests - require several of these fragments, which may be owned by multiple patent holders. To create the desired product, inventors have to engage in lengthy and costly transactions to bundle licences together before product development can begin.[56] Heller and Eisenberg argue that this can be daunting, forcing firms to choose less promising projects with fewer licencing obstacles, potentially limiting ongoing development. Such limitations, they warn, could harm the public by resulting in fewer, rather than more, products for improving human health.[57]

Whether or not patents incentivise innovation is therefore unclear. However, incentivising innovation is only one aspect of the patent bargain. The bargain also states that society benefits from the disclosure of an invention that would otherwise be kept secret. The subsequent section examines whether the public receives its side of the bargain in respect of the patentee's disclosure of the technical details of the invention.

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53 Heller, M. and Eisenberg, R. 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' (1998) Science 280 (5436): 698-701.

54 An example of this is seen in mobile phone patents, where there are overlapping patent rights which arguably create a patent thicket resulting in a 'patent war' between different technology companies. See Carrier, M. 'A Roadmap to the Smartphone Patent Wars and FRAND licencing' (2012) CPI Antitrust Chronicle 2; Hall, B. *et al.* 'A study of patent thickets' (2013) UK Intellectual Property Office 2013/26. However, some critics argue that the risks and criticisms of patent thickets relating to smartphone technology are overblown: see Lewis, J. 'The sky is not falling: Navigating the smart phone patent thicket' (2013) WIPO Magazine 1/2013.

55 Heller & Eisenberg, *supra* n.53.

56 *Ibid* at 699.

57 *Ibid* at 701.

2.3 Public Disclosure as *quid-pro-quo*

Central to the social contract justification of patent rights is the emphasis on disclosure as a key benefit for society. Lord Briggs outlines this in *Regeneron Pharmaceuticals Inc v Kymab Ltd:*

> *"The essence of the bargain between the patentee and the public is that the patentee dedicates the invention to the public by making full disclosure of it, in return for a time-limited monopoly over its use…If the patentee were able to obtain a product monopoly without disclosing how they make the product, the public would get nothing of substance in return for the grant of the monopoly. Furthermore, other inventors would be deterred from conducting the research and development in fact necessary to take advantage of the inventive idea for the benefit of society as a whole…"*

This section considers this question by exploring what the legal standards for disclosure are, and whether patents are meeting this standard. To be beneficial to the public, patents – and the information contained within them – also need to be accessible. This section subsequently examines how patents are disclosed through patent databases and argues that public access is a fiction.

2.3.1 Standards of Disclosure

Disclosure plays a fundamental role in the patent bargain, forming the main reason for the grant of the patent. Lord Sumption in *Warner-Generics* describes disclosure as "fundamental to the public interest that justifies the issue of the patent."[58] The legal standards for disclosure aim to ensure that the information within the patent applications contains adequate disclosure to justify the grant of the patent. Article 83 EPC states that:

> "*The European patent application shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art."*[59]

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58 *Warner-Lambert Company LLC v Generics (UK) Ltd t/a Mylan and another* [2018] UKSC 56 at para 11.

59 This standard of the EPC is replicated in the UK under s.14(5) Patents Act 1977 which states that "The specification of an application shall disclose the invention in a manner which is clear and complete enough for the invention to be performed by a person skilled in the art." There are similar standards in Australia and the US. s.40 Australian Patents Act 1990 requires that a patent specification "disclose the invention in a manner which is clear enough and complete enough for the invention to be performed by a person skilled in the art". In the US, s.112(a) 35 U.S.C states that "the specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same…". The US legal standard under s.112(a) also requires an inventor to disclose "the best mode contemplated by the inventor…" to carry out the invention.

The EPC standard carries over into the national laws of EPO member states.[60] The application of the standard of disclosure was recently discussed by the UK Supreme Court in *Regeneron v Kymab.*[61] In this case, Regeneron were granted European patents covering a method for creating mice which had been genetically modified to produce chimeric antibodies, as well as for a range of mice made in that way. Such antibodies have therapeutic uses for the treatment of human patients. Kymab produced its own genetically modified mice, and Regeneron sued for infringement. Kymab countersued, arguing that Regereron's patents were invalid as they failed to provide sufficiently clear and complete disclosure. Kymab argued that whilst Regeneron's patents claimed a range of mice, they only detailed the teachings to make some of that range. Notably, the patents did not disclose how to make the mice at the most effective end of the range. This, Kymab argued, meant that Regeneron's patents did not sufficiently disclose the invention. The Supreme Court, in a majority decision, agreed, finding Regeneron's patents invalid because of insufficient disclosure. The Court held that clear and complete disclosure requires there to be substantial disclosure of the invention claimed. That is, anything more than "a tiny or inconsequential number of embodiments" which are not enabled by the patent would fail to meet the standards under Article 83 EPC.[62] This does not mean that disclosure requires enough detail to enable a member of the public to make the invention. Rather, the correct standard is to establish whether a notionally skilled person in the art, with the general knowledge of the date of priority, would be able to make the invention claimed without "burdensome experimentation."[63] Such experimentation should not require a "great deal of inventive thinking" nor "as is sometimes said, imaginative" thought when attempting to replicate the invention claimed.[64]

The standards of disclosure in Australia and in the US echo the legal requirements contained in the EPC, although both have an additional requirement that patents disclose the best manner or

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60 s.14(5) Patents Act 1977 corresponds to Article 83 EPC requiring that "the claim or claims shall a) define the manner for which the applicant seeks protection; b) be clear and concise; c) be supported by the description; and d) relate to one invention or to a group of inventions which are so linked as to form a single inventive concept." There is a difference in wording between the EPC which requires "clear and complete" disclosure and the UK Patents Act which requires "clear and concise" disclosure. Lord Sumption, in the majority decision in *Warner Generics* however, cites the EPC articles without referring to the difference between the two. The term "clear and concise" mirrors the US requirement for disclosure contained in s.112(a) 35 U.S.C which states that "the specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same…".

61 *Regeneron Pharmaceuticals Inc v Kymab Ltd* [2020] UKSC 27.

62 *Ibid* at 36.

63 *Ibid* at 24.

64 *Ibid* at 24. See also *Illumina Cambridge Limited v Latvia MIG Tech SIA and others* [2021] EWHC 57 (Pat) for a recent exploration of the standards of sufficiency in the UK Patents Court.

mode to carry out the invention claimed. s.40(2) Australian Patents Act 1990 requires that a complete patent specification must "disclose the invention in a manner which is clear enough and complete enough for the invention to be performed by a person skilled in the art". The patent must also "disclose the best method known to the applicant of performing the invention."[65] In the US, s.112(a) 35 U.S.C states that "the specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same…" The US legal standard under s.112(a) also requires an inventor to disclose "the best mode contemplated by the inventor…" to carry out the invention.

Given the importance of this requirement to the public interest in the patent bargain, the next question is whether the legal standards of disclosure are being met. There is evidence that they are not. Despite requiring that patents be clear and concise, patent drafting practice typically avoids such disclosure in favour of broader, incomplete, or more opaque language.[66] This is because opaque, open ended language gives patent holders more manoeuvrability to defend their patents should questions concerning the validity or boundaries of their patent claim ever end up in opposition or in courts.[67] Such practice makes determining the scope of patent claims difficult, even for specialists working in the area covered by the claims.[68] Patents are also rarely concise, often being lengthy documents and sometimes containing information which does not go to disclosing the claimed invention. Freilich analysed 40,000 US patents and found that, within the claims, nearly a quarter of the language used related to information that was ancillary to the invention in question – either because it described concepts not part of the new product or process, or because it described newly conceived concepts not made or not capable of being made by the patent holder.[69] Freilich argues that such 'patent clutter' can, among other things, impede readability and hamper patent clarity.[70] Bessen and Meurer are particularly critical, arguing that the language used in patent claims is often vague and unpredictable,

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65 s.40(2)(aa) Australian Patents Act 1990.

66 Roin, B. 'The Disclosure Function of The Patent System (Or Lack Thereof)' (2005) Harvard Law Review 118(6): 2007-2028.

67 Roin observes that, in the US, 'the goals of clarity and brevity take a back seat to drafting strategies meant to ensure that patents are broadly interpreted by the Courts' in Roin, *ibid* at 2025.

68 Roin argues that "whilst patent specifications are ostensibly written for the benefit of those 'skilled in the art' most engineers actually find reading them "an uncomfortable experience [where] the document seems to be unreasonably repetitive and, in parts, almost incomprehensible" *ibid* at 2025. Fromer states that "qualitative evidence suggests that technologists, trained in the relevant art, frequently find the legalized jargon in the patent document incomprehensible" Fromer, J. 'Patent Disclosure' (2008) Iowa Law Review 94: 539

69 Freilich, J. 'Patent Clutter' (2018) Iowa Law Review 103(3): 925-983 at 939.

70 *Ibid* at 966-970.

leading to patents which fail to clearly demarcate the boundaries of the invention claimed and are difficult to read.[71] Such indeterminacy in patents may be beneficial to patent holders, but is not without risk. Broad patent drafting may invite challenges from competitors on the grounds that the claims do not meet the sufficiency of disclosure requirement, as was successfully argued at the UK Supreme Court in *Regeneron*, outlined above.[72]

If patent claims are failing to be clear and concise, it may be that the public can still benefit from the teachings in the patent if they communicate knowledge to a person skilled in the art who can learn from and build upon that knowledge. However, the evidence that patents achieve this is mixed. There is some evidence that certain industries do utilise patents to find technical information. Ouellette's 2011 study exploring whether nanotechnologists viewed patents as a source of technical information found that 64% of respondents had read a patent related to their research.[73] Cohen *et al's* 2002 study exploring manufacturing R&D found that patents were viewed in the top three sources of technical information (along with conferences and publications).[74] However, other studies have shown that patents fail to communicate the knowledge and 'teachings' of the invention. Roin argues that patent disclosures have limited impact on the flow of information between US firms, and that often other sources than patents are used to learn technical information.[75] Devlin highlights that "the extent to which patent documents teach the inner workings of cutting-edge technologies is quite limited."[76] Fromer highlights that inventors rarely read patents before embarking on research and Lemley states that scientists just ignore them.[77] Although the evidence is mixed, most studies agree that a significant problem is that patent document itself which is referred to as "poorly structured"[78],

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71 Bessen, J. and Meurer, M. *Patent Failure: How Judges, Bureaucrats, and Lawyers Put Innovators at Risk* (Princeton University Press, 2008) at 10-11.

72 Regeneron's patent covering genetically modified mice was initially found invalid at the first instance. Justice Carr held that the Regeneron patent did not sufficiently disclose the invention as, at the priority date, it could not have been performed without undue burden or invention (see [2016] EWHC 87 (Pat)). The Court of Appeal overturned the decision at first instance, finding the patents valid as it would be unfair to limit Regeneron's monopoly to the types of hybrid mice which would be made when the patent was filed, particularly "in a fast moving field, where new products quickly outperform their predecessors so as to render them obsolete, the reward of a monopoly limited to those immediately capable of being made would be short lived and illusory" (Lord Briggs, summarising the reasoning of the Court of Appeal [2018] EWCA Civ 671 at 27)

73 Ouellette, L.L 'Do Patents Disclose Useful Information?' (2012) Harvard Journal of Law and Technology 25(2): 545-608 at 570.

74 Cohen, W. *et al* 'R&D Spillovers, patents and the incentive to innovate in Japan and the United States' (2002) Research Policy 31: 1349-1367.

75 Roin, *supra* n.66.

76 Devlin, A. 'The Misunderstood Function of Disclosure in Patent Law' (2012) Harvard Journal of Law and Technology 23(2): 401-446 at 403.

77 Fromer. *supra* n.68 ; Lemley, M. 'Ignoring Patents' (2008) Michigan State Law Review 19-34.

78 Lemley, *ibid.*

full of vague and opaque language, and lacking specificity.[79] This can limit ongoing research by obscuring the disclosure of the invention, undermining the public benefit which is central to the patent bargain.

So far, this section has questioned the reality of whether the patent document itself effectively discloses the technical teachings of the invention claimed. For disclosure to be effective, scientists, researchers, inventors, and members of the public have to be able to find the knowledge contained within the patent. Public disclosure requires effective systems to disseminate the new technical knowledge and teachings contained in the patent claims. However, empirical research shows that patent databases are not user friendly and require extensive training to be used effectively.[80] Even then, systemic obstacles arise from the categorisation of patents by patent offices. Allison and Lemley's study of patent prosecutions at the USPTO found that the office's database sometimes incorrectly categorised patents based on their title, rather than on the substance of the invention claimed.[81] The database also grouped together disparate technologies despite the industries being substantially different. For example, biotechnology, pharmaceuticals, and petroleum were clustered together under 'chemical' inventions.

Other systemic problems concern the timeliness and accuracy of the details of the patent claims stored in the databases. The EPO's Espacenet database contains explicit warnings to its users that "the EPO does not guarantee that the information is exhaustive, accurate or up to date".[82] Individual patent documents contain a warning that "the EPO does not accept responsibility for the accuracy of data originating from authorities other than the EPO, nor does it guarantee that such data is complete, up-to-date or fit for specific purposes".[83] There is a similar warning attached to AusPat, the patent search database of IPAustralia. This warning states that "IP Australia does not make any representation or warranty that the information the system

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79 Devlin, *supra* n.76 at 404.

80 Van Dulken, S. 'Free Patent Databases on the Internet: a critical view' (1999) World Patent Information 21(4): 253-257. Whilst somewhat outdated, van Dulken's views reflect many of the concerns with modern patent system databases such as the requirement for expert assistance see Drahos. P. 'Patent Lies and Public Goods: Ten Lessons from When Patents and Pandemics Meet' (2021) EUI Working Paper, LAW 2021/5 which states "Mapping patent landscapes requires access to fee-charging databases…and specialist expertise" at 6.

81 See Allison, J. and Lemley, M. 'Who's Patenting What-An Empirical Exploration of Patent Prosecution Systems' (2000) Vanderbilt Law Review 53(200) at 2114.

82 EPO Espacenet 'Terms and Conditions of use for the website of the European Patent Office' available at https://www.epo.org/footer/terms.html last accessed 12/03/21.

83 See, for example, the 'description' of EP0705902A1 which contains the information for Myriad's European BRCA1 patent. Available at https://worldwide.espacenet.com/patent/search/family/027575337/publication/EP0705902A1?q=EP0705902 (last accessed 07/04/2021).

provides is reliable, adequate, current, accurate or complete or that access to the information will be uninterrupted, timely or secure".[84] Similarly, WIPO's Patentscope database emphasises that "WIPO bears no responsibility for the content of PCT international applications and related documents."[85] Patentscope also contains warnings about the accuracy of its text as a result of the scanning procedures used to update the database.[86]

Finally, public patent databases vary significantly in the amount of information and patent documents published. In particular, details of the claims disclosed in patent applications are not readily available.[87] For these reasons, companies and researchers cannot rely on the information published in free, public databases but must turn to, fee-paying, private databases in order to obtain full, accurate and timely technical details of the 'teachings' in patent applications and the outcome of patent examination of the claims by different patent offices. As a consequence, a burgeoning industry of patent database specialists has emerged across the world, specialising in providing search capabilities and mediating public access to patent data.[88] In short, there are considerable reasons to doubt whether the quid-pro-quo social function of disclosure in the patent bargain is met in reality.

2.3.1.1 The Role of Patent Offices

Disclosure lies at the heart of the patent bargain and is what inventors must provide in return for the grant of the exclusionary rights. However, as outlined above, there are problems with how the disclosure function is working in the patent system. If disclosure is, as Lord Sumption states, fundamental to the public interest then it is hard to reconcile the "black art" of patent drafting and problems with accessing patent information with the disclosure requirement. Some critics argue that this tension arises because those responsible for the application and enforcement of standards disclosure – patent offices and the courts - have failed to uphold the requirement in a substantive way, leading to a surge in large numbers of 'low-quality' patents

84 IPAustralia AusPat 'AusPat Disclaimer' available at http://pericles.ipaustralia.gov.au/ols/auspat/quickSearch.do (last accessed 07/04/2021)

85 WIPO Patentscope 'Content of the Database' available at https://patentscope.wipo.int/search/en/content.jsf last accessed 12/02/21.

86 WIPO, Patentscope 'Data Formats' available at https://patentscope.wipo.int/search/en/data_formats.jsf last accessed 12/03/21.

87 Jurgens, B. and Herrero-Solana, V. 'Espacenet, PatentScope, and Depatisnet: A comparison approach' (2015) 42: 4-12 noting that Patentscope, WIPO's database of PCT applications, held significantly less patent data than Espacenet or Depatisnet, the database from the German Patent and Trademark Office.

88 Drahos, *Global Governance of Knowledge*, *supra* n.33 at 302.

being granted by patent offices, only to be overturned by courts later.[89] There is evidence that, in the case of patent offices, insufficient time or resources are linked to quality of patents granted.[90]

Other studies suggest the gap between the legal standard of disclosure and what is communicated in patent claims are due to deeper fault-lines in the governance of patent offices. In particular, Drahos' extensive study of leading patent offices in the world reveals the dynamics of an environment prone to diluting the quality of patent standards. Drahos shows that there is a symbiotic relationship between patent offices and their clients which has led to, among other things, a lax approach to the disclosure requirement. This relationship is driven, in part, by the way patent offices are funded: fees relating to the grant, administration, and renewal of patents are paid by directly by inventors to patent offices. This creates an environment in which, Drahos argues, inventors become customers and patent office's act as businesses, eager to encourage as much customer engagement as possible to ensure a steady flow of funds.[91] For patent offices, one way of achieving this is by working with patent applicants to advise on ambiguities within patent law to strengthen patent claims which might otherwise fall below the required standards of novelty, inventive step or industrial application. The downside for the public is the risk of eroding standards of patentability. Opaque disclosure is one aspect of this symbiotic relationship.

One potential bulwark against the dilution of disclosure requirements by patent offices are the courts. Here, the concern expressed by some critics is that courts often take a *laissez-faire* approach to the disclosure requirement. Bessen and Meurer, for example, argue that the US Federal Circuit is "[itself] reluctant to invalidate an indefinite claim."[92] They cite the Federal Circuit's decision in *Exxon Research and Engineering Co v US* wherein the Federal Circuit held that "if the meaning of the claim is discernible, even though the task may be formidable…we have held the claim sufficiently clear."[93] However, *Exxon* was eventually overturned by the US

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89 Bessen & Meurer, *supra* n.71at 18 where they highlight that low patent quality is associated with poor examination as a result of stretched patent offices. This, they note, has also contributed to overly broad, vague, abstract patents. They note that low patent quality also arises from the failure of the Federal Circuit to uphold standards of patentability, most notably novelty and obviousness.

90 Jaffe, A. and Lerner, J. *Innovation and Its Discontents: How Our Broken Patent System is Endangering Innovation and Progress and What to Do About It* (Princeton University Press 2004). Chapter 5 explores the issues of increasing patent backlogs and observes that: "While there is a formal process of patent examination, in practice it appears that a determined patentee can get almost any award he seeks…This is a predictable result when underpaid, inexperienced, and overworked examiners are pushed to resolve cases as quickly as possible, and are given flawed and obsolete tools for finding and searching the prior art" (at 142.) See, also Drahos, *supra.* n.33, at 114-15.

91 Drahos, *supra.* n.33.

92 Bessen & Meurer, *supra* n.71 at 57-58.

93 *Exxon Research & Engineering Co. v. United States,* 46 Fed. Cl. 278 (2000).

Supreme Court in *Nautilus Inc v Biosig Instruments Inc* where it was emphasised that disclosure required clear boundaries and reasonable clarity for the person skilled in the art to read and understand what was claimed.[94]

Similarly, in the UK, the Supreme Court in *Regerenon* emphasised that a low standard of disclosure would tilt the balance of the patent relationship too far toward the patent holder:

> *"the sufficiency requirement…is part of the bedrock of the law…To water down that requirement would tilt the careful balance thereby established in favour of the patentees and against the public in a way which is not warranted by the EPC…"*[95]

The approach of courts in the construction and application of the legal standard of sufficiency disclosure is thus an emerging field of interest where comparative research could yield important insights.[96] A study of judicial governance of patents could thus illuminate further and complement Drahos' study on the role of patent offices in tilting the balance in favour private interests. Gene patents are a particularly illuminating case study because they became a site powerful clashes between private and public interests in the political sphere and in courts around the world.

2.4 Gene Patents

2.4.1 Public Morality

The patent wars on the human genome and gene patent controversies in the 1990s prompted calls on the public and moral dimensions of patents to be addressed in patent policy. The Nuffield Council on Bioethics report *The Ethics of Patenting DNA* argued that the incentive to innovate should be linked to innovation for public good.[97] The report argued that the right to innovate is "subject to wider constraints, such as public interest…the overall goal of the patent system are the stimulate innovations for the public good".[98] It further argued that 'public interest' is not inextricably linked to those rights of the patent holder by defining it as "primarily a matter of making it possible for individuals to further their own interests as far as circumstances and the interests of others permit…it is the interests of individuals in securing

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94 *Nautilus, Inc. v. Biosig Instruments, Inc.* 572 US 898 (2014).

95 *Regeneron Pharmaceuticals, supra* n.61 at 59.

96 It may be that the approach to the disclosure requirement differs according to the court in question. Research into the relationship between specialist patent courts and more generalist courts have found that there is a tension between the courts in how they reach decisions; see Eisenberg, R. 'The Supreme Court and Federal Circuit: Visitation and Custody of Patent Law' *(*2007) Michigan Law Review 106: 28-33.

97 Nuffield Council on Bioethics, *The Ethics of Patenting DNA: A Discussion Paper* July 2002.

98 *Ibid* at p12.

access to new medicines and other products and services that are especially important".[99] Similarly, the International Bioethics Committee (IBC) report on patents and the human genome argued that attempts to patent the human genome were undesirable based on public order, morality, and the protection of human life and health. In this report, public concerns about gene patents were considered on an equal footing with the rights of patent holders.[100] The adoption of the EU Biotechnology Directive with an explicit list of moral exclusions from patentability was a legislative response to these concerns.[101]

2.4.1.1 Gene Patents: Politics

There is a significant body of academic scholarship highlighting the political dimensions in the governance of the patent system and the role the public can and/or should play in determining patent policy.[102] For instance, Parthasarathy's comparative study of US and European patent policy highlights the contrasting policy approaches to the public outcry to patents on genetically modified animals, isolated DNA, and human stem cells.[103] Building on her extensive empirical study comparing life science patent controversies in the US and Europe, Parthasarathy argues that patent systems, though often framed as purely technical institutions, are in reality densely political and shaped by each country's political culture, ideology, and history.[104] As such, the regulation of patents is permeated with political decisions about whose knowledge, expertise, and experience is relevant. The US approach, she argues, views patents as techno-legal objects divorced from broader moral and socio-economic concerns, with the interest of the public

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99 *Ibid* at p13.

100 International Bioethics Committee, *Report of the IBC on Ethics, Intellectual Property and Genomics* July 2002 at p 8 9.

101 See Plomer, A. 'Stem Cell Patents: European Patent Law and Ethics Report' (2006) FP6 Life Sciences, Genomics and Biotechnology for Health', SSA LSSB-CT-2004-005251. Nottingham: School of Law laying out the history of the Biotech directive and the difficulties associated with its implementation. These issues are returned to later in the thesis.

102 See Parthasarathy, S. *Patent Politics: Life Forms, Markets, and the Public Interest in the United States and Europe* (University of Chicago Press, 2017); Sideri, K. *Biomedicine, Bioproperty, and Deliberative Governance: Patents as Discourse on Life* (Ashgate, 2014), Murray, K. *The Politics of Patent Law: Crafting the Participatory Patent Bargain* (Routledge, 2012). See also Drahos, P. 'Biotechnology, Markets, and Morality' (1999) European Intellectual Property Review 21(9): 441-449 at 441, where he states that "patent law is located within and not outside a public ethic of community values and shared economic and social interests".

103 Parthasarathy, *ibid*. See also Jasanoff, S. *Designs on Nature: Science and Democracy in Europe and the United States* (Princeton University Press, 2007).

104 Parthasarathy, *ibid* at 183-185. She highlights, for example, that the EPO created the Scenarios project-a "large scale, multi-year initiative to encourage strategic thinking about the future direction of the EPO and the role of the patent system in global society" in which the EPO invited a heterogenous range of responses including patenting organisations, as well as activists, philosophers, and social scientists. She notes that it was not just the range of views invited which facilitated public engagement but also the questions asked, including "how can public and private interests in IP be reconciled for the benefit of society?"

subsumed into the interests of the patent holder. Consequently, any objection on moral, ethical, or access grounds is considered extraneous to effective patent governance. In contrast, patents in Europe are seen as socio-economic objects, embedded in a regulatory system which views the grant of patents not as divorced from broader moral and social concerns, but as simply one part of a broader regulatory framework. She shows that the EPO opposition boards have shown a willingness to engage with moral arguments raised by members of the public who seek to invalidate patents on genetically modified organisms. But her conclusion does raise the question of whether or not the EPO should be a site for such public challenges in light of its limited competence and legitimacy in answering moral questions.[105] Parthasarathy argues that, despite some acknowledgement of these broader concerns, patent systems continue to fail to adequately acknowledge public worries surrounding developing science and technology.[106] This, she suggests, is the result of a regulatory gap between "procedurally objective and systematic decision making [and] responsiveness to the public."

Parthasarathy finds that the challenges to life science patents grew, in part, from the public no longer willing to be passive participants in a system which viewed their rights as, at best, synonymous with patent holders and, at worst, irrelevant to the regulation of patents at all.[107] Similarly, the grassroot movements challenging patents over lifesaving HIV treatments demonstrate the role that members of the public can play in challenging patent rights on moral and access grounds, with the aim of ensuring that the balance of the patent system is not too heavily weighted in favour of patent holders.[108] Public interest groups have also been involved in patent challenges concerning transgenic mice[109], stem cells[110], and GM foods[111] on the

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105 There is a broad literature on this topic: see, for example, Sideri, *supra* n.102; Plomer, *supra* n.101; Littoz-Monet, A. *Governing Through Expertise: The Politics of Bioethics* (Cambridge University Press, 2020)

106 Parthasarathy, *supra* n.102 at p191.

107 *Ibid*.

108 t'Hoen, Ellen. "TRIPS, pharmaceutical patents, and access to essential medicines: a long way from Seattle to Doha." *Chicago Journal of International Law* (2002) 3: 27, Epstein, S. *Impure Science: AIDS, Activism, and the Politics of Knowledge* (University of California Press 1998).

109 T0315/03 *(Transgenic Animal/Harvard)* 6.7.2004 (EPO) where animal rights activists, religious organisations, and other public interest groups sought to challenge the grant of a European patent claiming a method for creating transgenic mice which are more susceptible to developing tumours.

110 Case C-34/10, *Oliver Brüstle v Greenpeace,* ECLI:EU:C:2011:669 concerning a preliminary reference to the European Court of Justice from the German Bundesgerichtshof following a case brought by Greenpeace challenging the patentability of precursor human embryonic stem cells under the European Biotechnology Directive; *Consumer Watchdog v Wisconsin Animal Research Fund* 753 F.3d 1258 (2018) where Consumer Watchdog, a not for profit organisation, sought to challenge US patents held over human embryonic stem cell cultures.

111 See the decision of the Enlarged Board of Appeal (EBA) at the EPO G0002/13 (25.03.15) which consolidated oppositions to European patents on genetically modified tomatoes (G2/11) and Broccoli (G2/13). The EBA hearing attracted a substantial number of amicus briefs including

grounds that the patents tipped the scale too far against the social benefit claimed under the patent system (albeit with mixed success). Furthermore, there is growing public distrust that patent institutions operate in the public's best interests which she suggests, fosters the type of civil unrest seen in the life science controversies that she documents. To bridge this gap, she argues that there need to be systems to incorporate policy concerns into decision making, as well as a reflection on what and whose expertise is relevant and valued in the patent system.[112] Legitimate decision making, she concludes, requires a place for both governments and citizens to negotiate ongoing developments in science and technology. Other scholars have argued along similar lines.[113] Sideri, in her review of the role of regulatory agencies in governing biomedical patents, similarly argues that patent systems serve a variety of individual and collective interests and there thus needs to be broad democratic participation to ensure legitimate decision-making in the regulation of patents.

2.5 Private Governance of Patents

According to Drahos, many of the systemic weaknesses of the patent system arise from the patent system's evolution into a globally integrated private governance network, which focuses primarily on patent holder's rights, and which has made the social contract largely meaningless. This private governance network consists of businesses, patent attorneys, and patent offices working toward a common goal of more patents being granted more efficiently. These networks, he argues, represent "deep concentrations of power and dominance" and have colluded in the development of patent claims to overcome restrictions on patentability; formed coalitions to steer patent office responses so that they are responsive to big business users; pushed harmonization agendas opposed by developing countries; harmonized processes through technocratic cooperation; and come to dominate the national policy level approaches to patents.[114] This system dominates not only day-to-day patent administration, but also patent policy in the national and international forums. This has led to a steady strengthening of patent rights despite unclear empirical evidence on the supposed axiomatic benefits of patents, that of innovation and disclosure and in the face of empirical studies suggesting patents can limit access to research, access to medicine, and access to diagnostic tests in the biotechnology arena. The patent system is therefore controlled by insiders who push toward strengthened patent rights in the face of uncertain evidence to support such strengthening. Such an expansion has

submissions from independent organisation No Patents on Seeds, academics, and various agricultural organisations.

112 Parthasarathy, *supra* n.102 at 198.

113 Sideri, *supra* n.102. See also Drahos, *supra* n.33

114 Drahos, *supra* n.33 at 288-289.

squeezed out views and perspectives which would challenge this agenda, including those interests might seek to oppose the grant of patents on moral, ethical, or access grounds. The question is, then, how can social concerns about access to research and access to diagnostics be effectively heard by the patent system?

Drahos's study of leading patent offices around the world based on extensive interviews he conducted with patent officials points to the existence of what he describes as an 'insider' network of officials and their clients, whose interests are treated as paramount.[115]

Rather he argues that patent offices should be sites where patents are challenged to demonstrate their social value, through an examination of whether or not they meet the required standards of patentability. Patent examiners should be society's agent in this task: "patent offices are agencies…that have been created to do what citizens individually and collectively cannot do – to examine patent applications to determine whether the inventor has kept to their part of the bargain."[116] Yet, patent offices have largely abdicated this responsibility.

Given this, Drahos' study invites the further question of whether courts are or could be a site to address the social value in patents, and redress the balance between private and public interests in the grant of patent monopolies. Drahos is pessimistic about the likelihood of success in the battlegrounds of litigation, largely due to the high costs involved, putting legal challenges out of reach of members of the public, or non-commercial organisations.[117] Parthasarathy is marginally more optimistic about the utilisation of the courts, suggesting that – in the US context - one way of bridging the gap she identifies between patent decision making and responsiveness to the public, is through more easily accessed public interest litigation.[118]

Yet, where patent office's represent closed networks, litigation may present a crack through which patent outsiders can penetrate. Decisions by the Supreme Courts in the US and UK, and the Australian High Court have demonstrated a willingness to invalidate patents which fail to meet this social value requirement, sometimes in direct conflict with the practice of the patent offices. This was the case in both the US Supreme Court decision and Australian High court decisions in the *Myriad* cases wherein the courts recognised the broader social impacts of

115 *Ibid*, Chapter 11.

116 *Ibid* at 33.

117 *Ibid* at 292.

118 Parthasarathy, in her conclusion, argues that responses to this gap and suggestions need to be shaped according to the "distinct political cultures, ideologies, and histories that shape patent systems". She argues that the US generally supports public-interest litigation and so reform to make engaging in such litigation easier (such as through relaxed standing requirements or institutional support) may be an avenue through which to ensure "systemic, efficient, and responsive" decision making (*supra* n.102 at 197).

patents and went against longstanding patent office policies of granting patents over genes.[119] There has also been a recognition by the courts of the public and its rights as being central to the patent bargain. Lord Briggs in *Regeneron* held that "if the patentee were able to obtain a product monopoly without disclosing how to make the product, the public would get nothing of substance in return for the grant of the monopoly."[120]

The question asked by this research, then, is why are these opportunities to penetrate the closed networks and challenge the validity of challenges in the courts so rarely used? And - if and when they are used - do they present opportunities for effective challenge? These questions are pursued further in this thesis to include an examination of the challenges faced by the public in litigating patents in the courts drawing on Drahos' normative framework which points to the need for the public benefits side of the 'patent bargain' to be upheld.

2.5.1 Enhancing Public Benefits

Drahos argues that the social contract requires patent offices to take a different perspective to fulfil their role of society's agents; filtering out the patents which do not meet the socially agreed upon criteria of patentability. But this levelling out of interests also allows a perspective on 'society'. If, as Drahos theorises, the patent office is failing to uphold their end of the bargain by 'tilting' and co-evolving with their industry users then there must be a way to involve other groups or individuals who can play the role of 'society's agents'. Courts may be an opportunity to address whether a patent provides sufficient social value, but they cannot do so without cases upon which to decide. Drahos himself proposes this at the end of the *Global Governance of Knowledge* by calling for a counter network of outsiders to challenge the pervasive co-evolution of patent offices and patent clients.[121] It is this counter network of outsiders that are the focus of this research. Rather than starting with the focus on patent holders, this research begins with the assumption that there are a myriad of interested stakeholders in the patent system which include, but is not necessarily limited to, patent holders, patent offices, Courts, public interest groups, scientists, patients, and NGOs.

Undoubtedly, a reframing of the interests of inventors and society in the implementation of the social contract by patent offices and courts presents several challenges. Critics of the social contract justification have pointed to the ethereal nature of the bargain. Rubin argues that social contract theory can "vary the terms of the imaginary narrative…and can prove virtually

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119 See Section 4.4.2 and Section 5.4.2.

120 *Regeneron Pharmaceuticals, supra* n.61 at 23.

121 Drahos, *supra* n. 33 at 290-291.

anything".[122] Boucher and Kelly argue along similar lines by stating the problem of utilising the metaphor of a bargain is that "metaphorical constructs are ethereal constructs, moveable at will, that fail to aid in interpreting and applying patent law".[123] Ghosh draws on these criticisms to argue that the application of this theory also rests on how different interests are framed and pursued.[124] Ghosh argues that such a theory cannot be normatively or empirically tested, making its use problematic. Notwithstanding, patent offices and courts expressly approach the evaluation of patent applications through the language of balancing and quid-pro-quo between inventors and society. The social 'contract' perspective may function as a metaphor with the attending difficulties of interpretation and application this entails. But, at the core is the idea of balancing the interests of the inventor and society. Drahos' theoretical framework was applied to patent offices. This study complements Drahos' work by focusing on the balancing of public and private interests in opposition proceedings on gene patents at the European Patent Office and in the Australian and US courts.

2.6 Conclusion

The most often cited justifications for patents are economic in nature. Patents are conceptualized as a bargain between inventor and the public in which the inventor is granted an exclusionary right over an invention in return for publicly disclosing the invention. According to this theory, the public benefit from patents through increased innovation and the disclosure of knowledge and information that would otherwise be kept secret. This chapter has argued that the patent bargain, through a watering down of the disclosure requirement, has tilted in favour of the patent holder. This tilt obscures the role and interests of the public in the patent bargain.

Questions about the public benefit from patents were thrown into sharp focus by the controversies surrounding gene patents. Concerns about the morality, ethics, and public good which flowed from patents over isolated DNA led to a recognition that public concerns, should have a larger role to play in the regulation of patents but, as shown by Parthasarathy these concerns have been largely marginalized According to Drahos, this tilt in favour of patent holders stems from an insider governance network formed of patent offices and their (private)

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122 Rubin, E. *Beyond Camelot: Rethinking Politics and Law for the Modern* State (Princeton University Press 2007)

123 Boucher D. and Kelly P. 'The Social Contract and its Critics 'in Boucher D. and Kelly P. (eds.) *The social contract from Hobbes to Rawls* (Routledge1994).

124 Ghosh, S. 'Patents and the Regulatory State: Rethinking the Patent Bargain Metaphor After Eldred' (2004) Berkeley Technology Law Journal 12: 1315.

clients. To counterbalance such a network, he argues that there needs to be a reconsideration of the patent bargain to recentre the social value which should flow from the grant of patents. A counter network of outsiders is needed to enforce this social value. These outsiders are stakeholders in the patent system whose views are not represented in the current regulatory system. Litigation and opposition are ways this counter network could potentially represent and reassert the role of the public in the patent bargain. This research now turns to exploring this opportunity through a comparative case study of the Myriad litigation, beginning with the opposition process within a supranational patent office: the EPO.

Chapter 3: European Patent Office

3.1 Introduction

Drahos' study of global patent governance is centred on patent officials' approach to the examination of patent applications and grant of patents. Building on Drahos' findings and his normative framework on the insider/outsider network of patent governance, this thesis takes Drahos' further by focusing on the obstacles faced by the public in challenging the validity of gene patents through the appeal system at the EPO and in national courts. Specifically, this chapter focuses on the challenges faced by the public in opposing the Myriad patents at the European Patent Office (EPO) whilst the next two chapters examine the challenges to the same patents in the US and Australian courts.

A review of the literature found that Myriad's patents in Europe were only opposed through the opposition procedure at the EPO and were not challenged in national courts.[125] The focus of this chapter is therefore on the opposition procedure at the EPO. The first part sets out the background to the Myriad patent challenges in Europe, providing context to the discussion. The second part outlines the structure of opposition proceedings at the EPO and the relative lack of formal constraints for the public to challenge the validity of patents granted by patent examiners. The chapter then outlines the substantive rules of patenting genes in Europe, discussing how the EPO's interpretation of the criteria leaves limited scope for the access concerns which drove the challenges. The final part of this chapter reviews the EPO's opposition boards' response to the arguments raised by opponents, demonstrating the gap between the opponent's access arguments and the grounds upon which the EPO's decision was ultimately made.

3.2 Context to Myriad's Patent Challenges in Europe

In August 1995 Myriad filed for, and were subsequently granted, three European patents covering the isolated BRCA1 gene, mutations within the gene, and a method claim for diagnosing a predisposition for breast and ovarian cancer as a result of these mutations.[126] The grant of these patents was controversial. There were growing concerns that patents over isolated DNA would limit patient access to health services, particularly diagnostics for genetic

125 Parthasarathy found that there were discussions to challenge the BRCA patent in the UK Courts, but this did not occur-see Parthasarathy, 'The Patent Is Political' *supra* n.11.

126 The granted patents were EP0705902 (17q Linked Breast and Ovarian Cancer Susceptibility Gene), EP0705903 (In vivo mutations and polymorphisms in the 17q-linked breast and ovarian cancer susceptibility gene), EP0699754 (Method for diagnosing a predisposition for breast and ovarian cancer).

diseases.[127] There was also a concern that ongoing research and development into diagnostics would be hampered by the grant of such patents.[128] The behaviour of Myriad at the time also garnered controversy. Looking to capitalise on the success of their diagnostic testing in the US, the company sent pre-emptive cease and desist letters to European national health services, notifying them of their patent application and advising that they would enforce their patent once granted.[129] There was also acrimony following a 'patent race' between Myriad and Cancer Research UK (CRUK) to locate and isolate the BRCA genes. The two companies had initially collaborated on the project, but had decided to go their separate ways following a dispute about patents.[130] This led to a slightly more complex picture in relation to patents covering the BRCA2 gene, which was successfully located and isolated by CRUK in 1995. CRUK initially filed for a patent covering the isolated BRCA2 gene at the UKIPO, with the aim of granting open licences to facilitate ongoing research and prevent Myriad from gaining further patent coverage which the company viewed as creating a research "gridlock".[131] In 1996 Myriad filed for a European Patent also covering the BRCA2 gene and diagnostic methods. CRUK were granted a European Patent, which was opposed by Myriad on the grounds that the UK patent was not entitled to claim priority due to differences in the BRCA2 sequence claimed.[132] The CRUK European patent was consequently revoked, with Myriad's patent remaining in force.[133]

These concerns led to a series of challenges to the validity of Myriad's patents at the EPO. The patents were opposed by a variety of organisations and individuals including: various European human genetic societies; the Institut Curie; the Assistance Publique-Hospitaux de Paris; the Institute Gustav Roussey; the President of the Angela Serra Association for Cancer Research; Greenpeace; and members of the public.[134] Several national representatives from EPC Contracting States also opposed the grant, including The Minister for Health, Welfare and Sport in The Netherlands and the Social Democratic Party of Sweden. Four patents were opposed:

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127 Dr Mary Claire King and Dominique Stoppard, both instrumental in the development of BRCA research, felt that granting such patents would impact on access to research and access to health services, Van Zimmeren, *et al. supra* n.12.

128 *Ibid.* See also Gold, R. and Carbone, J. 'Myriad Genetics: In the Eye of the Policy Storm' (2010) Genetics in Medicine 12(1): 39-70.

129 *Ibid.* See also Parthasarathy, 'The Patent Is Political' *supra* n.11.

130 Aldhous, P. 'Patent Battle Could Hold Up Tests for Cancer Gene' (1996) New Scientist, Issue 2012 , 13 January; Mayor, S. 'Charity Wins BRCA2 Patent' (2004) The Scientist, 12 February.

131 "Charity Obtains Cancer Gene Patent" (2004) *BioNews* available at <https://www.bionews.org.uk/page_89176> (last accessed 19/04/2021)

132 T0902/07 (BRCA2/Cancer Research Technology) of 7.9.2010 (EPO)at IX-X.

133 Patent EP0785216 (Chromosome 13 linked Breast Cancer Susceptibility Gene BRCA2)

134 Dr Rolf Wilhelms, a Munich patent lawyer who was also involved in challenging the Oncomouse decisions , see Greens to challenge patent for Harvard mouse (1992) New Scientist, issue 1822, 23 May.

EP0705902 (claiming the BRCA1 gene); EP0705903 (claiming mutations in the BRCA1 gene); EP0699754 (a method claim for detecting a predisposition to breast cancer); and EP96309211 (claiming BRCA2 mutations). The initial hearings took place at the Opposition Division in 2004 and 2005, resulting in the revocation of one of Myriad's patents (EP0699754) but the maintenance, albeit in an amended and narrowed form, of the other three. The decisions to maintain the patents claiming the BRCA1 genes and mutations were subsequently appealed to the TBA, heard three years later, and remained in force in the amended form. These patents were narrowed as a result of issues relating to the priority date and filing errors.[135] The decision to revoke the method claim patent was also appealed to the TBA and resulted in the patent being held valid – again, albeit in a significantly narrowed form. The decision to maintain the patent claiming the BRCA2 mutations was not subsequently appealed.

The next section outlines the legal standards for the grant of patents, which form the grounds of the Myriad oppositions.

3.2.1 Opposing a patent at the EPO

How patents are granted in Europe impacts the ways in which members of the public can challenge the patent. This section therefore briefly outlines the nature of European patents and the relationship between the EPO and national patent offices to demonstrate the different routes which can be taken to challenge patents.

The EPO is an autonomous, supranational organisation created by the European Patent Convention (EPC) 1973.[136] The aims of the EPC are to establish the EPO, strengthen cooperation between the states of Europe in the protection of inventions, provide a single procedure for the grant of patents, and establish certain standards for governing those granted patents.[137] As such, the EPC lays down the standards for the grant and administration of European Patents (EP) by the EPO. Inventors seeking patent protection in Europe can apply directly to each individual national patent office in which they seek protection. Alternatively, an inventor can apply, via a single application, to the EPO for a European Patent. A European Patent allows applicants to designate one or more contracting states in their application in which to seek patent protection, subject to the patentability criteria laid down in the EPC.[138] If granted, the European Patent

135 This is explored further below. For an overview see Lai, J. 'Myriad Genetics and the BRCA Patents in Europe: The Implications of the U.S. Supreme Court Decision' (2015) UC Irvine Law Review 5: 1041.

136 Art.4(2)(a) Convention on the Grant of European Patents, Oct. 5, 1973, 1065 U.N.T.S. 199 [hereinafter European Patent Convention (EPC)].

137 Preamble to the European Patent Convention .

138 Art.3 EPC.

"shall have the effect of and be subject to the same conditions as a national patent" granted by a contracting member of the EPC. Upon grant, applicants designate the countries in which they seek to enforce the patent.[139] As such, European patents are subject to infringement, enforcement and invalidity proceedings in accordance with national laws in each of the designated Contracting State in which the applicant seeks enforcement (typically four or five states out of the 38 signatories of the EPC).[140]

An EPO patent can be challenged for invalidity through two routes: through the opposition procedure at the EPO[141] or in national courts in each of the designated states in which the inventor sought protection.[142] These challenges can occur concurrently, although in some cases national courts may stay proceedings until the case has been heard at the EPO.[143] If a patent is invalidated as a result of the opposition proceedings at the EPO, the finding will apply to the European Patent in all the states in which it has been granted. In effect, this terminates any ongoing litigation on validity or infringement proceedings in national courts, since there is no 'valid' EPO patent any more.[144] However, if the EPO Technical Board of Appeal affirms the patent, any concurrent challenges or future challenges in national courts proceed on the basis of national laws.[145] This presents another opportunity to challenge the validity of granted

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139 Art.2(2) EPC.

140 For a full list of signatories see EPO Website, 'Member States of the European Patent Organisation' available at <https://www.epo.org/about-us/foundation/member-states.html> (last accessed 07/04/2021).

141 Art.99-Art.105 EPC.

142 Art.2 EPC states that a European patent shall have the same effect and be subject to the same conditions as a national patent granted in that state, and so can be challenged in national courts in accordance with national laws. Whilst challenges to the validity of patents can be made through the EPO and national courts, issues of enforcement and infringement are the sole jurisdiction of contracting states. This was summarised by Lord Justice Mummery as: "in practice national courts exercise exclusive jurisdiction on infringement issues and they have concurrent jurisdiction with the EPO on validity issues" (in *Glaxo Group Limited v Genentec Inc and Biogen Idec Inc* [2008] EWCA Civ 23 at para 83).

143 Whether or not to stay proceedings in national legislatures varies according to each contracting state. In the UK, if there are concurrent proceedings, the default position is to stay the hearings until the EPO has reached its decision (see *IPCom GmbH & Co KG v HTC Europe Co Limited, Brightpoint Great Britain Limited, HTC Corporation* [2013] EWCA Civ 1496 at para 68). However, although the default is to stay proceedings, the court has discretion to stay proceedings to achieve a balance of justice between the parties. Factors relevant to this balance include, but are not limited to, whether the stay will irrevocably deprive a party of a benefit "which the concurrent jurisdiction of the EPO and national court is intended to confer" (as occurred in *Virgin Atlantic Airways Limited v Zodiac Seats UK Limited* [2009] EWCA Civ 1062) and whether commercial certainty would be achieved at a considerably earlier date in the UK proceedings than in those at the EPO (at para 68 of *IPCom).* The presumption of staying the hearings does not appear to be a difficult one to overcome as stated in the *IPCom* decision itself: "…some certainty, sooner rather than later, and somewhere, such as the UK, rather than nowhere, is, in general, preferable to continuing uncertainty everywhere" (*ibid).*

144 Art.105b (3) EPC.

145 Art.64(a) EPC.

European patents: an empirical analysis by Graham and van Zeebroeck's shows that national courts invalidate patents previously upheld at the EPO at a rate of between 30-50%.[146] For potential challengers, opposing a bundle of national patents through a single process is beneficial as it is considerably less costly than seeking revocation in multiple national courts. However, a significant drawback of challenge patents through the EPO opposition procedure is the length of time it takes.[147]

3.2.1.1 Standing and Procedure

The Opposition Procedure of the EPO is governed by Part V EPC and the accompanying implementing regulations.[148] Within nine months of the publication of a European Patent any person may give notice to oppose the patent.[149] The term "any person" has been interpreted expansively by the EPO. This was confirmed by the EBA in G0009/93 which concerned whether or not a patent holder was entitled to file an opposition against their own granted patent. The Enlarged Board of Appeal (EBA) found that, whilst there was no explicit exclusion stating that the patent holder could not oppose their own patent, Part V EPC was "clearly posited on the assumption" that the opposition process would be *inter partes*.[150] As such, the term "any person" should be interpreted to include the public at large, although would exclude the patent proprietor themselves.[151] This was reaffirmed by the EBA in G0004/97 where the board held that opponents acting on behalf of unknown third parties – or 'straw men' – were permitted to file oppositions as long as doing so did not constitute an abuse of process.[152] Despite this expansive right to challenge the validity of patents, oppositions are rare. Of the 105,635 European patents that were granted in 2017 4072, or a little under 4%, were challenged under

146 Graham, S.J.H. & van Zeebroeck, N. 'Comparing Patent Litigation Across Europe: A First Look' (2014) 17 Stanford Technology Law Review 655.

147 There are significant delays between filing for opposition and hearings on validity at the EPO. The 2019 EPO Annual Report found that the average pending time for hearings is currently 65 months. European Patent Office, 'Annual Review' (2019). Statistics on the length of time involved if the decision is appealed are not included, but England's research found that if the patent is appealed to the Technical Board of Appeal, it can take a further two years to reach a final decision, see England, P. 'Parallel Patent proceedings between the European Patent Office and UK Courts'. (2015) Journal of Intellectual Property Law and Practice 10(7): 509-517. Similarly, in *IPCom v HTC* [2013] EWCA Civ 1496, the Court of Appeal noted a case which took a decade from the filing of opposition to conclusion.

148 Part V, Chapter 1 Implementing Regulations, EPC.

149 Art.99(1) EPC.

150 G0009/03 (Opposition by Patent Proprietor) 6/7/1994. Here, a patent holder wished to challenge their own patent.

151 *Ibid*.

152 An abuse of process may arise if the opponent is acting on behalf of the patent holder or if the opponent acts in a professional representative capacity without holding sufficient qualifications under Art.134 EPC.

the Opposition Procedure at the EPO.[153] Such oppositions are infrequently filed by non-patent holders driven by non-commercial grounds. This is surprising because where patent oppositions are filed on social, ethical, or moral grounds they attract a significant amount of attention and can spur policy debates. For example, in 2000 the grant of controversial patents over animal transgenic stem cells attracted oppositions, as well as protests at the EPO building in Munich by Kein Patent Auf Leben (No Patent On Life) and Greenpeace.[154] Similar protests were held by NGOs and public interest groups during the *Myriad* opposition proceedings.[155] Opposition proceedings can also serve as a catalyst to spark public policy debates over the morality and ethics of patenting certain inventions, as occurred in the case of stem cells and isolated DNA.[156] Given the relatively low procedural barriers and the potential impact, this raises the question of why this mechanism is so rarely used. This research explores this question further in the analysis of the interviews.

Whilst the EPC text and the EPO Boards show an expansive approach to standing, in contrast to national courts, the grounds upon which the validity of patents can be challenged are limited to those specified in Article 100 EPC namely a) the subject matter of the European patent is not patentable under Article 52 to 57; b) the patent does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art; and c) the subject matter of the application extends beyond the content of the application filed.[157] These grounds are considered in more detail below. Once filed, oppositions are reviewed by the Opposition Division (OD) of the EPO. [158]

Decisions by the OD can be appealed to the Technical Board of Appeal (TBA) by those who are "adversely affected by a decision".[159] TBA decisions are made by a board comprising at least two technically qualified members and one legally qualified member although this may increase to three technically qualified members and two legally qualified members if the OD was an enlarged board or because the board determines that the case merits an enlarged composition.[160] The TBA is the final point of appeal for parties involved in the opposition. If

153 EPO Annual Report 2017, available at <https://www.epo.org/about-us/annual-reports-statistics/annual-report/2017.html> (last accessed 07/04/2021).

154 Parthasarathy, *Patent Politics, supra* n.102 at 139. Protestors also barricaded the doors to the EPO in response to the stem cell patents.

155 Parthasarathy, *ibid* at 172.

156 *Ibid.*

157 These grounds are explored in more detail below in Section 3.3.

158 The OD consists of at least three technically qualified examiners, at least two of whom were not involved in the grant of the patent. If the OD determines that it "so requires" the panel can be enlarged to include a legally qualified examiner. Art.19(2) EPC.

159 Art.19 EPC and Art.107 EPC.

160 Art.21 EPC.

there is a question concerning "uniform application of the law or, if a point of law of fundamental importance arises" the Board of Appeal or the President of the European Patent Office may refer a question on a point of law to the EBA.[161] The composition of the EBA is different than the OD or TBA in that the balance favours legally qualified members of the boards. Under Article 22 EPC an EBA shall consist of five legally qualified members (one of which will Chair the proceedings) and two technically qualified members. Referrals to the EBA are rare; in 2019 of the 3292 cases heard by the TBA, 12 were subsequently heard by the EBA.[162]

It is worth noting Leith's empirical study which reveals that, at the time the study was conducted in 2000 the "culture of the EPO is a largely technical one".[163] He highlights that the balance on the boards favours technically qualified members over legally qualified members in all boards.[164]

> *"The Board of Appeal have not put themselves forward as lawmakers: rather, they have proposed that they are relatively conservative, and that this is not the proper role[…] By emphasising that they are the "caretakers" of a piece of legislation, the notion spread is that the written text and the will of the legislators is their goal."*[165]

However, as Leith argues, in reality, legal texts are reinterpreted in the context which they are read and "in practice, the Boards of Appeal have in fact developed law in a properly "judicial sense" rather than mechanically following the wording of the EPC without regard to context In reality, determining whether the patent application meets the EPC requirements for an 'invention' is not purely a technical matter but has important political and economic dimensions As argued by Plomer, patents are a "hybrid mix of technical and legal components encompassing economic and social consideration" which are embedded in but obscured in the legal requirements of novelty, inventive step and industrial application for an invention.[166]

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161 Art.112 (a), Art.112 (b) EPC.

162 EPO Annual Review 2019, available at <https://www.epo.org/about-us/annual-reports-statistics/annual-report/2019.html> (last accessed 07/04/2021). The composition of the EBA and its rulings are a matter of ongoing controversy due to conflicts of interest and lack of compliance with the rule of law. See the comments by Professor Bross who stated that the EPC is not sustainable under the principles of the rule of law cited in Kluwer Patent Blog available at < http://patentblog.kluweriplaw.com/2017/05/25/rule-law-epo-ugly-writing-wall/> (last accessed 05/08/21)

163 Leith, P. 'Judicial or Administrative Roles: The Patent Appellate System in the European Context' (2001) Intellectual Property Quarterly 1: 50-99 at 65.

164 *Ibid* at 68.

165 *Ibid* at 87, although he highlights that this is not a uniform belief from all EPO officials and that some members of the boards of appeal highlighted that the development of the law around software patents clearly demonstrated the EPO's role as law maker (*ibid).*

166 Plomer, A. 'The EPO as Patent Law-Maker in Europe' (2019) European Law Journal 25(1): 57-74.

Judicial deference to the decisions of EPO Boards thus carries the risk of legitimizing decisions which obscure the real social and economic dimensions of patent applications.[167]

There are three potential outcomes following opposition proceedings; the opposition is rejected, and the patent is maintained as granted; the patent is maintained in amended form or; the patent is revoked.[168] If revoked or amended, this revocation or amendment shall take effect in all Contracting States in which the patent has been designated, as outlined above.[169] If the patent is maintained, however, it is still subject to invalidity proceedings in national courts and in accordance with national laws. In the case of the opposition to the BRCA genes, despite the patents being maintained (albeit in a significantly narrowed form), the challengers did not seek invalidation in national courts. This section has explored how the public can challenge patents. The next section will outline the patentability of isolated DNA by outlining the legal standards of patentability as detailed in the EPC, and the Biotechnology Directive which determines the patentability of isolated DNA in Europe.

3.3 Substantive rules on Patenting Genes in Europe

European patents can be opposed under Article 100 EPC for failure to meet the requirements of novelty, inventive step and industrial application in Article 52 EPC. Myriad's patents were challenged at the EPO both under Article 52 EPC and Article 53 (a) which excludes patents whose commercial exploitation would be contrary to order public and morality or Article 53 (b) which contains a specific list of exclusions imported from the EU Directive on Biotechnological Inventions. As will be seen in the discussion below, it was the challenges to the Myriad patents under Article 52 which ultimately succeeded.

3.3.1 Invention vs. Discovery

Article 52 EPC states that patents shall be granted for any invention, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application. Much like the challenges in the US and Australia, one of the key questions before the EPO was whether isolated DNA could be properly considered an "invention". 'Invention' is not further defined in the EPC but there is a non-exhaustive list of what is not regarded as an invention. Article 52(2) states that discoveries, scientific theories, and mathematical models

167 *Ibid*.

168 Art.102 EPC (if the patent is maintained in amended form, a new patent specification is published see Article 103 EPC).

169 Art.105b EPC.

shall not be regarded as inventions.[170] Further guidance is offered in the EPO Guidelines for Examinations which highlights that the distinction between an invention and discovery turns on the question of "technical effect":-

"If a new property of a known material or article is found, that is mere discovery and unpatentable because discovery as such has no technical effect and is therefore not an invention within the meaning of Art. 52(1). If, however, that property is put to practical use, then this constitutes an invention which may be patentable."[171]

The explosion of biotechnological innovation in the 1980s forced a prompted a debate on whether products or processes containing biological material could be considered an 'invention' – and, as such, were patentable subject matter as distinct from being unpatentable 'discoveries'.[172] Central to this controversy were concerns raised by scientists that patents over biotechnological material would tie up the basic research tools of science, and hamper downstream research.[173] There were also significant moral and ethical concerns about private ownership of biological materials.[174] Conversely, patent advocates argued that to capitalise on the potential of the burgeoning biotechnology sector there had to be sufficient legal protections: biotechnological advances are risky and expensive, and patents provide a buffer to these risks in a similar way to pharmaceutical development and other high risk areas.[175] Despite these concerns the EPO began to grant patents on biotechnological materials, including isolated DNA.

There were other developments in Europe in response to the ongoing moral, ethical, and social controversies about gene patents. In 1998, following protracted discussions, the European Parliament approved a revised text of the Directive on The Legal Protection of Biotechnological Inventions[176] (herein referred to as the Biotechnology Directive) which included a list of specific moral exclusions.[177] The Biotechnology Directive starts by expressly stating that elements

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170 Art.52(2)(a) EPC. Other exclusions from patentable subject matter are aesthetic creations (Art. 52(2)(b)); schemes, rules, and methods for performing mental acts, playing games or doing business, and programmes for computers (Art.52(2)(c)); and presentations of information (Art. 52(2)(d).

171 EPC Guidelines for Examination Part G, Chapter II, 3.1 (March 2021 edition).

172 For a history of the development of biotechnology in relation to genetic inventions see Eisenberg, R. 'Genes, Patents, and Product Development' (1992) Science 5072 (257): 903-908.

173 Gold & Carbone, *supra* n.128128.

174 *Ibid.* See also, for example, *Report of the IBC on Ethics, Intellectual Property and Genomics, supra* n.100.

175 This is explicitly stated in Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, OJ L 213, 30.7.1998, 13–21 (the Biotechnology Directive), s(2).

176 Directive 98/44/EC, *ibid*.

177 These exceptions to patentability were introduced at the very last stages to secure an agreement on the Directive from the European Parliament - see Plomer, *supra* n.101.

isolated from the human body, including genes and cells, are patentable. Article 5(2) and (3) state that:

> *"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…*
>
> *"The industrial application of a sequence or partial sequence of a gene must be disclosed in the patent application."*

As an independent, autonomous body the EPO is not bound by the Directives of the European Parliament. However, the Biotechnology Directive set the legal standard for the patentability of isolated DNA in EU Member States, all of which are signatories to the EPO. In order to avoid patents granted by the EPO being subsequently invalidated in the national courts of member states the EPO transposed Article 5(2) and (3) into Rule 29 (2) and (3) in the EPC Implementing Regulations.

This European legislative and regulatory landscape on the patentability of isolated DNA significantly impacted on how the European challenges to the BRCA patents proceeded. As will be seen in Chapters 4 on the US and 5 on Australia, in which there was no legislation on the patentability of genes, the challengers to the BRCA patents in Europe were faced with a legislative hurdle which expressly construed isolated genes as potential 'inventions'. The US and Australia similarly have broader opportunities to challenge the granted patents for validity. In the US there are judicially recognised exceptions to patentability – notably that products of nature are not patentable subject matter. In Australia, the Patents Act 1990 states a definition of invention as requiring a "manner of manufacture" which the courts have interpreted flexibly and can be argued as to render some inventions not patentable subject matter. At the EPO, in the event the patent application on isolated genes fulfilled the requirements for an 'invention' under the EPC, the case for revocation had to be made under the moral exclusions in Article 53. This chapter now outlines the exceptions to patentability under Article 53 EPC, and argues that its application by the TBA has set a high bar to overcome for patent challengers seeking invalidation of patents on moral grounds.

3.3.2 Exceptions on the grounds of "*ordre public*" or morality

The opposition to the BRCA patents was driven by moral and ethical concerns about patents on human life and nature, as well as fears by the scientific community that such patents would adversely impact on research and limit access to diagnostic tools for both patients and researchers. Even though the challengers to Myriad's patents were limited by the express

patentability of isolated DNA, there remained exceptions to patentability on the grounds of *ordre public* or morality which presented a potential route to challenge the BRCA patents for validity. Article 53(a) EPC states that:

"*European Patents will not be granted in respect of:*

(a) inventions the commercial exploitation of which would be contrary to "ordre public" or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States…"

However, the interpretation of this standard by the EPO had resulted in a high bar to overcome to find an invention contrary to *ordre public* or morality. This was firstly due to the approach by the Technical Board of Appeal in interpreting these standards, which required such exceptions to patentability to be narrowly applied. In *Plant Genetic Systems N.V., et al* the TBA held that exceptions to patentability must be narrowly construed. In determining the validity of patents over genetically modified plant cells and seeds, the TBA held that:

"From the historical documentation relating to the EPC it appears that the view according to which "the concept of patentability in the European patent law must be as wide as possible" predominated…Accordingly, the exceptions to patentability have been narrowly construed, in particular in respect of plant and animal varieties."[178]

The TBA in the decision go on to emphasise that this narrow reading applies equally to Article 53(a):

"This view is consistent with the requirement that the exceptions to patentability under Article 53(a) EPC have to be narrowly construed…"[179]

The bar for establishing an exception under *ordre public* or morality is made higher still by the threshold required to overcome to argue a patent is invalid under Article 53(a). The EPO's Guidelines for Examination state that the exception much only be granted in exceptional cases:

"*The purpose of this is to deny protection to inventions likely to induce riot or public disorder, or to lead to criminal or other generally offence behaviour…This provision is likely to be invoked only in rare and extreme circumstances. A fair test to apply is to*

178 T0356/93 *Plant Genetic Systems N.V., et al* (Plant cells), Board of Appeal (EPO), 21 February 1995, ECLI:EP:BA:1995:T035693.19950221at para 8.

179 *Ibid* at para 18.

consider whether the public in general would regard the invention as so abhorrent that the grant of patent rights would be inconceivable."[180]

The decisions of the EPO also emphasise this high bar, as demonstrated in the OD decision of *Howard Florey/Relaxin*.[181] In determining the patentability of a gene sequence which coded for human relaxin, a hormone used in childbirth, the TD held that "invention concerning a human gene was not an exception to patentability because it would not be universally regarded as outrageous."[182] Demonstrating this standard is also subject to a high threshold. It is not clear how an opponent can establish the view of the public in general. Article 53(a) itself states that it is not sufficient that all contracting states legally prohibit the invention. Cases interpreting this standard have also excluded a range of arguments as irrelevant to questions under this exception. In *Transgenic Animals/Harvard* the TBA determined that a method for producing transgenic rodents was patentable subject matter, despite significant opposition to the inventions under the *ordre public* or morality exception.[183] In doing so, it argued that many of the basis for the arguments put forward did not assist in determining the exception to patentability:

"The many bases (economic, religious, etc.) for definitions of morality suggested by the appellants are of no assistance since no single such basis represents an accepted standard in European culture."[184]

Furthermore, the EPO has been particularly critical of attempts to utilise surveys or opinions polls to determine the view of the public in general.[185] In *Plant Genetics Systems* the TBA held that even opinion polls showing that the majority of people in some or all contracting states opposed the grant of a particular patent "cannot serve as criterion for establishing that the subject matter is contrary to "*ordre public*" or morality."[186] This decision is relied upon, along

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180 EPC Guidelines for Examination Part G, Chapter II, Section 4.1 "Matter contrary to "ordre public" or morality. (March 2021 edition).

181 T0272/95 *Howard Florey Institute/Relaxin*, Board of Appeal (EPO), 23 October 2002, ECLI:EP:BA:2002:T027295.20021023

182 *Ibid* at IV. The case proceeded to be heard at the TBA, by which time the Biotechnology Directive had been enacted and transposed into the EPC. The TBA consequently decided that the human gene did not contravene Art.53(a) as it was explicitly patentable under Rule 29(2) Implementing Regulations.

183 T315/03 *Transgenic Animals/Harvard* Board of Appeal (EPO), 06 July 2004, ECLI:EP:BA:2004:T031503.20040706

184 *Ibid* at 10.10.

185 See T356/93 *Plant Genetic Systems N.V. et al supra* n.178 where the TBA held that opinions polls were not necessarily indicative of the "ordre public" concerns or moral norms that were deeply rooted in European culture, may reflect biased beliefs and therefore were not probative for assessing patentability.

186 *Ibid* at 15.

with various criticisms of the methodological approaches to the opinion polls, in *Transgenic Animals/Harvard* to exclude various opinion polls put forward which supported the argument that the European public were against patenting genetically modified mice.[187] To successfully argue that an invention is an exception to patentability under Article 53(a) then is a significant challenge. The narrow interpretation of the exception, along with the high threshold of establishing the view of the public makes opposition difficult. Establishing a general view of the public on biotechnological inventions is also likely to be complicated by the complex nature of such inventions. As outlined in Chapter 2, experts in the field often struggle to read and understand what is being claimed in patents, much less the general public.

This section has shown that, where an invention meets the patentability criteria in the EPC, Article 53(a) is the grounds under which revocation can be argued. However, use of this ground is only applicable in rare and exceptional circumstances, with a high legal standard to overcome – a standard which, given the divergence of opinions about biotechnology – is likely to be difficult to meet. This significantly narrows the opportunity for challengers to argue against patents on public interest grounds. This chapter now moves on to analysing the oppositions to Myriad's BRCA patents at the EPO to demonstrate the barriers faced by the substantive applications of the patentability criteria.

3.4 Opposing the BRCA Patents

The preceding discussion has outlined how, and on what grounds, members of the public can challenge the validity of European patents at the EPO. This has shown that there are low procedural barriers to overcome, but that arguing under Article 53(a) is a significant challenge which is unlikely to be overcome by a member of the public in relation to biotechnological inventions. This section moves on to analyse the institutional barriers of challenging patents at the EPO, beginning by outlining the concerns which drove the challenge and demonstrates a gap between the access concerns which drove the case, the arguments which were put forward by the challengers at the hearings, and the grounds upon which the BRCA patents were determined patentable subject matter.

3.4.1 "Harmful To Public Health"

The challenges to Myriad's BRCA patents were driven by a broad range of individuals, professional societies, and not for profit organisations.[188] What linked these challengers were

187 T315/03 *Transgenic Animals/Harvard supra* n. 183 at 13.2.20-13.3.

188 A full list of opponents to each BRCA patent is available at Matthjis, G. 'The European opposition against the BRCA gene patents' (2006) Familial Cancer 5: 95-102 at 98.

concerns that Myriad's BRCA patents would have a significant limiting impact on public health and research. There were concerns that the BRCA patents would cause a significant harm to women's health due to a lack of access to the test and a lack of accuracy in the test itself. Matthijs notes that, if the patents were allowed to remain in force, BRCA testing would become impossible or significantly more expensive to carry out.[189] Unlike in the US, where individuals pay for diagnostic tests individually or through insurance coverage, most European countries offer testing through nationalised health services which would bear the brunt of exorbitant testing fees, potentially impacting public health generally. Matthijs, in a paper providing a first-hand account of the challenges at the EPO, highlights the concern that Myriad's patents were harmful to public health systems.[190] As Matthijs and Halley note elsewhere, there was a belief that the BRCA patents would "wreck existing and well-functioning reimbursement systems and will negatively influence health care all over Europe."[191] The concerns about the impact on national health services is echoed by Rob Elles, the then secretary for the British Society of Human Genetics, who stated "Myriad wants to enforce a monopoly on the provision of a service. That is an unwarranted and novel restriction on medical practice".[192]

There was also a concern that Myriad's tests were not accurate, or less accurate than the tests European laboratories were able to carry out themselves.[193] Critics argued that Myriad's tests failed to detect the BRCA mutations in 15% of cases.[194] Furthermore, there was a concern that ownership of the BRCA patents would substantially hinder ongoing research,[195] which was particularly critical at a time when the understanding of genetic disease and its causes was still evolving.[196] Critics of the BRCA patents argued that permitting patents over isolated DNA would tie up the basic tools needed to research genetic disease, hindering scientific understanding and the development of diagnostic testing and treatment. Licence agreements had been offered to laboratories in Europe but were turned down due to concerns about the cost of the agreement

189 *Ibid* at 97; see also Benowitz, S. 'European Groups Oppose Myriad's Latest Patent on BRCA1' (2003) Journal of the National Cancer Institute 95(1): 8-9 where Charis Eng notes that "the cost of doing clinical genetics could skyrocket from such a comprehensive patent".

190 *Ibid* at 99.

191 Matthjis, G and Halley, D 'European Wide Opposition Against the Breast Cancer Gene Patents' (2002) European Journal of Human Genetics 10: 783-785.

192 Wadman, M. 'Testing Time for Gene Patent as Europe Rebels' (2001) Nature 413: 443.

193 Butler, D. and Goodman, S. 'French researchers take a stand against cancer gene patent' (2001) Nature 413: 95-96; Benowitz, *supra* n.189.

194 Gad, S. *et al.* 'Significant contribution of large BRCA1 gene rearrangements in 120 French breast and ovarian cancer families' (2002) *Oncogene* 21: 6841-6847

195 Lucrubier, A. 'Patents and public health' (2002) EMBO Rep 3: 1120-1122. Lucrubier also notes that there was a further concern that researchers would lose expertise in their field as the patents would prevent them from improving on or developing new diagnostic methods.

196 Soini, S. *et al* 'Patenting and Licensing in Genetic Testing: Ethical, Legal, and Social Issues' (2008) European Journal of Human Genetics 16: 10-50.

and resentment at being asked to send samples to the US to be tested by Myriad's laboratories, when the samples were capable of being tested in Europe.[197] As one geneticist notes: "We have developed a test in our own labs. It works. It is not more expensive than Myriad's. And now we should start paying royalties to Myriad?'[198]

Finally, there was incredulity amongst the challengers that Myriad was able to claim the isolated BRCA gene as an invention. Lenoir, the head of research at Gustave-Roussay, commented that "no company should own this genetic information. This monopoly is an abuse of power."[199] Matthijs and others questioned whether the EPO was correctly applying its own standards of patentability, arguing that not only was isolated DNA a discovery but that – even if it met the standard of an invention – it could not be considered novel or having an inventive step as Mary Claire King's discovery of the BRCA location meant that locating the gene would only take a matter of time and was "obvious."[200]

3.4.2 Translating Socio-Economic Concerns

To challenge the BRCA patents, the socio-economic concerns which drove the challengers to Myriad's patents had to be packaged into the permissible grounds of opposition under Article 100 EPC outlined above. This was done predominantly with arguments related to Article 52(2)(a) and Article 53(a). Much of the reasoning by the opposition boards in relation to these arguments is provided in T1213/05 which concerned the opposition to the isolated BRCA1 gene. At the OD hearings, the opponents argued that the BRCA1 patent essentially claimed a link between a disease and gene. The patent as it stood monopolised that concept, meaning the claims were not patentable under Article 52(2)(a) by virtue of being a discovery rather than an invention.[201] The opponents argued, under Article 53(a), that Myriad's patents limited research and would likely lead to a "serious obstruction of the health care systems" which would be contrary to public morality.[202] The OD disagreed on both points. They held that the patents were not irreducible to merely its informational content, and that under Rule 29(2) – which transposed the Biotechnology Directive into the EPC – DNA isolated by a technical process was patentable.[203] In relation to the arguments surrounding public policy, the OD argued that the

197 Wadman, *supra* n.192.

198 *Ibid*.

199 Lucrubier, *supra* n.195.

200 Benowitz, *supra* n.189; Soini, *supra* n.196.

201 T1213/05 *Breast and ovarian cancer/University of Utah,* Opposition Division (EPO) at 11.

202 Ibid at 12.

203 The decision itself refers to the relevant section of the EPC Implementing Rules at Rule 23(e). The relevant provisions of the EPC have been subsequently updated and Rule 23(e) now corresponds to Rule 29. To ensure consistency the more recent ordering of the EPC has been used.

Implementing Rules, guidelines, and previous decision making of the EPO meant that the patentability of isolated DNA could not be found intrinsically immoral. To be sufficiently contrary to *ordre public* or morality, an invention must "be in clear conflict with the fundamental legal or ethical values and such a conflict must exist with all uses of the invention as claimed."[204]The OD held that the arguments about limiting access to research and the impact on national health care services were concerns about the impact of patenting rather than the invention itself. Further, they held that the EPO had not been vested with authority to take into account the economic effects of patents.

Prior to the oral hearings at the OD, Myriad had submitted a claim to amend the patent under Article 123 EPC which permits one opportunity to amend a European Patent during proceedings before the EPO as long as the amendment does not extend the protection conferred by the patent. The OD held the patent valid in its amended form and the case was appealed to the TBA. The opposition to the patent on the grounds of invention remained although the TBA note that the point was not pursued further in oral proceedings.[205] The challengers continued to argue that the invention was contrary to *ordre public* or morality both as a result of the socio-economic concerns identified but also due to Myriad's lack of informed consent from the female donors whose samples led to the location and isolation of the BRCA1 gene. The challengers argued that although Myriad had sought consent, they had not sought consent for the explicit purposes of the invention and, as such, the patents were contrary to human dignity.

Similarly to the OD, the TBA rejected these arguments. The argument that the BRCA1 gene was a discovery was dismissed on the same grounds as the OD. That is, the Implementing Rules of the EPC explicitly defined isolated DNA achieved via a technical process as an invention. The arguments about informed consent were dismissed as not being relevant to the grant of patents and rather the responsibility of national legislatures to regulate.[206] The board noted that the EPC made no provision to establish whether or not informed consent had been obtained and turned to the Biotechnology Directive as a supplementary means of interpretation. In doing so, the board relied on the jurisprudence of the ECJ in *Kingdom of Netherlands v European Parliament and Council of the European Union* which concerned a challenge by the Netherlands to annul the Biotechnology Directive.[207] One of the pleas put forward by the Netherlands was that the absence of a requirement in the directive to have obtained consent from donors

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204 T1213/05 *Breast and ovarian cancer/University of Utah,* Opposition Division (EPO) at 12.2.

205 T1213/05 *Breast and ovarian cancer/University of Utah*, Board of Appeal (EPO), 27 September 2007, ECLI:EP:BA:2007:T121305.20070927 at para 43.

206 *Ibid* at paras. 46-49.

207 C-377/98 *Netherlands v European Parliament and Council of the European Union*, ECLI:EU:C:2001:523.

undermined human dignity. The TBA relied on the ECJ decision and Advocate General Opinion, which rejected the challenge to annul the Biotechnology Directive, stating that:

> "*The Court rejected this plea stating that reliance on the fundamental right of human integrity was "clearly misplaced as against a directive which concerns only the grant of patents and whose scope does not therefore extend to activities before and after that grant…""*[208]

The TBA do not provide reasons as to why reasoning directed at the proper scope and application of the Biotechnology Directive would be applicable to the proper scope and application of the EPC. On the issue of *ordre public* or morality the TBA upheld the decision of the OD that the socio-economic concerns raised were concerned with the consequences of the exploitation of the patent, not the exploitation of the invention and it was the latter which would give rise to a finding of invalidity under Article 53(a). The TBA held that, in essence, the objections were rather about the nature of patents, stating that:

> "*the objection… reduced to its essence, is that the inevitable consequences of the exploitation of the patent in suit are contrary to "order public" or morality. Logically, such an objection applies to the exploitation of any patent*…"[209]

It is not clear how the arguments put forward by the opponents could be applicable to any patent granted by the EPO. Not all patents – nor even all biotechnological patents - pose a risk to public health. Building on the finding that the objections were about patenting rather than the invention itself, the TBA held that the possible consequences raised by the opponents were about the exclusionary nature of the rights, "that is the right to stop competitors using the invention" despite the fact that none of the opponents were commercial competitors.[210] They further reiterated that the EPO had "not been vested with the task of taking into account the economic effects of the grant of patents in specific areas and restricting the field of patentable subject matter accordingly."[211]

This reasoning demonstrates the difficulties in advancing socio-economic arguments against gene patents. Unlike in the US or Australia, the Biotechnology Directive limited the opponent's ability to argue that isolated DNA was a discovery rather than an invention. The TBA's reasoning dismissing the access concerns is particularly problematic for challengers who wish to raise objections to the grant of patents on public health concerns. Such concerns are often about

208 T1213/05 *supra* n.205 at para 50.

209 *Ibid* at para 53.

210 *Ibid*.

211 *Ibid*.

access – whether to diagnostics, medicines, vaccines, or information for ongoing research. The reasoning effectively precludes any arguments on access to an invention as being concerned with patentability rather than the invention itself, suggesting that even if there is universal abhorrence of the invention, any argument going to accessibility would fail under Article 53(a). It is not clear why this has to be the case. The term "invention" in the EPC could be interpreted to mean having met the legal standards required to be a patentable invention– i.e. being new, novel, and having industrial application. Similarly, the TBA does not distinguish between commercial competitors and non-commercial parties. In dismissing the argument based on the patent holders rights to exclude competitors the TBA side steps the consideration of socio-economic arguments. The oppositions put forward were not concerned with commercial availability, but with fears that the patents would harm public health and leave individuals unable to access vital health services.

Despite the lack of success with the above arguments, Myriad's BRCA1 patent was substantially narrowed. In doing so, the TBA focussed on the technical grounds of patentability. Myriad relied upon an earlier US patent application to establish priority for the European patent.[212] The US patent application in question had disclosed the BRCA1 sequence with errors: fifteen nucleotides of the cDNA were incorrectly disclosed. Under Article 87(1)(b) EPC an application for a patent can claim a right of priority for the same invention for 12 months after filing the first application. The TBA narrowly applied the criteria of "the same invention", holding that difference between the US patent application and the European patent resulting from the errors meant that they could not be considered the same invention. This meant that Myriad could only claim priority from a later US patent, which narrowed the European patent to cover only short sections of the BRCA1 gene, rather than the isolated gene as a whole.[213] Whilst meaning that Myriad retained its patent, it was significantly narrowed in its coverage. This narrowing may have contributed to a lack of challenges in national courts: the patent did not have the same restrictive effect as initially envisaged.

A narrowing of coverage on technical grounds is seen in the other oppositions to Myriad's patents. Socio-economic concerns were similarly raised in these cases. In T0080/05, which challenged Myriad's patent claiming a method for diagnosing a predisposition for breast and

212 Priority dates are important in patent applications as they establish the date when "novelty, inventiveness and other aspects of the invention are assessed. As such it is often of critical importance for the validity of the patent" Bentley, L. *et al. Intellectual Property Law* (5th ed. OUP, 2018) 445-446.

213 T1213/05 *supra* n.205 at 19-34. For a further discussion see Lai, *supra* n.135.

ovarian cancer,[214] the opponents argued that Myriad's BRCA patents limited individual ability to access their own genetic information, and there had been no guarantee that genetic information extracted for medical purposes would be kept confidential from law enforcement agencies.[215] They also argued that the method claimed merely claimed a mental process, which should be excluded under Article 52(2)(c) which excludes "schemes, rules and method for performing mental acts…" In T0666/05, which challenged Myriad's patents covering the mutations within the BRCA1 gene, the opponents argued that the commercial exploitation of the patent was unethical, was contrary to *ordre public* or morality, and was a discovery. They highlighted that the patent would result in increased patient costs and would influence how diagnostic research would be organised in Europe, which could cause significant detriment to patients and doctors. Patients suspected of carrying the mutation would also be dependent on the patent holder, which was contrary to human dignity.[216] Furthermore, the opponents claimed that the invention should not be patentable under Article 53(c) which excludes "methods for treatment of the human body or animal body by surgery or therapy and diagnostic methods practiced on the human body or animal body." Myriad's BRCA2 patent was challenged on similar grounds, but was only heard at the OD. The BRCA2 patent was directed to diagnosing a pre-disposition to breast cancer in Ashkenazi-Jewish women and the challenges to the patent on the grounds of *ordre public* or morality focused on whether the patent was discriminatory against Ashkenazi women.

In each of the cases, the socio-economic arguments were summarily dismissed by the board. In each case before the TBA the board merely noted that the concerns had been previously dealt with the socio-economic and ethical arguments under T1213/05, and that it will follow that reasoning in the present case and reject the opposition on those grounds.[217] The OD's decision against the BRCA2 patent relied on the reasoning that the EPO had not been vested with the authority of taking into consideration the economic effect of patents and so rejected the opposition. Instead, the patents were limited due to technical filing errors. T0080/05 was initially revoked by the OD as Myriad had registered the incorrect genetic sequence – again resulting in losing priority. Myriad filed an amended patent before the oral hearings at the TBA, significantly limiting the diagnostic test to detecting frame shift mutations. T0666/05 was limited from claiming 34 mutations to 1: again, significantly limiting the scope of the application

214 T0080/05 *Method of diagnosis/University of Utah*, 19 November 2008, ECLI:EP:BA:2008:T008005.20081119 a challenge to EP0699754 - Method for diagnosing a predisposition for breast and ovarian cancer.

215 *Ibid* at paras 64-65.

216 T0666/05 *Mutation/University of Utah*, 13 November 2008, ECLI:EP:BA:2008:T066605.20081113 at para 81.

217 See T0080/05 at para 65 and T0666/05 at para 80-82.

of the patent. Finally, Myriad's BRCA2 patent was narrowed to a single claim over a nucleic acid sequence.

What has been shown in this section is that, whilst the challenges were driven by socio-economic concerns about the impact of Myriad's BRCA patents, the grounds on which the patents were successfully narrowed were technical ones. The opponent's attempts to translate the concerns about access were largely unsuccessful before the opposition boards. These concerns were side-lined in the hearings, and the interpretation of the objections significantly limits opportunities for public health concerns centring on access to be considered in future cases.

3.5 Conclusion

Despite being unsuccessful in invalidating the BRCA patents at the EPO, no litigation took place in national courts. Van Zimmeren, in her case study of the BRCA patent controversies, notes that as a result of the oppositions the fears about the impact of Myriad's patents diminished significantly.[218] This may account for the lack of national litigation. This does not, however, mean that the challengers were wholly pleased with the outcome of the EPO oppositions. Mathijs notes, discussing the initial revocation of the method patent, that whilst they were happy with the news he "remained sceptical" and was "disturbed that we had won the case on the basis of formal criteria."[219] This statement, made in frustration that they had not successfully argued for invalidation on the grounds of a lack of inventive step, could equally reflect the gap between the concerns that drove the challenges and the grounds upon which the patents were eventually challenged and narrowed. This chapter has shown that whilst the challenges were driven by public interest concerns, these were side-lined in the discussions of patent validity at the EPO. This side-lining was possible, in part, due to the narrow interpretation of the grounds under which such social concerns can be brought. The concerns about Myriad's patents tying up the building blocks of science by permitting patents over isolated DNA were hampered as a result of the adoption of the Biotechnology Directive in the EU and its subsequent transposition into the EPC. This left the challengers with very little space under which to argue concerns about public health, access to diagnostics, and its impact on research. Translating these concerns into patentability arguments was met with limited success, with the patents ultimately being narrowed on technical grounds as a result of filing errors.

218 Van Zimmeren, *et al. supra* n.12.at 156.

219 Matthjis, *supra* n.188 at 100.

This thesis now moves on to analyse the barriers faced by litigation in national courts, beginning with the litigation in the US.

Chapter 4: The United States

4.1 Introduction

Much like the challenges to the European patents, the USSC ruling in *Association for Molecular Pathology v Myriad Genetics*[220] invalidating the BRCA genes has been the subject of significant attention.[221] The Supreme Court found that isolated DNA was not patentable subject matter, overturning a 30-year policy which recognised them as patentable. There have been numerous studies, analysing the impact of the USSC decision. [222] There have also been several empirical studies studying the effect of *Myriad* on patenting behaviour.[223] The case has also attracted discussions concerning human rights, and access to science.[224] The history of the BRCA challenge in the US has therefore already been substantially documented. This chapter does not aim to replicate these studies, Instead, the analysis seeks to show the significant barriers confronting public challenges to patents in US law.

Whilst the challengers in Europe faced relatively low procedural barriers to overcome, the challengers in the US were nearly stopped from bringing their case as a result of the procedural limits on standing. In 2009 the American Civil Liberties Union (ACLU) and Public Patent Foundation (PubPat), representing the Association for Molecular Pathology (AMP) and twenty

220 AMP v Myriad Genetics 569 U.S. 576 (2013).

221 Many of the commentaries outlined in Chapter 3 also have case studies exploring the BRCA challenges in the US including Van Zimmeren, et al. supra n.12; Parthasarathy, *supra* n.102; and Gold and Carbone, *supra* n.128.

222 Tup Ingram, '*Association for Molecular Pathology v. Myriad Genetics, Inc.:* The Product of Nature Doctrine Revisited.' (2014) Berkeley Technology Law Journal 29(4): 385; Aboy, M. *et al.* 'After Myriad, what makes a gene patent 'markedly different' from nature? (2017) Nature Biotechnology 35(9): 820-825. There have also been several studies discussing how the Myriad decision has led to a divergence in the standards of patentability of patents claiming isolated DNA between the US and Europe see, for example, Nicol, D. *et al.* 'International Divergence in Gene Patenting' (2019) Annual Review of Genomics and Human Genetics (2019) 20: 519-541.

223 Aboy, M. *et al.* 'Myriad's Impact on Gene Patents' (2016) Nature Biotechnology 34(11): 1119-1123; Dreyfuss, R. *et al.* 'Patenting Nature-A Comparative Perspective' (2018) Journal of Law and the Biosciences 5(3): 550-589; Aboy, M. *et al.* 'How Does Emerging Patent Case Law in The US and Europe affect Precision Medicine?' (2019) Nature Biotechnology 37: 1118-1126; Cook-Deegan, R. *et al.* 'After Myriad: Genetic Testing in The Wake of Recent Supreme Court Decisions about Gene Patents' (2014) Current Genetic Medicine Reports 2(4): 223-241; Cook-Deegan, R. and Chandrasekharan, C. 'Patents and Genome-Wide DNA Sequence Analysis: Is It Safe To Go Into The Human Genome?' (2014) Journal of Law, Medicine, and Ethics 42(1): 42-50; Offit, K. *et al*. 'Gene patents and personalized cancer care: impact of the *Myriad* case on clinical oncology.' (2013) Journal of Clinical Oncology 31(21): 2743; Evans, B. J. "Mining the human genome after *Association for Molecular Pathology v. Myriad Genetics*." (2014) Genetics in Medicine 16(7): 504; There have also been studies exploring the implication of the *Myriad* decision in other areas of genetic testing, including non-invasive pre-natal testing-see Hawkins, N. *et al*. 'The Continuing Saga of Patents and Non-Invasive Pre-Natal Testing' (2019) Prenatal Diagnosis 39(6): 441-447.

224 See, for example, Plomer, A. *Patents, Human Rights and Access to Science* (Edward Elgar, 2015).

other plaintiffs, filed a claim against the United States Patent and Trademark Office (USPTO) and Myriad Genetics Inc for a declaratory judgment that several of Myriad's US BRCA patents were invalid.[225] Nearly all the plaintiffs were found to lack standing, with only one challenger remaining as the case reached the US Supreme Court. The challenge was a rare example of public interest litigation succeeding in invalidating patents. Other public legal challenges over other controversial patents, such as those claiming stem cells[226] or genetically modified seeds[227], were unsuccessful due to the plaintiffs being barred from bringing the claim due to lack of standing.

This chapter details how and why – given the significant public policy dimensions – the Myriad case nearly did not reach the Supreme Court. The chapter begins by outlining the history of the identification and isolation of the BRCA gene before detailing what patents were granted to Myriad. The second part outlines the ACLU's challenge to the patents, focusing on how a public interest approach impacted the plaintiffs represented and the framing of the legal arguments presented. These sections provide detail to the subsequent section, which outlines the legal test for determining standing in declaratory judgment actions laid down in two seminal cases: *Lujan v Defenders of Wildlife* and *MedImmune v Genentec*. The analysis of these cases shows that standing creates a significant procedural barrier to public interest challenges, and that this barrier is higher for patent litigation. The decisions on standing in *AMP v Myriad* demonstrate these difficulties. The final section of the chapter outlines the legal arguments put forward by the ACLU in the litigation and the decision of the Supreme Court which found that Myriad's patents were invalid. This analysis shows that there was a significant gap between the public interest grounds which drove the challenges, and the Courts decision which predominantly focused on the legal determination of whether an isolated gene was "markedly different" from that found in nature.

The overall analysis shows that the rules on standing created a significant procedural barrier to the BRCA patent challenges on behalf of the public in the US. There is no dearth of attention paid to the Myriad case and the focus on the public interest aspect is not unique, but this chapter

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225 See 35 U.S.C s.101 which states "Whoever invents or discovers any new and useful process, machine, manufacture, or 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 ACLU argued that the isolated genes were invalid as they were a "product of nature" and therefore not patentable subject matter.

226 *Consumer Watchdog v Wisconsin Animal Research Foundation* 753 F.3d 1258.

227 *Organic Seed Growers and Trade Association et al. v Monsanto* 718 F.3d 1350.

highlights the barriers which almost prevented the challenge from being heard in the US courts.[228]

4.2 Overturning 30 years of patent policy

The ACLU[229] decided to challenge the validity of the BRAC patents held by Myriad because of the barriers they created for women seeking diagnosis and treatment of breast cancer . The organisation argued that ownership of isolated DNA "has very dangerous implications for women's health and scientific research" as it restricted access to testing, as well as to information about their own genetic information. [230] Myriad were not the only biotechnology company which held patents over isolated BRAC DNA. However, few had attracted the level of concern directed at Myriad Genetics. This was, in part, due to Myriad's conduct in the BRCA 'patent race', the company's business strategy, and its aggressive enforcement of its patents which ultimately prompted the ACLU to take on the case on behalf of patients, doctors and scientists, as explained below.[231]

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228 Similarly to Europe, there are studies exploring the role that the public played in challenging the US BRCA patents. Parthasarathy's *Patent Politics* mentioned in chapter 2 above, in particular, compares the US and European BRCA challenges through case studies, exploring how public interest groups were able to bring challenges and how the different jurisdictions dealt with those challenges. Parthasarathy's work argues that the difference between the US and European approach to the question of life science patents are shaped by distinct moral and socio-political orders embedded within each patent system. This, in turn, shapes how the patent system functions, including the opportunities available to challenge the grant of patent rights. However, Parthasarathy's work is not a doctrinal legal analysis, and she does not explore in depth the substantive legal and procedural aspects which might limit challengers. This research contributes this analysis by examining the nature and scope of the procedural barriers on standing faced by patients, NGOs, public interest groups, researchers and scientists in bringing gene patent challenges on public interest grounds.

229 The ACLU is an organisation focused on civil liberties and civil rights in the US and, as such, uses the terminology 'civil rights' when discussing the Myriad case. The terminology 'public interest' is more commonly used in the UK and Australia and so this terminology is used in this research, and in this chapter for consistency.

230 See the 'The Fight to Take Back Our Genes' (ACLU Website) https://www.aclu.org/issues/privacy-technology/medical-and-genetic-privacy/fight-take-back-our-genes?redirect=fight-take-back-our-genes (accessed April 2018). See also Park S. 'Gene patents and the public interest: litigating Association for Molecular Pathology v. Myriad Genetics and lessons moving forward' (2014) North Carolina Journal of Law & Technology 15(4): 519.

231 Baldwin and Cook-Deegan's analysis of the difference in treatment between biotechnology companies who held patents over isolated DNA argued that whilst Myriad's patents were part of the controversy, the company's business strategy and bad press it attracted contributed significantly to the level of criticism and litigation levelled at it. See Baldwin, A. and Cook-Deegan, R. 'Constructing narratives of heroism and villainy: case study of Myriad's BRCAnalysis compared to Genetech's Herceptin' (2013) Genome Medicine 5(8): 1-14.

See also Gold, R. and Carbone, J. *supra* n.123. Some scholars argue that the unique 'policy storm' and circumstances surrounding Myriad's BRCA patents mean that it is difficult to draw inferences from when discussing patents more broadly. However, whilst the policy storm may have meant

4.2.1 Context of the ACLU BRCA Challenge

In 1990 Professor Mary-Claire King and her team at the University of California announced that they had discovered, through a linkage analysis of various families, that the gene responsible for causing hereditary breast cancer were located on chromosome 17 of the human genome.[232] This finding triggered a fierce global race between several research teams to locate, isolate, and patent the gene.[233] In 1994 Dr Mark Skolnick's team at the University of Utah, working with Skolnick's biotechnology company Myriad Genetics Inc, announced that they had successfully isolated and cloned the BRCA1 gene.[234] In June of the same year Myriad applied to the US Patent and Trademark Office (USPTO) for a series of patents covering the isolated BRCA1 gene, mutations within the gene, diagnostic methods for detecting genetic mutations, and cDNA – a synthesised copy of DNA with the non-coding proteins removed. In total, between 1994 and 1998 Myriad applied for, and were granted, 8 US patents relating to the BRCA1 and BRCA2 genes totalling hundreds of claims.[235] Myriad were not the only company which held patents over the BRCA gene in the US; OncorMed, a pharmaceutical company, held patents covering some mutations whereas Myriad held others creating a "relatively muddled" landscape in which both companies had overlapping claims to the entire BRCA1 gene.[236] This complex landscape led to litigation where the companies sued each other for patent infringement The case settled a matter of days before the Court hearing. The upshot of this litigation was that Myriad gained OncorMed's BRCA1 patent rights. This acquisition gave Myriad a monopoly on BRCA diagnostic testing in the US: a position they aggressively asserted through infringement litigation and enforcement of their intellectual property rights.[237]

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that the patents and subsequent litigation attracted more attention than other patent cases, it did not shape the procedural, legal, or institutional barriers to patent challenges. Conversely, there is an argument that the attention made the challenge in the US easier. Chris Hansen, lead attorney for the ACLU in *AMP v Myriad,* noted in an interview that he believed that the Federal Circuit "bent their own…standing rules" so as to facilitate defeating the ACLU on the merits of the claim, see Young, A. 'Prelude to Pigs Fly: The Early History of the Myriad Case' (2014) in Thesis Outside the Disciplines. (Duke University, 2014)

232 Hall, J. *et al.* 'Linkage of Early-Onset Familial Breast Cancer to Chromosome 17q21' (1990) *Science* 250(4988): 1684-1689.

233 For a history of the race see Gold & Carbone, *supra* n.128128; Van Zimmeren, *et al. supra* n.12. Parthasarathy, S. *Building Genetic Medicine: Breast Cancer, Technology, and the Comparative Politics of Health Care* (MIT Press, 2012)

234 Miki, Y. *et al.* 'A Strong Candidate for the Breast and Ovarian Cancer Susceptibility Gene' (1994) *Science* 266(5182): 66-71.

235 For a full list of the USPTO granted BRCA1 and BRCA2 patents see Cook Deegan R, DeRienzo C, Carbone J, Chandrasekharan S, Heaney C, Conover C.. 'Impact of gene patents and licensing practices on access to genetic testing for inherited susceptibility to cancer: comparing breast and ovarian cancers with colon cancers' (2010) Genetics in Medicine, Apr 12(4 Suppl): S15 at A50-A51.

236 Van Zimmeren, *et al. supra* n.12. at 160-161.

237 Gold & Carbone, *supra* n.128 at 42.

Myriad's enforcement activities attracted significant attention and criticism.[238] Patents covering genes generally had been controversial since their initial grant in the 1980's but Myriad's marketing strategy brought to the fore many of these concerns. Scientists argued they were prevented from continuing BRCA related research after Myriad sent cease and desist letters to laboratories following the grant of its patents. The *de facto* market monopoly granted by the broad coverage of the US Myriad's patents meant that the company set the price for the diagnostic test, which it priced at around $3,000.[239] Paying this fee out of pocket was unaffordable for many women, and there was piecemeal insurance coverage for such genetic tests.[240] There were criticisms that Myriad's BRCA analysis was inaccurate, and that its patents stymied attempts to develop more sensitive diagnostic testing.[241]

Against this background the ALCU identified gene patents as a potential area which raised concerns about civil rights, particularly those rights of women. Park, who acted as Counsel in the Myriad litigation on behalf of the ACLU, summed up the broader civil rights concerns as:

> "*On a more fundamental level, our commitment to ensuring people's rights to bodily integrity, human dignity, and scientific freedom gave rise to a deep discomfort with the*

238 *Ibid.*

239 Cook-Deegan, R. *et al.* 'Impact of Patents and Licensing Practices on Access to Genetic Testing for Inherited Susceptibility to Cancer: Comparing Breast and Ovarian Cancers to Colon Cancers', Annex A1 in Secretary's Advisory Committee on Genetics, Gene Patents and Licencing Practices and Their Impact on Patient Access to Genetic Tests: Report of the Secretary's Advisory Committee on Genetics, Health and Society (2010).

240 This is as a result of the US privatised health system in which insurance companies and private businesses have to arrange coverage before patients can be reimbursed for medical tests and treatment. As Myriad was the only company offering the BRCA testing in the US, this meant that insurers had to negotiate with them alone which was reported as a lengthy process (see Cook Deegan *et al*, *supra* n.235). The situation in the US was complicated further as a result of potential genetic discrimination. Some employers were unwilling to offer health insurance for employees who were at risk of developing a genetic disease. As such, some women who did have insurance for diagnostic tests did not wish to use their insurance as it risked minimising or eradicating their health coverage. The US eventually passed the Genetic Information Non-Discrimination Act (GINA) 2008 which prohibited discrimination on the basis of genetic information.

241 Concerning the accuracy and cost of Myriad's tests see Dr Wendy Cheung's testimony and Cook-Deegan et al, *Impact of Patents and Licencing Practices on Access to Genetic Tests for Inherited Susceptibility to Cancer: Comparing Breast and Ovarian Cancers to Colon Cancers* in Secretary's Advisory Committee on Genetics, Health and Society, *Report on Gene Patents, Licencing Practices and Their Impact on Patient Access to Genetic Tests* (2010). The SACGHS report, in its case study comparing the patenting landscape of the BRCA gene and the gene responsible for causing hereditary colon cancer, found that there was some impact on access to testing and research although this could not conclusively be drawn to patents and licencing practices. It did note that there were significant accuracy issues with Myriad's BRCA testing, and that Myriad as the sole provider of diagnostic testing effectively dictated industry standards and stunted the development of cheaper, alternative diagnostic tests, see Cook-Deegan, R. *et al.* 'Impact of Patents and Licensing Practices on Access to Genetic Testing for Inherited Susceptibility to Cancer: Comparing Breast and Ovarian Cancers to Colon Cancers', Annex A1 in Secretary's Advisory Committee on Genetics, Gene Patents and Licencing Practices and Their Impact on Patient Access to Genetic Tests: Report of the Secretary's Advisory Committee on Genetics, Health and Society (2010).

notion that the government could grant rights over the human body, simply because they are isolated from the body."[242]

This approach – challenging patents as litigation on behalf of the public – shaped who the ACLU represented, the procedural barriers it had to overcome, and how it framed its legal arguments challenging the validity of the BRCA patents. Amongst the difficulties faced by the ACLU in fighting the case was the hurdle of overcoming US rules on standing which severely restrict the type of plaintiffs and the nature of complaints which can be heard by the courts whereby plaintiffs are required to show 'harm'. The next section sets out the US rules on standing and the following section the 'harm' doctrine before analysing how the ACLU navigated these rules.

4.3 The Doctrine of Standing

Standing is "the question of who can obtain access to the courts."[243] The answer to this question has its roots in the US constitution and has been interpreted to exclude organisations and individuals acting on behalf of the public interest from bringing litigation.[244] To argue that the BRCA patents were invalid, the ACLU filed a claim under the Declaratory Judgment Act which states that "in a case of actual controversy within its jurisdiction…any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such a declaration…".[245] Such declarations will "have the force and effect of a final judgment or decree and shall be reviewable as such".[246] To establish a "case or controversy" under the Act, parties have to demonstrate "under all the circumstances…that there is a substantial controversy, between parties having adverse legal interests, of sufficient

242 Park, *supra* n.230230 at 520.

243 Richard Pierce Jr, 'Is Standing Law or Politics?' (1998) North Carolina Law Review 77(5): 1741.

244 Article III, Section 2 US Constitution limits judicial power to reviewing cases or controversies; Sunstein, an American constitutional scholar, argues that an interpretation which excludes claims on behalf of the public interest is a relatively recent approach, identifying the late Supreme Court Justice Scalia's treatise in 'The Doctrine of Standing as an Essential Element of the Separation of Powers' (1983) Suffolk University Law Review 17(4): 881 and subsequent judgment in *Lujan v Defenders of Wildlife*-explored below-as a turning point where such public interest challenges were significantly restricted as a purported exercise in judicial restraint and adherence to the constitution. Justice Scalia argued that a strict interpretation of standing was essential to upholding the separation of powers in the US, and ensuring the judiciary exercise restraint and do not make decisions more appropriately determined by the executive branch. See Sunstein, C. 'What's Standing After Lujan of Citizen Suits, "Injuries" and Article III' (1992) Michigan Law Review, 91(2): 163

245 28 U.S.C. s.2201.

246 *Ibid*

immediacy" to warrant issuing a declaratory judgment.[247] To meet this test, parties have to prove that they have sufficient standing to bring an action for declaratory judgment.[248]

Establishing sufficient standing has been difficult for bodies acting on behalf of the public interest as a result of how this standard has been interpreted by the judiciary. This is surprising as early cases in the nascent US judicial system post-independence welcomed interventions by those with no specified interest beyond representing the public at large.[249] As Jaffe states: "the public action- an action brought by a private person primarily to vindicate the public interest…had long been a feature of our English and American law".[250] However, the opportunity for such interventions were significantly narrowed by the Supreme Court decision in *Lujan v Defenders of Wildlife,* which laid out the three-pronged test for standing in the US and described as "one of the most important standing cases since World War II."[251]

Lujan concerned conservationists seeking a declaratory judgment under the Endangered Species Act (ESA). The ESA aims to protect endangered species and requires any action by US federal agencies which may threaten such species to consult with the Secretary of the Interior before taking such action. The Secretary of the Interior sought to interpret the statute as only requiring consultation where the federal agency proposed actions in the United States, rather than requiring consultation where such action took place either in the US or in foreign nations.[252] The Defenders of Wildlife, a not-for-profit conservation organisation, sought a declaration that the correct interpretation was the broader one, namely that consultation was required regardless of the geographical location of the proposed action. The injury claimed was the potential lost opportunity to visit international locations and observe endangered species should federal agencies not have to take into consideration the risks to these species when debating whether to provide funding to proposed developments outside the United States.

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247 *MedImmune v Genentec* 549 US 118 at 127.

248 Parties also have to show ripeness and mootness, see *Association for Molecular Pathology et al, v Myriad Genetics and United States Patent and Trademark Office* 689 F.3d 1303 (2012) at 1318. The main argument put forward in Myriad were those around standing, and standing has been the test which has prevented other public interest groups from proceeding and, as such, this chapter focusses on standing.

249 See Berger, R. 'Standing to Sue in Public Actions: Is it a Constitutional Requirement?' (1968) Yale Law Journal 78(5): 816.

250 Jaffe, L., 'Standing to secure judicial review: Public actions' (1961) Harvard Law Review 74(7): 1265 at 1270.

251 *Lujan v Defenders of Wildlife* 504 U.S. 555 (1992). Sunstein, C. 'What's Standing After Lujan of Citizen Suits, "Injuries" and Article III' Michigan Law Review, 91(2) (1992): 163 at 165.

252 *Lujan, ibid,* Justice Scalia, at 558.

Justice Scalia, in handing down the majority opinion, denied the conservationists standing to challenge the Interior's interpretation. In doing so he laid down a three-pronged test for establishing whether a plaintiff had standing to bring suit:

> "*Over the years, our cases have established that the irreducible constitutional minimum of standing contains three elements: First, the plaintiff must have suffered "an injury in fact" – an injury of a legally protected interest…and [the injury be] "actual or imminent" not 'conjectural' or 'hypothetical'…Second, there must be a causal connection between the injury and the conduct complained of – the injury has to be "fairly traceable" to the challenged actions of the defendant and not the result of the independent action of some third party not before the Court. Third, it must be "likely", as opposed to merely "speculative" that the injury will be "redressed by a favourable decision".*[253]

The Defenders of Wildlife were found to lack standing as they failed the "injury-in-fact" test and their injuries could not be adequately redressed by the declaration sought. Justice Scalia argued that the injuries claimed were not "real and immediate" as the conservationists only had the intention to travel to international locations "some-day". As the conservationists had provided no evidence or description of concrete plans, they failed to demonstrate an "actual or imminent" injury.[254] An injury-in-fact equally could not be found simply because the conservationists had a cognizable interest in the endangered species. To demonstrate an injury-in-fact the individual seeking the review "himself must be among the injured" and must be able to show a direct effect, rather than merely a special interest.[255] In terms of redressability, the Court held that the federal agencies would not necessarily be bound by the Secretary's opinion, nor that the United States would be the only nation involved in funding projects in areas where there were endangered animals. As such, the declaration would not remedy the injury claimed.[256]

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253 *Ibid* Scalia, at 560.

254 *Ibid* Scalia, at 564.

255 *Ibid* Scalia, at 563.

256 On a broader point about public interest challenges the *Lujan* decision also discusses the "citizen-suit" provision within the Endangered Species Acts which permits any individual to "commence a civil suit on his own behalf…to enjoin any person, including the United States and any other government agency…who is alleged to be in violation of any provision of the [ESA]". Justice Scalia continued to find the Defenders of Wildlife also did not have standing to bring suit, despite this provision, but the Patent Act contains no similar provision. As such, this is not discussed further here. However, see Sunstein, *supra* n.251251 at 165 for a discussion concerning how Scalia's decision "ranks among the most important in history in terms of the sheer number of federal statutes that it has apparently had invalidated".

4.3.1 Demonstrating Harm

The decision in *Lujan* has been criticised as creating a too significantly high bar for public interest challenges.[257] Justice Blackmun, in his dissenting opinion, is particularly critical of the majority decision holding that:

> *"I cannot join the Court on what amounts to a slash-and-burn expedition through the law of environmental standing. In my view, "[t]he very essence of civil liberty certainly consists in the right of every individual to claim the protection of the laws, whenever he receives an injury."*[258]

Justice Blackmun was particularly critical of the court's analysis for demonstrating injury. He held that there were no barriers stopping the plaintiff's from purchasing plane tickets to go and visit the endangered species and, in fact, would have been more likely than an average citizen to do so as a result of their special interest. The requirement for a concrete plan, he argues, is an "empty formality and….will do little to weed out those who are genuinely harmed from those who are not".[259] He points out that all this requirement will do will force judges to "demand more and more particularized showing of future harm" from plaintiffs.[260] Future cases have not clarified the line between a particularized harm and special interest.[261]

The judgment also does not provide any guidance on what act would distinguish between "someday" intentions and concrete plans – an important distinction which, as will be shown below, was central to the finding that many of the researcher plaintiffs in Myriad did not have standing.

For patent challenges, the injury-in-fact requirement has also been difficult to prove and has tended to focus on commercial injuries to the exclusion of those outside a business relationship. In *Consumer Watchdog v WARF,* Consumer Watchdog argued that they had standing to challenge the grant of patents over stem cells due to the impact on tax payers implicated by such

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257 Curry, I. 'Establishing Climate Change Standing: A New Approach' (2019) 36 Pace Environmental Law Review 36(1): 297-331 at 304, discussing environmental challenges – ""thus these decisions have increased the burden that environmental plaintiffs must meet to establish standing".

258 *Lujan, supra* n.251 Judge Blackmun, at 606.

259 *Ibid.* Blackmun, at 592-593.

260 *Ibid*.

261 For a comparison to *Lujan* see *Friends of the Earth Inc v LaidLaw Environmental Services 528 U.S. 167* which went so far as to hold that "reasonable concerns" about the effect of environmental harm could be enough to give rise to standing at 181-184. Curry, discussing the injury-in-fact requirement in public interest claims in environmental cases, argues that "the doctrine of standing expands and contracts without any discernible patterns." See Curry, I. 'Establishing Climate Change Standing: A New Approach' (2019) 36 Pace Environmental Law Review 36: 297 at 315.

research.[262] The Federal Circuit refused the grant of standing, focussed its analysis on whether Consumer Watchdog would, or would claim to, engage on commercial activities. The Court held that:

> "*does not allege that it is engaged in any activity involving human embryonic stem cells that could form the basis for an infringement claim. It does not allege that it intends to engage in such activity. Nor does it allege that it is an actual or prospective licensee, or that it has any other connection to the '913 patent or the claimed subject matter."*[263]

As such, the Court held that the organisation strongly opposed the grant of the patent which would only give rise to a general grievance and therefore not be particularized or concrete.

A similar approach was utilised by the Federal Circuit Court to exclude most of the plaintiffs in *AMP v Myriad.* Initially, in the District Court, Sweet recognised that preventing access to testing options and second opinions were recognisable harms sufficient enough to grant standing to the non-researcher plaintiffs. Their injuries were not speculative, nor concerned with the mere granting of patents over isolated DNA. Instead, they had definitive harms causally linked to a specific patent, as well as linked to the policy of the USPTO in granting these patents. The Federal Circuit, in contrast, significantly narrowed the harms which were recognised by Judge Sweet in the District Court. The Judges spend some time discussing the three plaintiffs who could point to a direct action by Myriad (Drs Ostrer, Kanguly and Kazazian) but dismissed all the other plaintiffs collectively, despite their differing claims. In dismissing their arguments for standing, the Federal Court stated that the "various other plaintiffs" should not be granted standing as "simply disagreeing with the existence of a patent on isolated DNA sequences or even suffering an attenuated, non-proximate, effect from the existence of the patent does not meet the Supreme Court's requirement for an adverse legal controversy…"[264] Going on, the Federal Court states that "the various organizational plaintiffs in this suit….accordingly suffered no injury and thus lack standing…". This decision conflated the patient harms (i.e. lack of access to genetic testing) and the organizational harms (i.e. lack of access to information and data for research or for genetic counselling). Both harms are dismissed as not being an injury and are instead referred to as an "attenuated, non-proximate effect" of the BRCA patents.

The only harm recognised by the Federal Circuit Court is that of individual researchers, with the harms suffered by the patient and organisational plaintiffs dismissed. In effect, this restricts the

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262 Consumer Watchdog v Wisconsin Alumni Research Foundation 753 F.3d 1258 (2014).

263 *Ibid* at 1261.

264 *Association for Molecular Pathology v Myriad,* 653 F. 3d 1329 (2011) at 1323.

range of individuals who can bring an action to those who are at risk of being sued for infringement by the patentee.

4.3.1.1 The (De)selection of ACLU Plaintiffs

To represent the range of harms caused by Myriad's patents, the ACLU approached a broad range of plaintiffs in an approach akin to other public interest cases they had filed previously. The Courts approached the question of standing by approaching the plaintiffs broadly in two categories: the non-researcher plaintiffs, and the researcher plaintiffs.

Of the twenty plaintiffs represented, four were not-for-profit professional organisations whose members were "ready, willing, and able to engage in research and clinical practice involving the BRCA1 and BRCA2 genes if the patents [were] invalidated".[265] Two were not-for-profit public interest organisations who were seeking to utilize additional resources for analysis and provide information about other laboratory testing.[266] Six were individual women who required BRCA testing, or additional BRCA testing following earlier indeterminate results about their genetic risk. Myriad's monopoly also meant that the women were unable to seek a second opinion as Myriad were the only laboratory in the US able to offer diagnostic testing.[267] Two of the plaintiffs were genetic counsellors who argued they would be able to gain access to more accurate tests at a lower price for their patients.[268]

The remaining six plaintiffs were scientists and researchers. Drs Cheung, Warren and Ledbetter argued that were capable of evaluating the samples themselves but were required to send them to Myriad for examination. Dr Cheung's specific research interests were on the BRCA genes, whereas Drs Warren and Ledbetter were heads of laboratories capable of evaluating the BRCA gene. Drs Ganguly and Kazazian were co-directors of the Genetic Diagnostics Laboratory at the University of Pennsylvania. The laboratory was sent a 'cease and desist' letter by Myriad, addressed to Dr Kazazian, in 1998 and stopped genetic testing on the basis of that letter. They confirmed in their affidavit that they were ready and able to begin testing should Myriad's patents be invalidated.[269] The final plaintiff, Dr Ostrer, was the director of the Molecular

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265 See complaint of Association for Molecular Pathology et al, submitted to the United States District Court Southern District of New York in *Association for Molecular Pathology et al, v Myriad Genetics and United States Patent and Trademark Office,* 702 F. Supp. 2d 181 (2009).

266 *Ibid*. The two groups were Boston Women's Health Book Collective and Breast Cancer Action.

267 The women were Lisbeth Cerani, Patrice Fortune, Vicky Thomason, Runi Limary, Kathleen Raker, and Genae Girard. See ACLU, 'BRCA-Plaintiff Statements' available at < https://www.aclu.org/other/brca-plaintiff-statements> last accessed 01/06/21.

268 *Ibid*.

269 See complaint of Association for Molecular Pathology et al, submitted to the United States District Court Southern District of New York in *Association for Molecular Pathology et al, v Myriad Genetics and United States Patent and Trademark Office,* 702 F. Supp. 2d 181 (2009).

Genetics Laboratory at New York University. Dr Ostrer claimed that he was capable of evaluating the BRCA samples, and his laboratory was ready to begin BRCA testing immediately if the patents were invalidated.

Despite this multitude of plaintiffs and variety of harms claimed, nearly all the plaintiffs were found to lack standing. *Association for Molecular Pathology et.al v USPTO and Myriad Genetics Inc* was filed and subsequently heard in 2009[270] but, before a hearing on the substantive issues could take place, the USPTO and Myriad challenged the proceedings on the basis that the plaintiff's represented by the ACLU lacked sufficient standing to bring a suit against them. Despite the District Court finding that all twenty plaintiffs could pursue the claim, the Federal Circuit held, on appeal, that only Dr Ostrer had sufficient standing to challenge the validity of the BRCA patents. This is significant because, when the case eventually reached the Supreme Court, a unanimous decision determined that Myriad's patents claiming the BRCA1 gene and its mutations were invalid. In reaching this decision, the Court held that Myriad's BRCA1 patents was not patentable subject matter as isolated DNA was "found in nature" and therefore fell within one of the exceptions of patentability under s.101 35 U.S.C.[271] Vitally, the Court recognised that patent law required a balance:

> "*On the one hand, the promise of exclusive rights provides monetary incentives that lead to creation, invention, and discovery. On the other hand, that very exclusivity can impede the flow of information that might permit, indeed spur, invention…"), the court in AMP stating that "We must apply this well-established standard to determine whether Myriad's patents claim any "new and useful composition of matter" s.101, or instead claim naturally occurring phenomena."*[272]

Myriad's patents tied up the "basic scientific tools", thus lying beyond the domain of patent protection.[273] The substantive decision is discussed in more detail below.

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270 The ACLU eventually challenged fifteen claims across seven US Patents; US5,747,282 (Claims 1, 2, 5, 7, and 20), US5,837,492 (Claims 1, 6, and 7); US5,693,473 (Claim 1), US5,709,999 (Claim 1), US5,710,001 (Claim 1); US5,753,441 (Claim 1); US6,033,857 (Claims 1 and 2) *Association for Molecular Pathology et. al. v. USPTO and Myriad Genetics Inc et. al 702 F.Supp.2d 181 (S.D.N.Y. 2010)* at 211-212.

271 *Association for Molecular Pathology et al v Myriad Genetics Inc* 569 U.S. 576 (2013) This exception was elucidated by the court in *Diamond v Chakrabarty* 447 U.S. 303 (1980) where it was held that "laws of nature, physical phenomena, and abstract ideas are not patentable."

272 *Association for Molecular Pathology, ibid* at 2115-2120, citing Justice Breyer in *Mayo Collaborative Servs. v. Prometheus Labs., Inc.* 132 S.Ct. 1289 at 1305.

273 *Ibid*.

4.3.2 Judicial Application of Standing in *Myriad*

The *Lujan* test also presents a unique difficulty for patent challenges. The constitutional requirement that the judiciary are limited to hearing cases or controversies means that the "mere existence" of a potentially adverse patent is not sufficient to permit potential infringers to sue for a declaration that the patent is invalid. To do so would require courts to issue advisory opinions on the validity of patents, rather than determining a genuine dispute. Competitors would have to infringe the patent to create a case or controversy before challenging the patent for validity in court. Taking such infringement action is risky: the cost of defending such actions is exorbitant and there is no guarantee the court will find the patent invalid. [274] Federal Courts have struggled with this difficulty, and struggled to find an appropriate balance between awareness of the "mere existence" of a patent, and requiring infringing activity to create a "case or controversy."[275] As such, a distinct legal test has been established to determine standing in cases where there has been no violative action against the patent holders rights. This test – outlined in *MedImmune v Genentec*[276] – plays a significant role in determining the standing of those acting on behalf of the public interest as it is likely that those plaintiffs will not have taken infringing action.

MedImmune v Genentec arose out of the difficultly establishing standing to seek declaratory relief before taking infringing action against a granted patent. Although this case particularly concerns actions between two commercial competitors it is worth outlining as the Federal Circuit applied these standards to plaintiffs in *AMP v Myriad.* Prior to *MedImmune* the Federal Circuit had established a two-stage test for establishing standing in patent infringement cases where there had been no infringement action by the plaintiff. First, the alleged infringer had to have a 'reasonable apprehension of suit' at the time it filed the action; and secondly, the alleged infringer must have produced, or made meaningful preparations to produce, an allegedly infringing product".[277] However, this meant that if a competitor agreed a licence and continued adhering to the terms agreed it would not be able to pursue litigation to challenge the patent's

274 American Intellectual Property Law Association, *Report of the Economic Survey 2019* which places the cost of patent litigation between $250,000 and $4 million depending on the complexity of the case.

275 La Belle, M. 'Standing to Sue in the Myriad Genetics Case' (2011) California Law Review Circuit 2: 68-94.

276 *MedImmune, Inc v Genentec, Inc* 549 U.S. 118 (2007).

277 *Ibid* quoting *Shell Oil Co v Amoco Corp* 522 F.2d 33 (8th Cir. 1975).

validity as they could have no 'reasonable apprehension of suit' whilst they were adhering to the terms of the licence agreement.[278]

The question about whether a licence holder had to breach the terms of the licence demonstrate sufficient "controversy" eventually reached the Supreme Court in *MedImmune v Genentec*.[279] Genentec sought a declaration, under the Declaratory Judgment Act, that MedImmune's patent covering Synagis, a respiratory drug, was invalid.[280] Genetec was the sole licensee of Synagis and had not engaged in any activity that would breach the licence agreement with MedImmune. As such, both the District Court and Federal Court held that a licensee in good standing "cannot establish an Article III case or controversy with the regard to the patent's validity, enforceability or scope".[281] A valid licence obliterated any reasonable apprehension of a lawsuit, and therefore there was no "real or immediate" injury. The US Supreme Court disagreed and held that the aim of the Declaratory Judgment Act was to ameliorate the issue where the potential patent infringer is stuck between abandoning their rights or risking prosecution.[282] In determining that MedImmune had standing the Supreme Court held that there were no bright lines delineating what circumstances satisfied the "case or controversy" requirement in declaratory judgement actions.[283] Instead, "the question in each case is whether the facts alleged, under all the circumstances, show that there is substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of declaratory judgment."[284] There is no guidance in *MedImmune* as to contours of the "all the circumstances" test nor was there any discussion concerning what level of immediacy would count as "sufficient".

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278 This was the situation in *Gen-Probe v Vysis* , 926 F. Supp. 948 (S.D. Cal. 1996) Vysis owned a patent which covered a method and diagnostic kit which screened blood for HIV and hepatitis C. Shortly after the patent was granted it came to the attention of Vysis that Gen-Probe were developing a test which would potentially infringe their existing method and diagnostic kit claims. Gen-Probe, in the course of litigation covering other issues the two companies were involved in, decided to obtain a licence for use of the Vysis patent rather than engage in potentially infringing activities. Shortly after the licence agreement Gen-Probe sued, under the Declaratory Judgment Act, alleging that their diagnostic tests did not infringe Vysis's patents and claiming that Vysis's patents were invalid. Vysis sought to dismiss the claim for lack of standing as Gen-Probe continued to pay the licence fees due to them, "albeit under protest". Vysis argued that as Gen-Probe remained a licensee in good standing they could not have a reasonable apprehension of a suit. The Federal Circuit agreed, finding that the absence of a breach meant there could be no reasonable apprehension of suit. As such, Gen-Probe were denied standing.

279 *MedImmune, Inc. v. Genentech, Inc* 549 U.S. 118 (2007).

280 *Ibid* at 118.

281 *Ibid* at 122.

282 *Ibid* at 129.

283 *Ibid* at 127.

284 *Ibid* at 126.

A broad reading of the "all the circumstances test" could facilitate public interest claims. This is demonstrated by the decision at the District Court. However, the Federal Circuit Court read the claims narrowly, creating a significant barrier to public interest challenges. This chapter now outlines how each Court applied the "all the circumstances" test and how the Federal Circuit interpretation presents significant difficulties for public interest groups bringing patent litigation.

4.3.2.1 "All The Circumstances" In Myriad

The lack of guidance as to the contours of the "all the circumstances" was beneficial for the plaintiffs in *AMP v Myriad* at the District Court. Judge Sweet held that the correct test to apply was, taking into account all the circumstances, whether there was a "substantial controversy, between two parties having adverse legal interests, of sufficient immediacy and reality to warrant the issue of a declaratory judgment".[285] Specifically relating to patent rights Judge Sweet found that there was "a trend [to] find an actual controversy…[where] the plaintiff's product arguably practices a patent and that patentee has some indication that it will enforce its rights".[286] First, Justice Sweet held that a finding of apprehension of suit did not require an overt and specific act directed toward an individual plaintiff. Instead, the totality of Myriad's actions were considered.[287] Myriad had taken direct action against Drs Kazazian and Ganguly in the form of a cease and desist letter sent ten years prior to the litigation, and there was no jurisprudence which suggested that a letter sent a significant time in the past could not form part of "all the circumstances". More than that, the general acceptance that Myriad enforced their patents aggressively over the course of several years should be taken into consideration. The fact that they had not pursued enforcement action within recent years was, instead, evidence of their monopoly position in the US.

Secondly, Judge Sweet held that all the plaintiffs represented had made sufficiently meaningful preparations to satisfy the "all the circumstances" test. The researcher plaintiffs and medical organisations demonstrated sufficient preparation through their laboratory equipment, expertise and desire to begin commercial BRCA testing.[288] The evidence that they were "willing and ready" to begin commercial genetic testing satisfied the requirement that the plaintiff be meaningful prepared to engage in BRCA testing. The non-researcher plaintiffs demonstrated sufficient meaningful preparations by being willing to engage in, solicit, or encourage others to

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285 *Association for Molecular Pathology v Myriad Genetics,* Inc 702 F.Supp.2d 181 (S.D.N.Y) Judge Sweet at 387.

286 *Ibid*.

287 *Ibid*.

288 *Ibid*. Judge Sweet at 390.

solicit genetic testing via individuals or companies.[289] There was no jurisprudence that required contributory infringers should not be granted standing in declaratory judgment actions. This decision demonstrates how the standing requirements can be read to include a broad interpretation of harm and causality. Using the "all the circumstances" test laid down in *MedImmune* Judge Sweet was able to interpret the laws to permit an inclusive approach to gene patent challenges. However, his decision was overturned by the Federal Circuit, limiting the ability of challenges to gene patents by patients and public interest groups.

In the Federal Court of Appeal, the standing of most of the plaintiffs was successfully challenged: only Dr Ostrer was found to have a fairly traceable, real and immediate injury stemming from Myriad's actions.[290] Most of the non-researchers plaintiffs were summarily denied standing on the basis that they were not the target of any enforcing action, nor had they made any preparatory actions to undertake potentially infringing activities and thus suffered no injury.[291] The Federal Court of Appeal determined that Judge Sweet's consideration of a real and immediate threat was too broad. It was insufficient that there was a widespread understanding that Myriad would actively and aggressively enforce its patents.[292] Rather, it was necessary that there be an affirmative act directed at the plaintiff.[293] Only three plaintiffs were able to identify an affirmative act aimed at them directly: Dr Kazazian, Dr Ganguly and Dr Ostrer. All three had received the cease-and-desist letter, although in different capacities.

Drs Kazazian and Ganguly were found to have an injury traceable to Myriad's actions but were denied standing on the basis that they lacked a 'real and immediate' threat of infringement action from Myriad. This was because the two doctors, in their affidavits, stated that they would immediately consider resuming BRCA testing should the patents be invalidated. Vitally, they stated that they would "immediately consider" rather than "immediately begin".[294] It was not sufficient that these two doctors had the equipment and expertise nor that they had the desire to potentially begin BRCA testing. Relying on *Lujan* held that "some-day" intentions were not sufficient to justify standing.[295] Thus, the Federal Court overturned the District Court's decision and held that Drs Kazazian and Ganguly were unable to point to specific intentions, and therefore lacked standing.

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289 *Ibid*. Judge Sweet at 392.

290 *Association for Molecular Pathology v Myriad Genetics Inc,* 653 F.3d 1329 Fed. Cir (N.Y). Judge Lourie at 1319.

291 *Ibid*. Judge Lourie at 1348.

292 *Ibid*.

293 *Ibid.*

294 *Ibid*. Judge Lourie at 1316.

295 *Lujan, supra* n.251251.

This left only Dr Ostrer who was found to have standing as the recipient of an affirmative act from Myriad (in the form of the 'cease and desist' letter). He had a 'real and immediate' injury because he alleged an intention to actually and immediately engage in infringing BRCA activities.[296] Finally, Dr Ostrer's injuries were directly traceable to Myriad. His laboratory had ceased commercial genetic testing following the above letter, and he had a desire to continue testing.[297]

4.3.3 Silence from the Supreme Court

Where does the above leave the question of standing in public interest challenges? There is a sharp contrast between the District Court and Federal Circuit's approach to standing, which continued to be argued at the Supreme Court. Myriad continued to challenge the standing of Dr Ostrer, but this was dismissed in a perfunctory footnote which held that "Dr Ostrer has alleged sufficient facts "under all the circumstances" [to] show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment".[298] This silence is particularly surprising given the presence of Justice Scalia, an advocate of a narrow reading of standing, on the bench.[299]

The Federal Circuit's narrow reading of the all the circumstances test presents several difficulties for challenging patents on public interest grounds. As outlined above, the injury-in-fact requirement narrows the opportunity down to commercial interests. The requirement that a plaintiff have an "unequivocal intent" to begin BRCA testing to be granted standing effectively bars any plaintiff who may have suffered harm as a result of a patent but is not in a position to infringe the patent itself: a situation a public interest groups is unlikely to find itself in. This significantly restricts the ability to bring cases on public interest grounds. If the ACLU had been unable to garner interest from the scientist or researcher plaintiff (which was nearly the case) it is possible that they would not have been successful at challenging the gene patents beyond the District Court. The requirement of immediacy is also problematic for challenges from

296 *AMP v Myriad supra* n290. Judge Lourie at 1319.

297 The Federal Court of Appeal also spent a significant amount of time detailing the adverse legal relationship between Dr Ostrer and Myriad. This was because one of the main arguments put forward by Myriad against standing was that the 'cease and desist' letter was too old and stale to justify finding a "real and immediate injury". The court held that the adverse legal relationship had formed because Dr Ostrer believed that he had the right to continue BRCA testing without a licence, on the basis that Myriad's patents were invalid. This relationship had not changed despite the passage of time; Myriad's assertions of its patent rights had not changed and Dr Ostrer's expertise and desire to continue BRCA testing had equally not changed.

298 *Association for Molecular Pathology et al v Myriad Genetics Inc* 569 U.S. 576 (2013) at 10.

299 See Scalia, A. 'The Doctrine of Standing as an Essential Element of the Separation of Powers' (1983) Suffolk University Law Review 17(4): 881.

organisations of scientists and researchers too, particularly given the length of time it takes to challenge a patent. Laboratories and researchers are unlikely to stop other's research activities or keep funds back in the hope that the patent will eventually be found invalid. If they did so, this would further hinder innovation.

The Federal Court decision also conflated the patient harms (i.e. lack of access to genetic testing) and the organizational harms (i.e. lack of access to information and data for research or for genetic counselling). Both sets of harms are dismissed as not being an injury and are instead referred to as an "attenuated, non-proximate effect" of the BRCA patents. This demonstrates a disconnect between the legal construction of harm, and those harms suffered by members of the public due to limits on access of genetic tests, data, research and the prevention of secondary opinions. The only harm recognised by the Federal Circuit Court is that of individual researchers, with the harms suffered by the patient and organisational plaintiffs dismissed. Moreover, it is not clear why these harms could not be considered an injury and be analysed under the *Lujan* test. The Court itself recognised that:

> *"certain patients also allege an injury based on their inability to gain access to affordable BRCA genetic testing because of Myriad's patent dominance of such services. While denial of health services can, in certain circumstances, state a judicially cognizable injury…Plaintiffs have not pressed this as an independent ground for standing. Moreover, we fail to see how the inability to afford a patented invention could establish an invasion of a legally protected interest for purposes of standing."*[300]

Future potential injury to health is a difficult ground upon which to pursue standing, but the Federal Circuit provides no reasoning as to why it would not be permissible here – particularly given the fact that the patients could demonstrate an immediate harm in the form of being unable to have certainty over their genetic risk. This lack of reasoning presents difficulties for future public interest cases to build upon and distinguish.

4.4 Invalidating the BRCA Patents

Once the procedural hurdle of standing had been overcome, the question of whether or not isolated DNA could be considered patentable subject matter could then be considered. This section briefly outlines the legal standards of patentability, along with the judicially recognised exceptions, before outlining how the ACLU were eventually successful in invalidating the BRCA patents.

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300 *Association for Molecular Pathology v. U.S. Patent and Trademark Office* 689 F.3d 1303 (Fed. Cir. 2012) at 1344, fn.7.

4.4.1 Legal Standard for Granting Patents

The legal threshold for being granted a patent in the US is contained in s.101 USC 35 which states that "whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor…" There are several judicially recognised exceptions to s.101, as outlined by the US Supreme Court in *Diamond v Chakrabarty*.[301] *Chakrabarty* concerned the patentability of bacteria which had been genetically modified to break down crude oil. At the time, the USPTO rejected Chakrabarty's application for a patent over the bacteria on the grounds that living things could not constitute patentable subject matter. Chakrabarty appealed and the case reached the Supreme Court, which found that the bacteria can constitute patentable subject matter. In its decision the court held that "anything under the sun that is made by man" is patentable subject matter.[302] However, they recognised that patentability under s.101 was not without limits and excluded "the laws of nature, physical phenomena, and abstract ideas" as such discoveries are "manifestations of nature, free to all men and reserved exclusively to none".[303] The court went on to find that the bacterium claimed was patentable as, although found in nature, it had markedly different characteristics from its natural form: notably, the bacteria in nature would not have been able to break down the crude oil the way the genetically modified bacteria could.[304]

This question of what makes an invention "markedly different" has attracted significant judicial and scholarly attention, and was central to the question of whether isolated DNA constitutes patentable subject matter.[305] The question turned on "whether the act of isolating the DNA – separating a specific gene or sequence of nucleotides from the rest of the chromosome" was sufficient to make the invention markedly different from that found in nature.[306] What constitutes 'markedly different' between natural and isolated DNA is subject to fierce debate. This is due to the nature of DNA which can be categorised according to its chemical, functional, structural, or informational content. The category through which the DNA is viewed shapes the

301 *Diamond v Chakrabarty* (1980) 447 U.S. 303.

302 *Ibid* at 447.

303 *Ibid* at 447 quoting *Funk Brothers Seed Co. v. Kalo Inoculant Co.* (1948) 333 U. S. 127.

304 The Supreme Court held that "judged in this light, respondent's micro-organism plainly qualifies as patentable subject matter. His claim is not to a hitherto unknown natural phenomenon, but to a non-naturally occurring manufacture or composition of matter -- a product of human ingenuity "having a distinctive name, character [and] use."

305 Aboy, M. et al. 'After Myriad, what makes a gene patent 'markedly different' from nature? (2017) Nature Biotechnology 35(9): 820-825; Dreyfuss, R. *et al.* 'Patenting Nature – A Comparative Perspective' (2018) Journal of Law and the Biosciences 5(3): 550-589.

306 *Association for Molecular Pathology et al v Myriad Genetics Inc* 569 U.S. 576 (2013) at 8.

answer to the question of difference and this difference in approach can be seen in the amicus curiae briefs submitted to the Supreme Court in *AMP v Myriad.*[307] For example, James Watson, the co-discoverer of the double helix, submitted an amicus brief arguing against the patentability of isolated DNA, emphasising its informational content:

> *"The [judicial] opinions admirably describe the scientific details of DNA and human genes, but the opinions by the appeals court miss the fundamentally unique nature of the human gene. Simply put, no other molecule can store the information necessary to create and propagate human life the way human DNA does. It is a chemical entity, but DNA's importance flows from its ability to encode and transmit the instructions for creating a human being."*[308]

In contrast, the amicus brief jointly submitted by the University of Baltimore School of Law and John Hopkins School of Medicine Centre for Medicine and Law argue that isolated DNA should be considered patentable subject matter as a result of its chemical, structural, and functional differences:

> "*These synthetic DNA strands differ from their natural counterparts in several significant ways: The synthetic strands are not found directly in nature, but rather are constructed or isolated using inventive laboratory techniques. The synthetic strands are smaller, isolated, and focused, while natural DNA incorporates massive genomic information unrelated to a specific gene, mutation, or disease. The synthetic strands possess unique molecular structures and chemical properties unlike anything found in nature. Perhaps most importantly, the synthetic strands provide useful functionality that their natural counterparts lack, specifically in the critical areas of diagnosis and therapy."*[309]

This section now turns to outline how the US courts resolved the question of the patentability of the isolated BRCA gene and details how the various courts applied the judicially recognised exceptions to s.101 USC 35 to reassert the balance between private rights and the public interest.

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307 In *AMP v Myriad* 41 amicus briefs were submitted by nearly 100 different individuals and corporations were filed, with a broad range of backgrounds and opinions. There was a significant range of approaches to the question of whether isolated DNA can be patentable subject matter, along with opinions ranged from simply highlighting that a particular corporation had a similar case in the judicial system, to reigniting the Constitutional debates which featured in the District Court, to arguing that the Justices did not have the jurisdiction to hear the case at all.

308 Amicus brief of James D Watson, submitted to the US Supreme Court in *Association for Molecular Pathology et al v Myriad Genetics Inc* 569 U.S. 576 (2013).

309 Amicus brief of University of Baltimore School of Law and John Hopkins Centre for Medicine and Law, submitted to the Supreme Court in *Association for Molecular Pathology et al v Myriad Genetics Inc* 569 U.S. 576 (2013).

4.4.2 Reaffirming the "product of nature" doctrine

Seven of Myriad's patents were challenged for lack of validity in the US courts. These patents broadly cover three claimed inventions: the isolated BRCA genes and mutations, cDNA (synthetic copies of DNA with the non-coding introns removed), and a method claim for identifying mutations correlated with a predisposition to breast cancer. The isolated BRCA genes and mutations are the main focus of the litigation, and so this section focuses on the arguments and judicial decisions related to these claims.

Following his finding that all of the plaintiffs had standing Judge Sweet proceeded to hear evidence on the question of whether Myriad's BRCA genes were not patentable subject matter. Myriad argued that isolating the BRCA gene was sufficient enough to render it patentable. The company went on to argue that the isolated DNA should be treated the same as any other chemical compound, and that the isolation made the BRCA gene structurally and functionally different from natural DNA.[310] Judge Sweet disagreed, finding that Myriad's argument ignored the informational content of genes and "fails to acknowledge the unique characteristics of DNA that differentiate it from other chemical compounds".[311] The utility of the BRCA gene came from the information contained within it, not from the differences in structure or chemical nature. As such, Myriad's claims to isolated DNA and mutations were not patentable as they were found in nature.[312] cDNA was equally found patent ineligible as simply isolating the gene, or removing the introns, in the case of cDNA, does not render the gene "markedly different" to the native DNA found in the human body.[313] Judge Sweet went on to find that the method claims for correlating DNA mutations to an increased susceptibility in breast and ovarian cancer, and the claim for comparing growth rates in potentially cancerous cells were equally unpatentable, as they were simply "data gathering steps" which were insufficient to transform the mental process into a patentable invention.[314] Myriad appealed, and the case proceeded to the Federal Circuit.

The case took a circuitous route between the District Court and the Supreme Court, with two hearings at the Federal Circuit. *AMP v Myriad* was initially heard in the Federal Circuit in 2011,

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310 *Association for Molecular Pathology v Myriad Genetics Inc and USPTO* 702 F.Supp.2d 181 (S.D.N.Y. 2010) at 228.

311 *Ibid*.

312 *Ibid*. Judge Sweet at 231-232.

313 *Ibid*. Judge Sweet at 227-228.

314 *Ibid*. Here, Judge Sweet held that the invention failed the "machine or transformation" test put forward in *Bilski v Kappos,* 561 U.S. 593 (2010) and discussed in *Mayo Collaborative Services v Prometheus Laboratories* Mayo 132 S. Ct. 1289 (2012). This test requires that a process transforms an article from one state to another.

in which the Federal Circuit found all bar one of the plaintiffs lacked standing and partially overturned Judge Sweet's decision – finding that isolated DNA and cDNA could constitute patentable subject matter. In doing so, the Federal Circuit court held that the fact that the patents had the same informational content both in nature and when isolated did not negate its patent eligibility. Rather, genes should properly be considered chemicals, and therefore the focus of the inquiry of difference should be structure, rather than function. The court found that the isolated DNA was markedly different as a result of its chemical structure:

> *"Applying this test to the isolated DNA in this case, the challenged claims are drawn to patent-eligible subject matter because the claims cover molecules that are markedly different—have a distinctive chemical structure and identity—from those found in nature."*[315]

The court argued that the BRCA gene in nature was part of the long strand of contiguous DNA molecules, and isolated DNA was 'cleaved' from this strand by human intervention to create just a fraction of the naturally occurring gene thus making it markedly different.[316] Despite the US Government filing an amicus to argue that isolated DNA should be considered a product of nature, the Federal Circuit argued that the actions of the legislature and the USPTO warranted a finding of patentability.[317] The failure to exclude isolated DNA as patentable subject matter in the American Invents Act 2011 (which was going through legislative proceedings whilst *AMP v Myriad* was progressing through the courts) and the long standing practice of the USPTO in granting the patents were both used as reasons to find that Myriad's patents were valid.[318]

In considering the role and balance between private rights and the public interest in granting patents, the court's perspective focused on the rights of the patent holder. There was a concern that a finding of invalidity would upset the settled expectations of inventors and risk impacting innovation:

> *"But, respectfully, it is the adverse effects on innovation that a holding of ineligibility might cause. Patents encourage innovation and even encourage inventing around; we must be careful not to rope off far-reaching areas of patent eligibility."* [319]

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315 *Association for Molecular Pathology v. USPTO*, 689 F.3d 1303 (Fed. Cir. 2012). at 1328.

316 *Ibid*.

317 Amicus Brief of the United States, submitted to the Court of Appeals for the Federal Circuit in *Association for Molecular Pathology v Myriad Genetics and USPTO* 689 F.3d 1303 (Fed. Cir. 2012) No. 2010-1406.

318 *Association for Molecular Pathology*, (Fed. Cir) *supra* n.315 at 1330-1331.

319 *Ibid* at 1333.

The public interest is therefore framed as flowing from increasing innovation and patenting. The decision also found cDNA as patent eligible subject matter, but upheld the District Court's findings that the method claims for analysing DNA sequences were not patentable, although the method claim for screening potential cancer therapies through cell growth rates were valid.[320] The ACLU appealed to the Supreme Court, but the case was remitted to the Federal Circuit to be reheard in light of the Supreme Court's decision in *Mayo v Prometheus.*[321] *Mayo* concerned the patentability of a process for comparing the concentrations of metabolites in a patient's blood with appropriate doses of an autoimmune treatment to establish the correct dosing level to avoid harm. Finding that this relationship was not patentable, the Supreme Court found that the relationship between the two was a product of nature, and any process seeking to claim that relationship needed additional features to ensure that the patent sought to claim, "genuine applications of [laws] rather than drafting efforts design to monopolize the correlations."[322] The Federal Circuit reheard *AMP v Myriad* in 2012, reaffirming its findings in 2011. The ACLU appealed the decision to the Supreme Court.

The ACLU narrowed its challenge at the Supreme Court, focussing on nine claims across three patents. These covered the isolated BRCA1 gene, the isolated BRCA2 gene, and cDNA. Myriad relied on the Federal Circuit reasoning and argued that they were entitled to the patents as the process of isolating the DNA sequences was sufficient to "markedly change" them from a product of nature to a patentable composition of matter. Although acknowledging that the informational content of the DNA remained the same both whether in the gene or isolated, Myriad argued that isolating the DNA requires severing the chemical bonds, thus changing its chemical structure. The ACLU response argues that the isolated BRCA genes are products of nature. Responding explicitly to Myriad's argument about the separation of the chemical bonds, the ACLU presented evidence that DNA with severed chemical bonds were sometimes present in nature. In respect of cDNA, the ACLU argue that the case should be resolved without reaching a determination on the patent eligibility of cDNA as none of the claims were limited only to cDNA, instead seeking to claim both isolated DNA and the related cDNA.

The Supreme Court, in a unanimous decision, held that isolated DNA is a product of nature and, in accordance with the judicially recognised exceptions under s.101, was therefore not eligible for patent protection. The Court recognised that Myriad did not "create or alter any of the genetic information encoded in the BRCA1 and BRCA2 genes" and that "the location and order

320 *Ibid* at 1334-1337.

321 *Mayo Collaborative Services v Prometheus Laboratories Mayo* 132 S. Ct. 1289 (2012).

322 *Ibid* at 8-24.

of nucleotides existed in nature before Myriad found them."[323] Although Myriad's argument at trial focused on the changes in chemical structure, the court held that its patent claims were properly read to focus on the information contained within the BRCA genes not on its chemistry or functions. As such, the invention was concerned with information, which was a product of nature and not markedly different from that found in its natural state.

4.4.2.1 Balancing private and public interests

Whereas the Federal Circuit were concerned with not "roping off far-reading areas of patent eligibility" the Supreme Court were explicitly concerned that Myriad's patents would stifle innovation by limiting access to the BRCA gene. The judges held that patents over products of nature would be deleterious to the public interest as they are the "basic tools of scientific and technological work" and that there "would be considerable danger that the grant of patents would "tie up" the use of such tools and thereby "inhibit future innovation premised upon them".[324] In doing so, the court were able to utilised the exceptions to patentability under s.101 to recognised that patents are a balance between private rights and the public interest. This decision also emphasised that this balance does not inexorably have to favour the patent holder or support unimpeded expansions of patentability. The court held that cDNA is patent eligible as the creation of an exon-only molecule is not naturally occurring; the method claims at issue in earlier courts were not argued.

Whilst this decision *prima facie* represents the court re-emphasising the balance necessary to justify the grant of patents, the Court's decision was made on the basis of the application of the patentability criteria and recognised exceptions. The reasoning of the decision does not take into consideration – or mention at all – the broad social concerns which drove the ACLU and the various plaintiffs to challenge the patent. The ACLU's submission to the Supreme Court emphasised these social concerns, highlighting the lack of access to diagnostic testing, genetic information, and further research. The introduction to its brief submitted to the court barely touches upon the question of patentability, but instead discusses the impact of Myriad's patents on patients and researchers. In focussing on the application of the patentability criteria, the court sidestepped any consideration of the social issues, taking a narrow view of what should be reviewed when determining the correct balance of the patent system.

The Supreme Court decision in *AMP v Myriad* demonstrates how the courts can assert and redress the balance between private rights and the public interest in the grant of patents, acting

323 *AMP v Myriad Genetics* 569 U.S. 576 (2013) at 11-12.

324 *Ibid* at 11.

as a bulwark against the risks of a patent holder centric system discussed in Chapter 2. However, this balancing takes a narrow view – excluding a discussion of the social harms that patents can cause when determining this balance. Here, the court relied upon the product of nature exception to s.101 to reassert the public interest in granting patents. These exceptions are currently under threat of being legislatively repealed. This section now briefly outlines the contemporary challenge to the judicially recognised exceptions under s.101 and discusses what this means for public interest challenges to patents.

4.4.2.2 Contemporary Challenges to s.101

In 2019 US Senators Tillis and Coons convened a series of hearings focussed on the question of whether or not to reform patent eligibility under s.101 35 USC. The concern which drove these hearings was a perceived lack of certainty regarding patent eligibility in the US. The Senators are particularly worried that the judicial application of s.101 and the recognised exceptions have created a lack of clarity in US patent law and thus undermined innovation. The hearings took place over three days, with a range of participants.[325] Summarising their findings following the hearings, the Senators concluded that,

> *"the U.S. patent system with regard to patent eligibility is broken and desperately needs to be repaired. The U.S. Supreme Court has confused and narrowed Section 101 of the Patent Act to the point that investors are reluctant to pursue the innovations that propel our country forward."*[326]

In response, the Senators put forward a proposed amendment to s.101 which would add a legislative presumption of patentability and remove all "implicit or judicially created exceptions to subject matter eligibility including "abstract ideas," "laws of nature," or "natural phenomena"".[327] These reforms would have a significant impact on bringing public interest challenges to patents. First, there is the potential that removing the product of nature doctrine would permit patents which 'tie up' the building blocks of science. This was a particular concern of the Supreme Court in its decision in *AMP v Myriad,* outlined above. Secondly, challengers to

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325 Videos of the three days of hearings are available at the Committee of the Judiciary website < https://www.judiciary.senate.gov/meetings/the-state-of-patent-eligibility-in-america-part-i> last accessed 11/07/201

326 Coons, C. and Tillis, T. 'Tillis and Coons: What We Learned at Patent Reform Hearings' (2019) available at < https://www.tillis.senate.gov/2019/6/tillis-and-coons-what-we-learned-at-patent-reform-hearings> last accessed 11/07/21.

327 Tillis, T. 'Sens. Tillis and Coons and Reps. Collins, Johnson, and Stivers Release Draft Bill Text to Reform Section 101 of the Patent Act' (2019) available at <https://www.tillis.senate.gov/2019/5/sens-tillis-and-coons-and-reps-collins-johnson-and-stivers-release-draft-bill-text-to-reform-section-101-of-the-patent-act> last accessed 11/07/21.

patent validity would be left to argue that the patents did not meet the patentability criteria of novelty, inventive step, and non-obviousness – which constitute narrower questions about the technical nature of the invention compared with the more flexible nature of the inquiry under the current s.101 exceptions. The benefits of this approach are analysed further in the next chapter, which outlines the "manner of manufacture" requirement in Australian patent law: a flexible provision to determining whether or not something is an 'invention'.

The proposal received mixed responses. The Electronic Frontier Foundation – a not for profit civil liberties organisation – argued that the reforms would significantly stifle innovation[328] and IPWatchdog, a popular pro-patent online IP blog, called the proposal "good news" and necessary to facilitate a strong US patent system.[329] The progress of the amendment has faltered due to a lack of stakeholder support, however reforming s.101 remains a potential policy initiative which may impact public interest challenges in the future.[330]

4.5 Conclusion

Prior to Myriad there were limited success stories of public interest challenges to patents, and there have been limited success stories since.[331] The analysis *of AMP v Myriad* demonstrates that the ACLU were right to approach the issue of standing strategically. Most of the plaintiffs who were initially involved in the litigation were found to lack standing when the case reached the Federal Circuit hearings.[332] This analyses has shown that the standing doctrine, through the narrow interpretation of injury-in-fact and the "all the circumstances" test creates a significant procedural barrier to individual patients and public interest groups from being able to bring gene patent challenges. Such a narrow interpretation of this doctrine is not necessarily inevitable. Early judicial cases recognised public interest litigation and the District Court decision demonstrates how the standing requirements could be read to include a broad

328 See, for example: Moss, A. 'The Tillis-Coons Patent Bill Will Be A Disaster for Innovation' (2019) Electronic Frontier Foundation available at < https://www.eff.org/deeplinks/2019/04/tillis-coons-patent-bill-will-be-disaster-innovation > last accessed 11/07/21

329 Quinn, G. 'The One Word That Will Help Restore the US Patent System' (2019) IP Watchdog available at < https://www.ipwatchdog.com/2019/05/30/one-word-will-help-restore-u-s-patent-system/id=109882/ > last accessed 11/07/21.

330 Borella, M. 'The Zombie Apocalypse of Patent Eligibility Reform and a Possible Escape Route' (2020) JDSupra, available at < https://www.jdsupra.com/legalnews/the-zombie-apocalypse-of-patent-52573/ > last accessed 11/07/21.

331 Potential reasons for this lack of cases are explored further in the Discussion chapter.

332 *Association of Molecular Pathology, et al. v. United States Patent and Trademark Office and Myriad Genetics Inc* 653 F3d: 2010-1406.

interpretation of harm and causality.[333] However, the silence of the Supreme Court on the issues leaves the narrowed interpretation of the Federal Circuit as good law concerning public interest challenges to patents. This chapter has also shown how the Supreme Court utilised the judicially created exceptions to s.101 to redress an imbalance in the patent system which tilted in favour of broad patent holder rights, although noted that the narrow grounds on which they did so excluded the main motivating factors which drove the patent litigation.

This research now turns to analyse whether challenges to the grant of gene patents are more successful in jurisdictions where there are no procedural limits on standing, using the litigation against Myriad's patents in Australia as a lens to explore these issues.

333 Although there is disagreement on whether such an approach would be beneficial. See Maxey, J. 'A Myriad of Misunderstanding Standing' (2011) West Virginia Law Review 113: 1033-1071 which argues that an application of the District Court's reading of the standard could "diminish patent incentives and potentially destroy the patenting process" at 1035.

Chapter 5: Australia

5.1 Introduction

As shown in Chapter Four, the US challengers faced significant barriers to overcome the limitations on standing when litigating to invalidate Myriad's BRCA patents. In contrast, the challengers at the EPO had little difficulty in establishing standing but were faced with a rigid application of the EPC which left little room to pursue the public interest arguments which drove their challenge. The opposition at the EPO took place within a patent office and its procedures are not judicial whereas the litigation in the US took place in the Courts. Similarly, the Australian litigation took place in the courts but, in contrast to the US, the Australian litigants had no difficulty in establishing standing. This chapter analyses the barriers to litigating the validity of patents in a jurisdiction where there are few procedural barriers to bringing patent challenges.

This chapter begins by outlining the history of the BRCA patents litigation in Australia. The chapter then outlines the legal requirements to challenge the validity of patents in Australia. Compared to the US, there are few procedural barriers to public challenges. Furthermore, the chapter shows that the statutory definition of an invention in Australian law and precedents left sufficient flexibility for the Australian High Court to invalidate the Myriad patents. However, the discussion also highlights how judicial construction of the statutory definition has narrowed the opportunity to challenge the validity of patents on public interest grounds.

5.2 Context to Myriad's patent challenges in Australia

The landscape of gene patents in Australia has been described as "less cluttered" than that of the US and Europe, with fewer patents over isolated genes granted than in the US and Europe.[334] This landscape is mirrored in the grant of the BRCA patents: there were fewer patents granted to Myriad than in the other jurisdictions studied in this research. An empirical study in 2003 also shows that there was generally less enforcement of gene patents, albeit with Myriad – and its sole Australian licensee Genetic Technologies Inc (GTG) – highlighted as exceptions to this finding.[335] Despite this clearer landscape, gene patents attracted significant controversy and

334 Van Zimmeren, *et al. supra* n.12.at 163.

335 Nicol, D. and Nielsen, J. 'Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry' (2003) University of Tasmania, Centre for Law and Genetics Occasional Paper No. 6. https://eprints.utas.edu.au/2550/1/NandN_final.pdf

criticism.[336] Concerns about cost, access to diagnostics, and the impact on research remained and ultimately led, in 2013, to litigation challenging the validity of Myriad's patents.[337]

The Australia litigation began later than the challenges in the US and Europe. That is not to say that the patents did not attract controversy: there were a range of concerns raised about the grant of patents over isolated DNA[338], and several policy reports exploring the wisdom of granting such patents.[339] The history of the grant of the patents and the licencing in Australia provides some insight into why the challenges were pursued sometime later than the others studied in this research. In 1998 Myriad were granted three patents covering the BRCA1 gene, mutations and related methods for diagnostic purposes, along with patents covering the BRCA2 gene.[340] Some of these patents were similar to those opposed and litigated in the other jurisdictions studied in this research: AU686004, for example, is closely related to US Patent

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336 Constand, S. 'Patently a Problem-Recent Developments in Human Gene Patenting and Their Wider Ethical and Practical Implications' (2013) QUT Law Review 13(1) 100-125; Palombi, L. 'Who owns the rights to the human body? It's patently obvious' (2011) The Conversation available at <https://theconversation.com/who-owns-the-rights-to-the-human-body-its-patently-obvious-835>; Palombi, L. 'Remind me again, how can companies patent breast cancer genes?' (2015) The Conversation available at <https://theconversation.com/remind-me-again-how-can-companies-patent-breast-cancer-genes-43410>; Palombi, L. 'Gene Cartels: Biotech Patents In The Age of Free Trade' (Edward Elgar, 2009); Rimmer, M. 'The Empire of Cancer: Gene Patents and Cancer Voices' (2013) Journal of Law, Information and Science 22(2): 18-55 (for a review of concerns and policy responses); Walpole, I. *et al.* 'Human gene patents: the possible impacts on genetic services healthcare' (2003) Medical Journal of Australia 18(4): 179-203; Concerns over gene patents also led to a review of the impact of patenting and licencing practices on human health see Australian Law Reform Commission, 'Genes and Ingenuity: Gene Patenting and Human Health' (2004) ALRC 99. For an alternative view see Poste, G. 'The case for genomic patenting' (1995) Nature 378: 534-536.

337 *Cancer Voices Australia v Myriad Genetics Inc and Genetics Technology Inc* [2013] FCA 65.

338 These included ethical concerns (see Constand *supra* n.336), concerns about accessing diagnostics and research (see Van Zimmeren, *et al. supra* n.12.)

339 Australian Law Reform Commission, 'Genes and Ingenuity: Gene Patenting and Human Health' (2004) ALRC 99.

340 The granted patents were AU691,331 (Method for diagnosing a predisposition for breast and ovarian cancer), AU691958 (17q-linked breast and ovarian cancer susceptibility gene), and AU686004 (In vivo mutations and polymorphisms in the 17q-linked breast and ovarian cancer susceptibility gene) – jointly held with the Centre de Recherche du Chul, the Cancer Institute of Japan and Genetic Technologies Limited. There was also one application – 1997014615 – which was not granted. AU773601 (Chromosome 13-linked breast cancer susceptibility gene) – granted to Endo Recherche Inc., Trustees of University of Pennsylvania, Myriad Genetics Inc and HSC Research and Development. There was also an earlier patent application by Cancer Research Technology Limited, the commercial arm of Cancer Research UK, relating to the BRCA2 gene claiming, 'Materials and methods relating to the identification and sequencing of the BRCA2 cancer susceptibility gene and uses thereof.' AusPat records concerning the opposition which led to this rejection are incomplete, and the archives of the Official Journal which might provide further information about the details of the opponent or substance of the opposition only date back to 2004 See https://www.ipaustralia.gov.au/tools-resources/patent-journals. However, Rimmer points out that the patent was opposed and successfully invalidated by Myriad Genetics. See Rimmer, M. 'The Attack Of The Clones: Patent Law and Stem Cell Research' (2003) Journal of Law and Medicine 10(4): 488-505. The opposition which led to the revocation of the CRUK patents is a distinct process than the litigation discussed in this chapter.

5747282, which had been invalidated by the US Supreme Court a year prior to the start of the Australia litigation.[341]

Unlike in the US – where Myriad's patents were swiftly and aggressively enforced – there was initially little enforcement of the BRCA patents in Australia.[342] Consequently, there was minimal impact on diagnostics and ongoing research.[343] This lack of enforcement was, in part, due to an ongoing infringement dispute and subsequent licencing agreement between Myriad and Melbourne based Genetic Technologies Inc (GTG).[344] The history of these disputes is explained in detail elsewhere, but it is worth outlining the relationship briefly as it explains the timing of the litigation in Australia.[345] GTG held patents over junk DNA which covered sections of DNA which did not code for proteins but which were necessary for Myriad to carry out full genetic testing. GTG sued Myriad for infringing these patents. To settle the case, Myriad granted GTG an exclusive licence over the BRCA testing in Australia and GTG granted a non-exclusive licence over the junk DNA. This agreement sparked significant concerns about access to diagnostic testing.[346] GTG were, at the time, engaged in a multitude of patent infringement cases which threatened to prevent public laboratories from testing for a range of genetic diseases including cystic fibrosis and Duchene muscular dystrophy[347] or to substantially increase the costs of carrying out such testing.[348] GTG did not initially enforce the BRCA patents, referring to them as a "gift from GTG to the people of Australia and New Zealand".[349] Gold and Carbone argue that this "gift" was offered as a result of the vehement public pressure and media scrutiny surrounding GTG's enforcement activities.[350] Whilst there remained financial costs associated with using the BRCA genes for diagnostics – GTG continued to charge royalties on its own 'junk-

341 Patent Claim AU684004

342 Nicol & Nielsen, *supra* n.335.

343 *Ibid*.

344 Nicol & Nielsen, *supra* n.335; Van Zimmeren, *et al. supra* n.12.

345 For histories of the dispute see Nicol & Nielsen, *supra* n.335. at 9-12 and Rimmer, M. 'The Alchemy of Junk: Patent Law and Non-Coding DNA' (2006) University of Ottawa Law and Technology Journal 3(2): 539-599 at 553-556; Gold & Carbone *supra* n.128 at 56-57.

346 Rimmer, *Ibid.*

347 Gold & Carbone, *supra* n.128128 at 56 and Rimmer, *Ibid.*

348 Nicol & Nielsen, *supra* n.335 at 205-206.

349 Gold and Carbone, *supra* n.128 at 56; ALRC, *Genes and Ingenuity, supra* n.339 at 491-492. Although this was referred to as a 'gift' to the Australia and New Zealand people, Rimmer demonstrated that the gift was not completely without financial strings: laboratories and researchers were still required to pay license fees on the non-coding portions of the gene, which were necessary to carry out the BRCA analysis. See Rimmer, *supra* n.345 345 at 555.

350 Gold & Carbone, *supra* n128 at 56.

DNA' patents - there was limited impact on research and diagnostics. [351] As such, whilst there remained ongoing policy discussions about updating the law surrounding gene patents, the public furore had somewhat calmed.[352]Despite the initial minimal impact of the patents, there were fears that Myriad or GTG could begin enforcing its patents at any moment [353] Nicol and Nielsen presciently observed that shifting international patent enforcement practices could potentially lead to more enforcement in Australia. [354] These fears came to fruition in 2008 when GTG controversially announced that it would begin enforcing its BRCA patents.[355] This change of practice appears to have occurred for financial reasons: GTG had a falling stock price and the BRCA patent was a lucrative asset.[356] Although GTG eventually backed down and reaffirmed that it would not enforce the BRCA patent, the decision sparked loud criticism from a wide range of stakeholders. The Head of Cancer Council Australia, a not-for-profit organisation in Australia warned that::

> "*There are…concerns about costs, and that it could stifle research by leading to a loss of expertise in public laboratories…There are also implications for the law: if a gene can be patented, where will that lead us*?"

These concerns were also expressed extensively in the Senate Committee hearings which followed GTG's announcement. The Senate Affairs Reference Committee received over 75 submissions about the adverse impact of GTG's enforcement of the Myriad patents – on diagnostic services, research, and education.[357] The tension between the public interest in research and diagnostics and the financial interests of the patent holder was summarised by Senator Heffernan who asked:

> "*given the overwhelming evidence from the clinically driven, vocationally guided and humanely inspired side of this debate, which is lining up against, from what I can see, a bunch of lawyers, bankers and people who are financially driven, is it time for the*

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351 Under the terms of the licence agreement Myriad would have equally been entitled to pursue enforcement of its BRCA patents, although similarly did not pursue enforcement. See Nicol & Nielsen, *supra* n.335.

352 ALRC, *Genes and Ingenuity, supra* n.339.

353 Nicol & Nielsen, *supra* n.335

354 *Ibid*.

355 Gold & Carbone, *supra* n.128 at 56.

356 For a discussed on GTG's motivations in changing its practice see Cook-Deegan, R. *et al.* 'Impact of Gene Patents', *supra* n.235 .

357 See Submission by Senator Heffernan to the Senate Community Affairs Reference Committee regarding the proposed Gene Patent Inquiry Report.

[Australian] Commonwealth to step up to the plate and fund a test case and we can just sort this out in the courts?"[358]

In 2012, Cancer Voices Australia and Yvonne D'Arcy filed an action in the Australia Federal Court, seeking invalidation of Myriad's BRCA patents. The next section sets out the history of the litigation in the courts.

5.2.1 The History of the BRCA litigation

Cancer Voices Australia v Myriad Genetics Inc and Genetics Technology Inc was heard in the Federal Court of Australia in February 2012.[359] This litigation challenged the validity of three of the claims in AU686004, which covered the BRCA1 gene, and associated cDNA. AU686004 is very similar to Myriad's US patent US5747282 although, as shown below, the grounds for invalidation in the US Supreme Court and High Court of Australia (the final court of appeal in each jurisdiction) were different.[360] The applicants were Cancer Voices, a non-profit alliance of cancer consumer organisations and Yvonne D'Arcy, a woman who did not have the BRCA mutation but who had been previously diagnosed with breast cancer. The case was driven by concerns that the grant, and licencing, of Myriad's patents was "morally and ethically corrupt"[361] as well as by concerns that the patent prevented women from accessing diagnostic tests. As stated by Yvonne D'Arcy:

"For all those people who do have the genetic footprint for breast cancer or any cancer basically, it's a win for them because now they're forewarned…the testing will be a lot cheaper and it will be more available ... rather than using only Myriad's agents at a price that nobody really can afford."[362]

The applicants sought revocation on the grounds that the patent did not meet the statutory definition of an invention as a "manner of manufacture" –under s.18(1)(a) PA 1990. Initially, the applicants also sought to argue that the patent was invalid for claiming human beings and biological processes for their generation which was an express exception to patentability under s.18(2) PA 1990. However, the applicants abandoned this line of challenge during the

358 Cook-Deegan, R. *et al.* 'Impact of Gene Patents', *supra* n.235 .at 38.

359 *Cancer Voices Australia v Myriad Genetics Inc and Genetics Technology Inc*., *supra* n.337.

360 See *D'Arcy v Myriad Genetics and Genetics Technology Ltd* [2014] FCAFC 115 for a discussion at 132 concerning the similarities and differences.

361 Griffiths, M. 'Breast cancer sufferers take gene patents to court' (2010) available at <https://www.abc.net.au/am/content/2010/s2921053.htm> accessed 10/06/21.

362 ABC News, 'Brisbane Grandmother Yvonne D'Arcy celebrates High Court victory in battle over BRCA-1 cancer gene patent' (2015) available at < https://www.abc.net.au/news/2015-10-07/breast-cancer-gene-cant-be-patented-high-court-rules/6833232> accessed 10/06/21

proceedings. The respondents, Myriad and GTG, argued that the claims were valid as it was an "artificial state of affairs providing a new and useful event that is of economic significance".[363]

The Australian statutory definition of an invention in s. 18(1)(a) PA 1990 is a retention of the old English definition of invention under the Section VI of the Statute of Monopolies 1624 which granted patent rights to "the sole working or making of any manner of new manufacture within this realm". Rules of construction to determine the scope of application of the definition have been developed by the courts applying a common-law methodology on a case-by-case basis.[364] The leading case is *National Research Defence Council v Commissioner of Patents. NRDC* where the High Court stated that general approach to determining whether an invention can be a "manner of manufacture", is that an invention must "[have] at its end an artificial effect" as well as "offer[ing] some advantage…in the sense that the process belongs to a useful art as distinct from a fine art [and] that its value to the country is in the field of economic endeavour".[365]

Applying the statutory definition of an invention in the light of prior case law, both the Federal Court, at first instance, and the Full Federal Court, on appeal, found that Myriad's patents were a "manner of manufacture" and therefore constituted a patentable invention.[366] Nicholas J, in the Federal Court, held that the invention satisfied the "manner of manufacture" test as the isolated genes could be considered "artificial". This artificiality came about as a result of human intervention in isolating the DNA, and that isolation changing the chemical nature of the DNA:

> "*Accordingly, the issue in this case turns upon whether an isolated nucleic acid, which may be assumed to have precisely the same chemical composition and structure as that found in the cells of some human beings, constitutes an artificial state of affairs in the sense those words should be understood in the present context…*
>
> *in the absence of human intervention, naturally occurring nucleic acid does not exist outside the cell, and "isolated" nucleic acid does not exist inside the cell. Isolated nucleic acid is the product of human intervention involving the extraction and purification of the nucleic acid found in the cell. Extraction of nucleic acid requires human intervention that necessarily results in the rupture of the cell membrane and the physical destruction of the cell itself…"*[367]

363 *Cancer Voices Australia, supra* n.337 at 7.

364 *National Research Defence Council v Commissioner of Patents* [1959] HCA 67.

365 *Ibid* at 24.

366 *Cancer Voices Australia, supra* n.337; Cook-Deegan, R. *et al.* 'Impact of Gene Patents', *supra* n.235; *D'Arcy v Myriad* (FCAFC), *supra* n.360.

367 *Cancer Voices Australia, supra* n.337 at 106-108.

Nicholas J concluded by reaffirming this chemical distinction as central to the finding of artificiality, holding that the BRCA patents did not cover naturally occurring DNA as they had been extracted and "*purged of other biological materials with which they were associated."*[368]

After the first instance decision, Cancer Voices were unincorporated and therefore unable to continue with the litigation, leaving D'Arcy as the sole plaintiff as the case was appealed to the Full Federal Court of Australia.[369] The Court dismissed the appeal, holding that the BRCA patents were a "manner of manufacture" as the isolated genes were both chemically and functionally distinct. The Court held that:

> *"What is claimed is an isolated nucleic acid, a chemical molecule characterised in a certain way, which is chemically, structurally and functionally different to what occurs in nature. There is a distinction between a claim to an isolated nucleic acid comprised in part of a sequence of nucleotide bases and a claim to a written sequence of nucleotides which may be identical to the corresponding sequence in the natural cell. The claim is to be construed according to the normal principles of claim construction. To identify the invention as lying in the concept of information said to be embodied in a sequence of nucleotides ignores the language of the claim."*[370]

The Full Federal Circuit's finding that the patents did not go to the informational content of the claim is a key difference to the approach taken by the High Court. Special leave was granted to appeal to the High Court of Australia and *D'Arcy v Myriad Genetics* was heard in 2015, with the court's decision handed down two months after AU686004 expired.[371]

The High Court overturned the lower courts findings holding that Myriad's BRCA patents were not a "manner of manufacture" and could therefore not be considered an invention. In a unanimous decision, the High Court held that although there were chemical, structural and functional differences between isolated DNA and natural DNA, the information contained within was the same.[372] Handing down the decision for the plurality – the majority decision of the Court – French CJ held that:

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368 *Ibid* at 136.

369 See Dreyfuss, *et al.* ' *supra* n.305.

370 *D'Arcy v Myriad* (FCAFC), *supra* n.360. at 194.

371 *D'Arcy v Myriad* [2015] HCA 37.

372 *D'Arcy v Myriad* (HCA), *ibid*. Although the decision was unanimous in its findings, the Court handed down three separate decisions. For a discussion of the different approaches in the decisions see Rimmer, M. 'An Exorbitant Monopoly: the High Court of Australia, Myriad Genetics, and gene patents' in Matthews, D. and Zech, H. 'Research Handbook on Intellectual Property and the Life Sciences' (Edward Elgar 2017).

> *"The code in the invention as claimed refers to the sequence of nucleotides which, in a cellular environment, can ultimately be translated into the BRCA1 polypeptide. That sequence can properly be described as "information"… It is the existence of that information which is an essential element of the invention as claimed. The product is the medium in which that information resides."*[373]

The Court further held that the BRCA patents were not within the established boundaries of a "manner of manufacture" and constituted a new class of claim.[374] The Court then went on to outline a list of factors to guide courts in determining when a new class of claim falls within the definition of a 'manner of manufacture', including *inter alia,* an assessment of conflicts of private and public interests.[375] These factors and their judicial application in subsequent cases are analysed in more detail below to evaluate the degree of flexibility open to courts to rebalance the 'tilt' in favour of patent holders against the public interest. The next section discusses how challengers can bring actions to pursue this rebalancing by outlining the procedural requirements for bringing such patent challenges.

5.2.2 Bringing Patent Challenges

Unlike in the US, there is a low procedural bar to bringing patent litigation. Under s.138 Patents Act individuals and organisations can seek revocation of granted patents from the courts in post-grant proceedings. An application for revocation can be brought as a counter claim to infringement proceedings,[376] but can also be sought independently as an action on its own.[377] The grounds on which revocation of a patent can be sought and granted are limited. These are;

> (3) After hearing the application, the court may, by order, revoke the patent, either wholly or so far as it relates to a claim, on one or more of the following grounds, but on no other ground:
>
> (a) that the patentee is not entitled to the patent;

373 *D'Arcy v Myriad Genetics* (HCA), *supra* n.371 at 89.

374 *Ibid* at 27-28.

375 *Ibid* at 28. Sherman argues that it was appropriate for the Court to consider the question of patentable subject matter, particularly as Parliament has traditionally had difficulty resolving IP issues (Bosse, J. 'In Conversation with Prof. Brad Sherman: D'Arcy v Myriad Genetics Inc (2015) and The Future of Australian Patent Law' available at <http://www.jatl.org/blog/2015/10/15/in-conversation-with-prof-brad-sherman-darcy-v-myriad-genetics-inc-2015-and-the-future-of-patent-law> accessed 10/06/21.

376 s.121 Patents Act 1990.

377 s.138(1) Patents Act 1990.

(b) that the invention is not a patentable invention;[378]

The requirements for a complete specification necessary for the grant of a patent are found in s.40(2) and (3).

Applications for revocation under s.138 above begin in the Federal Court. In language which echoes that of the EPC outlined in Chapter 4, any person can bring these proceedings. s.138(1) states that "the Minister or any other person may apply to a prescribed court for an order revoking a patent".[379] This means that, unlike the US, challengers do not have to demonstrate a particularized harm or injury to bring invalidity proceedings. And yet, public interest challenges to patents in Australia remain rare.

In *D'Arcy* it was not until the case reached the High Court that the patent was found invalid. Although there are low procedural barriers to bringing litigation to revoke the patent at first instance, to appeal to the High Court requires special leave. Applications for special leave to appeal to the High Court of Australia are outlined in the Judiciary Act 1903. The High Court have a relatively unfettered discretion in determining what cases are heard but must have regard to;

(a) whether the proceedings in which the judgment to which the application relates was pronounced involve a question of law:

(i) that is of public importance, whether because of its general application or otherwise; or

(ii) in respect of which a decision of the High Court, as the final appellate court, is required to resolve differences of opinion between different courts, or within the one court, as to the state of the law;

(…)[380]

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378 Other grounds for bringing the challenge are: (d) that the patent was obtained by fraud, false suggestion or misrepresentation; (e) that an amendment of the patent request or the complete specification was made or obtained by fraud, false suggestion or misrepresentation; and (f) that the specification does not comply with subsection 40(2) or (3).

379 Unlike at the EPO there is limited case law concerning standing in Australia and the scholarly discussion surrounding standing focusses on different sections of the Patents Act, which require different approaches to standing see, for example, Liddicoat, J. 'Standing on the Edge - What Type of "Exclusive Licensees" Should Be Able to Initiate Patent Infringement Actions?' (2017) International Review of Intellectual Property and Competition Law 48(6): 626-651.

380 s.35A; see also Wickham, B. (2014). *The Pragmatic Approach: The Myriad Gene Patents Before the Australian Courts Quick View The Full Court of the Federal Court of Australia in D ' Arcy v Myriad Genetics Inc [2014] FCAFC 115* 109–112.

This broad and public nature of the appeal process, rather than the right of private individuals to seek clarification of their rights, was confirmed by the High Court in *Smith Kline & French Laboratories (Aust) Ltd v The Commonwealth* where the court held that;

> *"It involves the exercise of a very wide discretion and that discretion includes a consideration of the question whether the question at issue in the case is of such public importance as to warrant the grant of special leave to appeal. To that extent at least, the Court… gives greater emphasis to its public role in the evolution of the law than to the private rights or interests of the parties to the litigation."*[381]

This approach stands at stark contrast to the US position, explored in Chapter 3, where the judicial focus is on the adjudication of disputes between parties as limited by the "case or controversy" requirement under the Constitution. The success rates of special leave to appeal is, however, low: between 2013 – 2015 around 10% of applications were granted special leave to appeal.[382] This is, as Stewart and Stuhmcke state, in part as a result of the nature of the role of the High Court as focussed on the public interest, rather than as another appellate opportunity.[383] However, they further note that there is a correlation between high success rates and "capable applicants" – that is those with significant resources and litigation experience. This correlation between litigation and resources has also been noted in relation to the Myriad litigation. Nicol, in an interview with the Sydney Morning Herald, welcomed the *D'Arcy* decision but noted that:

> *"Otherwise these are areas where you need public interest litigation, you need an Yvonne D'Arcy to come along and bring the case because it is in the broader public interest, but in Australia that doesn't normally happen…For public interest bodies that don't have any funding it's going to be really expensive."*[384]

This section has provided the background to the litigation against the Australian BRCA patents. The next section sets out the origins and rationale for Australian's retention of a statutory definition of an invention before examining the courts' interpretive approach.

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381 *Smith Kline & French Laboratories (Aust) Ltd v The Commonwealth* [1991] HCA 43 at 128.

382 Stewart, P. and Stuhmcke, A. 'Litigants and Legal Representatives: A Study of Special Leave Applications in the High Court of Australia' (2019) Sydney Law Review 41: 35-71.

383 *Ibid* at 43.

384 Nicol, D. in Cordeory, A. 'Breast Cancer Gene Judgment Opens Up Complex Questions' (2015) The Sydney Morning Herald available at <https://www.smh.com.au/healthcare/breast-cancer-gene-judgment-opens-up-complex-questions-20151008-gk4rbz.html#ixzz3wLb5CSEi> accessed 15/06/21.

5.3 The Significance of a Statutory definition of an invention.

The Patents Act 1990 (PA 1990) and the Patent Regulations 1991 (PR 1991)contain the current legislative framework for the grant and administration of patents. s.18 PA1990 provides that an invention

> Subject to subsection (2), an invention is a patentable invention for the purposes of a standard patent if the invention, so far as claimed in any claim
>
> (a) is a manner of manufacture within the meaning of section 6 of the Statute of Monopolies; and
>
> (b) when compared with the prior art base as it existed before the priority date of that claim:
>
> (i) is novel; and
>
> (ii) involves an inventive step; and
>
> (c) is useful; and
>
> (d) was not secretly used in the patent area before the priority date of that claim by, or on behalf of, or with the authority of, the patentee or nominated person or the patentee's or nominated person's predecessor in title to the invention.

Subsection 2 states that "Human beings, and the biological processes for their generation, are not patentable inventions."

In '*Genes and Ingenuity: Gene Patenting and Human Health'* the Australian Law Reform Commission (ALRC) noted that Australian patent legislation has always been modelled closely on that of the UK, but when the Australian Parliament amended their patent laws in 1990 they chose not to follow the UK's Patent Act 1977 (PA 1977). When the UK Patent Act was amended to bring it into line with the EPC, the statutory definition of an invention as a 'manner of manufacture' in the Statute of Monopolies was left out.[385] The decision not to follow the UK and retain the definition of invention under the Statute of Monopolies was a "deliberate legislative choice" by the Australian Parliament.[386] The choice to retain the old definition was guided by the recommendations of the Industrial Property Advisory Committee, reviewing Australia Patent Laws in 1984, recommending retention of "manner of manufacture" as:

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385 See the preamble to the 1977 Act which states that the Act was introduced to "amend the laws of patents applicable to existing patents and applications for patents; to give effect to certain international conventions on patents, and for connected purposes".

386 *CCOM Pty Ltd v Jiejing Pty Ltd & Others* (1994) 51 FCR 260.

> *"the existing concept operates quite satisfactorily. It has the advantage of being underpinned by an extensive body of decided case law which facilitates its application in particular circumstances…it has, in the past, exhibited a capacity to respond to new developments. To replace it with a codification would be likely to produce far more problems, with attendant costs, than it would solve."*

Other reports have similarly favoured retention. The Intellectual Property and Competition Review Committee (IPCRC) into IP and competition recommended the retention of the "manner of manufacture" test, advising that "Australia has, on the whole, benefitted from the adaptiveness and flexibility" which characterised the test.[387] On the other hand, ALRC report into gene patents commending its flexibility but noted that the language was ambiguous and obscure and therefore warranted further review.[388] In 2010 a report of the Advisory Council of Intellectual Property (ACIP) concluded that the test was "the best one available to us."[389] The ACIP report is notable for its focus on the balance between private and public rights in patent law. The report explicitly states that:

> *"In broad terms, the legislation should provide an environment that promotes Australia's national interest and enhances the well-being of Australians by balancing the competing interests of stakeholders…one set of stakeholders is those who hold patent rights…Australian society is also a stakeholder. They want to have access to the latest technology at a reasonable price. Costs to society include restricted access to and higher prices for the invention during the patent term."*[390]

The report advises that the "manner of manufacture" test in Australia is one way this balance is maintained, although it does recommend updating the wording to improve guidance and transparency in decision making.[391] Further, the report recommends a range of reforms to ensure the patent system strikes the correct balance, specifically relying on the social contract justification to do so.[392]

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387 Intellectual Property and Competition Review Committee, 'Review of intellectual property legislation under the Competition Principles Agreement' (2000) at 16.

388 ALRC, *Genes and Ingenuity, supra* n.339 at 91.

389 Advisory Council on Intellectual Property, 'Patentable Subject Matter' (2010) at 6.

390 *Ibid* at 4.

391 *Ibid* at 9. The report also recognises that the manner of manufacture test has significant overlaps with other tests of patentability including novelty and utility (at 10). For a criticism of the language used in the test see Sherman, B. 'Before The High Court' (2015) Sydney Law Review 37(1): 135-146.

392 Such reforms include codifying a statement of purpose of the patent system.

The definition of "manner of manufacture" therefore presents an opportunity for the judiciary to ensure that the balance between private patent holders and the public interest is maintained. The next section examines the judicial application of the test.

5.3.1 Judicial Application of "Manner of Manufacture"

The approach to construction of the statutory definition of invention as a "manner of manufacture" has been set out by the High Court in the leading case of *National Research Development Corporation v Commissioner of Patents* (herein referred to as *NRDC).*[393] Courts are enjoined to take a purposive approach, informed by purpose, breadth and context:

> "*The inquiry which the definition demands is an inquiry into the scope of the permissible subject matter of letters patent and grants of privilege protected by the section. It is an inquiry not into the meaning of a word so much as into the breadth of the concept which the law has developed by its consideration of the text and purpose of the Statute of Monopolies."*[394]

In *NRDC* the National Research Development Corporation sought to patent a new process for ridding crop areas of certain weeds. The Deputy Commissioner of Patents rejected the patent application on the grounds that to be an invention within the concept of 'manner of manufacture' there must be a vendible product. This, argued the Deputy Commissioner, excluded horticultural and agricultural processes and subsequently excluded the process claim for killing weeds. The chemicals which formed part of the patent claim were well known but were understood not to be useful for the purpose of weed killing as claimed in the Corporation's patent specification. The question for the High Court of Australia then was whether a new use of a known material, achieved by a well-known method of production can be patentable. Chief Justice Dixon, along with Justices Kitto and Windeyer unanimously held that the claim for the process for weed killing was an invention within the concept of "manner or manufacture." A new use of known material, even where the method of production is known, can be patented as long as it "consists in taking advantage of a hitherto unknown or unsuspected property of the material."[395]

Using a purposive, conceptual approach, the High Court held that relying on a literal interpretation of the concept was too narrow. Considering whether something fell within the

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393 *NRDC*, *supra* n.364, referred to as a "watershed" in this area of law in *Joos v Commission of Patents* (1972) HCA 38 and as a 'celebrated judgment' in *Grain Pool of Western Australia v Commonwealth of Australia* (2000) 202 CLR 479.

394 *NRDC*, *ibid* at 14.

395 *Ibid*.

ambit of the word 'manufacture' erroneously "called to mind tangible goods created by hand or machine".[396] This tangibility fed into the requirement for a vendible product. Instead, the High Court mandated a common law methodology for the application of the principle, on a case-by-case basis. The justification for this approach was its flexibility, particularly in the face of burgeoning fields of technology. The Court said that the Statute of Monopolies was enacted to encourage national development in "excitingly unpredictable" fields.[397] As such, attempting to outline the ambit of "manner of manufacture" by defining 'manufacture' was bound to fail. To "attempt to place upon the idea the fetters of an exact verbal formula" would be to truncate the development of patent law.[398] Instead, the correct approach was to develop the concept case by case. The Court further held that, to be considered a "manner of manufacture", an invention must "[have] at its end an artificial effect"[399] as well as "offer some advantage…in the sense that the process belongs to a useful art as distinct from a fine art [and] that its value to the country is in the field of economic endeavour".[400]

The flexibility afforded to judges to interpret the scope of application of the statutory definition of an invention as a 'manner of manufacture' has been used by Australian courts both to narrow and to widen the range of patentable subject matter.[401] For example, methods of medical treatment and "other processes for treating the human body" were excluded from patentability on the basis that they did not create a vendible product and, following *NRDC,* that such treatment did not provide economic value.[402] In *Joos v Commissioner of Patents* the High Court of Australia was asked to determine whether a treatment for human hair, still in situ, was properly excluded from patentability on the basis that it was a "treatment for the human body" and therefore did not result in economic value. By contrast, Chief Justice Barwick found that the patent should be granted, holding that there was a distinction between medical and cosmetic treatments. Reviewing the lack of binding precedent, he held that there were no ethical, logical or economic reasons for excluding such treatment from patentability. Advocating a widening of

396 NRDC relied on *Crone v Price* (1842) 1 Webster 375 which made explicit that 'manufacture' can equal a process and product.

397 *NRDC*, *supra* n.364 at 15.

398 *Ibid.*

399 *Ibid* at 25.

400 *Ibid* at 22.

401 Monotti points out that, prior to *NRDC,* there were some recognised exceptions to patentability (such as methods of medical treatment for humans, computer programmes, and presentations of information) but the Court's approach "opened the way for future Courts to approve the patentability of inventions that fell within this and other formerly included classes." Monotti, A. L. 'The Scope of 'Manner of Manufacture' Under the Patents Act 1990 after Grant v Commissioner of Patents [2006]' (2006) Federal Law Review 34(3): 461-479.

402 *NRDC*, *supra* n.364 at 24 and *Maeder v Busch* (1938) HCA 8, *Joos v Commissioner of Patents* (1972) HCA 38.

the economic value requirement he also noted that "economic value will not always be directly supplied by the nature of the activity that would utilize the process."[403] *Joos* was relied upon in *Apotex Pty Ltd v Sanofi-Aventis Australia Pty Ltd* to abolish this distinction and find that methods of medical treatment were patentable. The economic benefit flowing from Apotex's patent came from maintaining a healthy workforce and healthy population.[404] This expansion was accepted despite the Court noting the significant public policy concerns involved in extending the concept in this way and its explicit exclusion from the concept of "manner of manufacture" in *NRDC*.[405]

5.3.2 Flexibility compared with the US and Europe

One of the benefits of a flexible approach to the construction of the 'manner of manufacture' concept is that it gives challengers in Australia more scope to argue that socially controversial applications do not fulfil the eligibility requirements for an invention. By contrast, under the EPC and European national laws based on the EPC, challengers have to argue that the invention does not meet the criteria of novelty, inventive step or industrial application.[406] Alternatively, patents can be opposed on the exceptions to patentable subject matter under Article 52 (such as discoveries, scientific theories and mathematical models)[407] or that they are an exception to patentability under Article 53, which includes the *ordre public* or morality exception discussed in Chapter 4. In the US, applicants may rely on the judicial exclusion of products of nature, as in Myriad, or alternatively show that the invention does not meet the s. 101 35 USC statutory criteria of novelty, non-obviousness and utility.

In Australia, patents can also be challenged on the grounds that the inventions claimed do not meet the standards of patentability (in that they are not novel, lack an inventive step, or are not useful) [408] or that it falls within one of the statutory exemptions. These include exceptions to patentability for human beings and the biological processes for their generation are not patentable inventions[409] and inventions which are contrary to law, mischievous to the state, or generally inconvenient.[410] But the retention of the statutory definition of an invention facilitates

403 *Joos v Commissioner of Patents* at 67.

404 *Apotex Pty Ltd v Sanofi-Aventis Australia Pty Ltd* [2013] HCA 50 at 64.

405 *Ibid* at 33.

406 Art.52(1) EPC .

407 Art.52(2)(a) EPC.

408 s.18 Patents Act 1990.

409 s.18(2) Patents Act 1990. Additionally, patent, plants and animals, and the biological processes for the generation of plants and animals, are not patentable inventions for innovation patents. See s.18(3).

410 s.6 Statute of Monopolies 1624.

judicial consideration of the broad social, ethical, moral and economic facets of patents in a way that the technical criteria of novelty, inventive step, and industrial application do not.

There are issues with this flexibility. The language of "manner of manufacture" is obscure and archaic, and as noted earlier the ALRC report argued that subsequent case law had not provided clarity, which can create uncertainty in the application of the law.[411] However, the flexibility provides space for challengers to oppose inventions at the cutting edge of technology that may not necessarily easily fit within the recognised exceptions but which, none the less, raise significant concerns about the public interest. The next section examines the decisions of the courts in *D'Arcy v Myriad* to show how the lower courts and the HC utilised the flexibility in the statutory definition of an invention to weigh the balance between the patent holder rights and the public interest.

5.4 Balancing private rights and the public interest - the "manner of manufacture" test

As with the challenges in Europe and the US, *D'Arcy v Myriad* attracted significant scholarly and global media attention.[412] The decision led to empirical studies, analysing the impact of the *D'Arcy* decision on patenting behaviour and cost of testing.[413] There has also been significant doctrinal attention paid to the decision of the Courts. The Federal Circuit decision was criticised as focussed more on the US Federal Circuit decision than the first instance decision in the US, and also praised as being a "pragmatic approach" to the question of gene patents and "difficult to fault".[414] The High Court decision has attracted discussions about the application of the

411 ALRC, *Genes and Ingenuity, supra* n.339.

412 See Corderoy, A. 'Breast Cancer Gene Judgment Opens Up Complex Questions' Sydney Morning Herald available at < https://www.smh.com.au/healthcare/breast-cancer-gene-judgment-opens-up-complex-questions-20151008-gk4rbz.html#ixzz3wLb5CSEi> accessed 10/06/21; BBC News, 'Australia Court Rules Against Breast Cancer Gene Patent' (2015) available at <https://www.bbc.co.uk/news/world-australia-34461890 access 10/06/21<; The Guardian, 'Patient wins high court challenge against company's cancer gene patent' (2015) available at < https://www.theguardian.com/society/2015/oct/07/patient-wins-high-court-challenge-against-companys-cancer-gene-patent> accessed 10/06/21; ABC News, 'Brisbane Grandmother Yvonne D'Arcy celebrates High Court victory in battle over BRCA1 cancer gene patent' (2015) available at < https://www.abc.net.au/news/2015-10-07/breast-cancer-gene-cant-be-patented-high-court-rules/6833232> accessed 15/06/21; Vines, T. and Faunce, T. 'Cancer Voices Australia v Myriad Genetics Inc' [2013] FCA 65: Should Gene Patent Monopolies Trump Public Health?' (2013) Journal of Law and Medicine 20: 747; Gambini, E. 'In the aftermath of D'Arcy v Myriad Genetics Inc: Patent Isolated Nucleic Acids in Australia' (2016) European Journal of Risk Regulation 7(2): 451-459.

413 Nicol, D. Nielsen, J. and Dawkins, V. 'D'Arcy v Myriad Genetics: The Impact of the High Court's Decision on the Cost of Genetic Testing in Australia' (2018) University of Tasmania, Centre for Law and Genetics Occasion Paper 9, 1-101.

414 McEniery 'The pragmatic approach: the myriad gene patents before the Australian Courts' NTUT Journal of Intellectual Property Law and Management 3(2) 181-183.

Statute of Monopolies[415] as well as discussions arguing that – whilst the decision in *D'Arcy* was important in clarifying the patentability of isolated DNA, doctrinally it was a restatement of the principles within *NRDC* rather than a radical departure from them.[416] There has also been criticism of the decisions for failing to provide a lack of clarity. Sherman is critical of all the decisions for the lack of clarity and certainty the decisions provide about how to treat isolated DNA, and when such inventions should be considered chemical, functional, or information.[417] There have also been doctrinal studies highlighting and discussing the global divergences in patentability as isolated DNA no longer constitutes patentable subject matter in the US and Australia, but remains so in Europe as a result of the Biotechnology Directive.[418]

The Court's approach, therefore, has been significantly reviewed in the literature. The aim of this section is to outline the different approaches the courts took to utilising the 'manner of manufacture' requirement. It will specifically focus on how the High Court used the test to engage in a balancing exercise between the rights of patent holders and the public, which took into consideration a broad range of policy considerations – including those which drove the challenges.

5.4.1 The Public Interest in the Lower Courts

Cancer Voices Australia v Myriad Genetics Inc and Genetics Technology Inc was heard in the Federal Court of Australia in February 2012[419] The applicants sought revocation of patent AU686004 under s.138 Patents Act on the grounds that the patent did not meet the eligibility requirements for an invention under s.18(1)(a) PA 1990. Initially, they also sought to rely on s.18(2) which concerns an exception to patentability for human beings and biological processes

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415 Lai is critical of both the Federal and Full Federal Court's failure to consider whether Myriad's patents were the "proper subject of letters patent" rather than an artificial state of affairs leading to an economic benefit. Lai explains that the *NRDC* decision held that the correct question was whether the subject matter was a "proper subject of letters patent according to the principles which have developed for the application of s6 Statute of Monopolies" with the artificial state of affairs question being part of the broader question to be answered, not the sole criteria for considering patentability. See Lai, J. 'Gene-Related Patents in Australia and New Zealand: Taking A Step Back' (2015) Australian Intellectual Property Law Journal 25: 181.

416 Bartlett argues that the decision in *D'Arcy* is not a radical departure for the High Court, but rather a reassertion of the court's previous decision in *NRDC.* See, Bartlett, W. 'D'Arcy v Myriad Genetics Inc [2015] HCA 35: The Plurality's New Factorial Approach to Patentability Rearticulates the Question Asked in NRDC' (2015) Journal of Law, Information, and Society 24(1): 14.

417 Sherman, B. 'Before the high court: D'Arcy v Myriad Genetics Inc: Patenting Genes in Australia' (2015) Sydney Law Review 37(1): 135-146; Sherman, B. 'What Does It Mean To Invent Nature?' (2015) UC Irvine Law Review 5: 1193-1230.

418 Dreyfuss, *et al. supra* n.305; Minssen, T. 'Patenting human genes in Europe-and how it compares to the US and Australia' in Matthews, D. and Zech, H. *Research Handbook on Intellectual Property and the Life Sciences* (Edward Elgar 2017)

419 *Cancer Voices Australia, supra* n.337.

for their generation. However, the applicants abandoned this line of challenge during the proceedings. The argument of the applicants based on s.18(1)(a) was that isolating DNA does not make it materially different to that found in nature and can therefore not satisfy the 'manner of manufacture' requirement. The respondents, Myriad and GTG, argued that the claims were valid as it was an "artificial state of affairs providing a new and useful event that is of economic significance".[420] It was accepted by the applicants during the proceedings that the claims satisfied the 'economic significance' arm of the test.[421]

Nicholas J found that Myriad's BRCA1 patent did constitute a "manner of manufacture" within the meaning of s.6 Statute of Monopolies and therefore was entitled to patent protection. In his judgment he held that whether or not an invention constitutes a "manner of manufacture" must be determined in line with *NRDC.*[422] The decision at first instance was focussed on the effort that went into locating and isolating the BRCA genes which was held as central to the question of creating an artificial affair. Nicholas J held that:

> *"It would lead to very odd results if a person whose skill and effort culminated in the isolation of a micro-organism (a fortiori, an isolated DNA sequence) could not be independently rewarded by the grant of a patent because the isolated micro-organism, no matter how practically useful or economically significant, was held to be inherently non-patentable."*[423]

Nicholas J justified this position by noting the extensive effort required to be the first to isolate and patent the BRCA gene; a justification which sits at odds with the immense, international, collaborative effort that resulted in the location and isolation of the BRCA gene.[424] Nicholas J also reasoned that *NRDC* was deliberate in its use of expansive language, noting its status as a conceptual inquiry rather than a linguistic one.[425] Despite this, he was reluctant to distinguish patentable subject matter further and argued that the concepts should be applied in a manner that gives effect to the specific language used.[426] The decision is silent on the issue of whether ethical, social, or moral issues should be taken into consideration when determining patentable subject matter within the ambit of s.18(1)(a). Instead, the decision argues that the 'manner of manufacture' requirement was:

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420 *Ibid* at para.7.

421 *Ibid* at para.8.

422 *Ibid* at para.102

423 *Ibid* at para.109.

424 For a criticism of this notion of the "lone genius" narrative see Lemley, M. 'The Myth of the Sole Inventor' (2012) Michigan Law Review 3(1): 709-760.

425 *Ibid* at para.86.

426 *Ibid* at para.109.

"expressions that bring into play principles and concepts which have been developed over many years to ensure that patent law keeps up with advances in industry and technology."[427]

This analysis therefore focused on the role of the inventor in the patent process and the requirement that patent law maintain pace with technological advances, but without a broad discussion of balancing the protection of these new advances with the public interest. Nicholas J instead went on to explore two developments surrounding gene patents, which he noted did not have direct relevance to the question of whether an invention can be considered a 'manner of manufacture' but were worthy of some attention: recent legislative history in Australia, and approaches to gene patents internationally. Exploring the legislative history was to consider whether such a conclusion would be inconsistent with Parliament's intention. In doing so he considered the ALRC report, as well as some recently rejected amendments to the Patents Act which would have prohibited or significantly restricted the ability to patent isolated genes and noted a lack of legislative appetite to change the law.[428] He also noted that the Australian Parliament had introduced a new Act, the *Intellectual Property Laws Amendment (Raising the Bar) Act 2012* which introduced a new experimental use defence, and a new definition of 'useful' holding that the new defence would successfully negate concerns surrounding future access to research. Finally, Nicholas J considered the Biotechnology Directive and the US Federal Circuit Court decision in *AMP v Myriad* but does not draw any support or justification for his decision from these international developments.

The applicants appealed to the Full Federal Court of Australia[429] under s24 Federal Court of Australia Act 1976, which gives parties an entitlement to appeal without special leave following the decision of a single judge at the Federal Court.[430] At this stage, Cancer Voices Australia withdrew as a plaintiff to the proceedings, leaving Yvonne D'Arcy as the only appellant. The withdrawal of Cancer Voices was as a result of the organisation becoming unincorporated.[431] On appeal, the appellants argued that the correct interpretation of the question concerning the artificial state of affairs as per the *NRDC* decision was not the product *per se* but rather the end result produced. Acknowledging that isolation requires human intervention, the appellants argued instead that this intervention does not cause a change to the nucleic acid but rather

427 *Ibid* at para.79.

428 *Ibid* at paras 111-123.

429 *D'Arcy v Myriad Genetics Inc* (FCAFC), *supra* n.360.

430 s24(1)(a) Federal Court of Australia Act 1976.

431 Dreyfuss *et al, supra* n.305 The issue of organisations dedicated to the public interest becoming unincorporated or running out of resources and the impact this has on patent challenges is explored in more detail later in the thesis.

takes the naturally occurring nucleic acid out of its cell.[432] Linked with this argument, the appellants argued that something that occurs in nature cannot be considered 'artificial'.[433] Finally, the appellants argued that what Myriad attempt to claim is the information contained within the DNA itself.[434] Myriad argued that the claim was to an isolated nucleic acid which differed functionally, structurally and chemically from that found in a human cell and therefore satisfied the question of artificiality.

In September 2014 the Full Federal Court of Australia handed down their judgment finding that isolated DNA, including cDNA, was patentable subject matter as it resulted in an artificially created state of affairs. The Full Federal Court disagreed with the appellant's characterisation of the artificiality question, holding that the correct interpretation of the questions surrounding artificial effects were whether the product consisted of an artificial state of affairs, not whether it produced or failed to produce an artificial effect. The correct question was the former and as the nucleic acid was removed from its naturally environment which allowed it to function *in vivo* the artificial effect was created.[435] The Court rejected the arguments which stated that Myriad were attempting to claim information, holding that the isolated DNA was a chemical compound.[436] However, the Full Federal Court failed to elucidate their reasoning for treating Myriad's claims as chemical, rather than information in nature.[437] In reaching this decision the Full Federal Court explored the decisions of the US Federal Circuit and the US Supreme Court in *AMP v Myriad*, falling in favour of the decision of the former. In doing so the Full Federal Court attempt to draw links between the Federal Circuit decision in the US and the *NRDC* decision in Australia. The Full Federal Court drew extensively on Justice Lourie's analysis of Myriad's patents as resulting in useful tools and diagnostics to draw justification for the economic significant of the patents, although this was not in issue between the parties. The Court also utilised Judge Lourie's discussions surrounding 'markedly different to that found in nature' and his findings distinguishing natural products from those which were accurately considered 'products of men' to focus on the role of human intervention in making a finding of 'manner of

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432 *D'Arcy v Myriad* (FCAFC)*, supra* n.360 at paras.164-165.

433 *Ibid* at para.196.

434 *Ibid* at para.182.

435 *Ibid* at paras.167–169.

436 *Ibid* at para.210.

437 Lai, J.C. 'Gene-related patents in Australia and New Zealand: Taking A Step Back' (2015) Australian Intellectual Property Journal 25: 181 – 197. Lai argues that the Full Federal Circuit decision and reasoning for finding that Myriad's patents are for chemical compounds is "somewhat confused" at 191; Sherman, B. 'Before the high court: D'Arcy v Myriad Genetics Inc: Patenting Genes in Australia' (2015) Sydney Law Review 37(1): 135 – 146 arguing that "one of the problems with the Full Federal Circuit Court decision is that we were given no explanation as to why the decision was to read the claims chemically, rather than genetically" at 143.

manufacture'. The Court conclude that when determining whether what is claimed is a 'discovery' or 'invention' the focus should be on the "differences and functions effected by the intervention of man and not on the similarities".[438]

The Full Federal Circuit subsequently also considered the Australian legislative history to decline consideration of policy, moral, or ethical issues inferring that the legislature were responsible for determining the balance between incentivising innovation and the flow of information. In discussing this balance, the court focussed on the ALRC report which analysed – and concluded against – introducing a statutory exception for isolated DNA and the subsequent adoption of the *Raising the Bar* Act which introduced an experimental use defence and stated that these developments were made "in consideration of the balance between incentives and the flow of information."[439] Further, the Full Federal Court stated that:

> *"Parliament has considered the question of the patentability of gene sequences and has chosen not to exclude them but to make amendments to the Act to address, in part, the balance between the benefits of the patent system and the incentive thereby created, and the restriction on, for example, subsequent research."*[440]

The Court appeared particularly strident on this point, the first sentence of its conclusion stating that "this case is not about the wisdom of the patent system."[441]

5.4.2 The Social Contract at the High Court

Whilst the lower courts took a very narrow view of the range of factors implicated in the construction of a 'manner of manufacture' largely excluding consideration of the wider social and economic considerations, the High Court took a significantly different approach. In February 2015 D'Arcy applied for special leave to appeal to the High Court of Australia. Special leave was granted and, in October 2015, the High Court held that isolated DNA was not a "manner of manufacture" within the ambit of s.6 Statute of Monopolies, as required by s18(1)(a) PA 1990. The High Court decision was handed down two months after AU686004 had expired.[442] The majority of the High Court found that, although there were chemical, structural and functional differences between isolated DNA and natural DNA, the information contained within was the same. The Court held that:

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438 *D'Arcy v Myriad Genetics Inc* (FCAFC), *supra* n.360. paras.139–155.

439 *Ibid* at para.160.

440 *Ibid* at para.205.

441 *Ibid* at para.204 - McEniery 'The pragmatic approach: the myriad gene patents before the Australian Courts' NTUT Journal of Intellectual Property Law and Management 3(2) 181-183

442 AusPat website AU686004.

> *"The code in the invention as claimed refers to the sequence of nucleotides which, in a cellular environment, can ultimately be translated into the BRCA1 polypeptide. That sequence can properly be described as "information"… the information stored in the sequence of nucleotides coding for the mutated or polymorphic BRCA1 polypeptide is the same information as that contained in the DNA of the person from which the nucleic acid was isolated. It is the existence of that information which is an essential element of the invention as claimed."*[443]

The court held that Myriad's patent application was framed as information, holding that:

> *"The code in the invention as claimed refers to the sequence of nucleotides which, in a cellular environment, can ultimately be translated into the BRCA1 polypeptide. That sequence can properly be described as "information."*[444]

As such, the court concluded that Myriad discerned rather than invented the BRCA1.

The High Court's reasoning explicitly focussed on the policy concerns raised by isolated DNA, in its purposive interpretation of the PA 1990. The judges were particularly concerned that Myriad's claims were overly broad and that there was a risk of infringement without the infringer being aware:

> "*That it does lie at the boundaries is further evidenced by the odd consequence that if the claims are properly the subject of a patent, the patent could be infringed without the infringer being aware of that fact. That consequence coupled with the very large, indeed unquantified size of the relevant class of isolated nucleic acids, all of which bear the requisite information, 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."*[445]

This breadth, along with the finding that Myriad's patents were not 'made' contributed to the court finding that the BRCA patents constituted "new classes of claims" – those which sat at the boundaries of the concept of "manner of manufacture" and, if found patentable, would have required a extension of the concept "not appropriate for judicial determination."[446] Where inventions fell within the existing the existing concept of 'manner of manufacture' courts need only consider two factors for determining whether the invention can be considered patentable subject matter:

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443 D*'Arcy v Myriad Genetics* (HCA), *supra* n.371at para 89.

444 *Ibid* at para. 89.

445 *Ibid* at para.93.

446 *Ibid* at para.94.

1. Whether the invention as claimed is for a product made, or a process producing an outcome as a result of human action.
2. Whether the invention claimed has economic utility.

However, where the invention involves a significant expansion of the concept, there were further questions which required judicial consideration:

3. Whether patentability would be consistent with the purposes of the PA 1990, in particular:
    i. Whether the invention, as claimed, could give rise to a large new field of monopoly protection without potentially negative effects on innovation.
    ii. Whether the invention, as claimed, could have a chilling effect on activities beyond those formally the subject of exclusive rights granted to the patentee.
    iii. Whether to accord patentability to the invention as claimed would involve the court assessing important and conflicting public and private interests and purposes.
4. Whether the invention would enhance or detract from the coherence of the law relating to inherent patentability.
5. Consideration of Australia's place in the international community including Australia's obligations under international law, and the patent law of other communities.
6. Whether to accord patentability to the class of invention as claimed would involve law-making of a kind which should be done by the legislature. [447]

The Court were particularly concerned with the 'chilling effect' that the broad patents could have on research. Myriad's claims in AU686004 did not define the class of products it sought to claim and, in oral submissions to the High Court, conceding that the size of products potentially claimed had no upper limit. This, the High Court found, "would lead to the creation of an exorbitant and unwarranted de facto monopoly on all methods of isolating nucleic acids containing the sequencing coding for the BRCA1 protein."[448] This monopoly, and the potential barrier to research it created, would go against the purpose of the patent system.

Justice Gordon's decision – agreeing with the majority – was particularly forceful concerning the risks overly broad patents have on research and medical care. Her judgment was relied upon in the majority's decision when considering the risks of Myriad's patents.[449] Gordon J's decision

447 *Ibid* at para.28.

448 *Ibid* at para.8.

449 *Ibid* at para.93.

outlines the claims in detail, emphasising that Myriad utilised commonly known techniques for isolating the BRCA gene.[450] Concerning the approach to balancing the private rights and public interest she held that:

> "*Here, a grant of a monopoly for claim 1 has the potential to inhibit other researchers and medical practitioners from diagnostically testing the BRCA1 gene for an entirely different purpose. Here, unlike in Apotex, the interests of inventors, investors and the public will not conflict if the patentability of claim 1 is rejected. Those interests will not conflict because other researchers and medical practitioners will be able to continue to isolate and test the BRCA1 gene, regardless of the purpose for which they are testing, and Myriad will have the benefit of the patentability of the applications specified in claims 4-30."*[451]

5.4.3 Challenges post *D'Arcy*

Although the concept of "manner of manufacture" in Australian patent law provides an additional avenue for judicial consideration of ethical, social, and economic issues than in US and European patent law, there remain potential barriers for those wishing to challenge the validity of patents. It is commonly acknowledged that the language within the test remains arcane, obscure, and feeds uncertainty about the application of the principle.[452] The High Court's use of "information" to distinguish between patentable and unpatentable subject matter has also been criticised as unhelpful, vague and uncertain to determine the threshold for patentability.[453] In turn the delineation of the concept of 'information' raises related issues about the (dis)connect between scientific and legal language and their use in patent law. Similarly, "artificial" can mean different things as a legal, scientific, or lay term. The overlapping layers of scientific and legal concepts and their relation to the ordinary member of the public's understanding of the terms, raises further critical issues for those seeking to challenge the

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450 *Ibid* at para.210.

451 *Ibid* at para.263.

452 See Sherman, B. 'Before the High Court', *supra* n.391.

453 Prior to the High Court decision, Sherman argued that 'information' as a terminology was unhelpful as the information within genes is not necessarily important, but the function of genes in shaping human development (Sherman, *supra* n.391.at 142); Sherman discusses how unequipped patent Courts are to handle the taxonomy of patentable subject matter, and how the *D'Arcy* decision did not improve this position (Sherman, B. 'What Does It Mean to Invent Nature?' (2015) UC Irvine Law Review 5(5): 1193-1230; Lai, comparing the US and Australian decision, argued that the definition of 'information' can create a Pandora's Box about what information is and when it is patent eligible (see Lai, J. 'D'Arcy v Myriad Genetics: a demand for the "made" or "non-information" and clear subject matter' (2016) 47(5): 537-568 at 550); Lawson also argues that the use of 'information' at the High court introduces uncertainty and could be applied to any matter and "eviscerate the patent system" (Lawson, C. 'Patenting Nucleic Acid Sequences: More Ambiguity From The High Court?' (2018) Journal of Law and Medicine 25(3): 741-764.

validity of patents on public interest grounds. These difficulties are investigated and discussed further in the empirical part of the thesis.

Finally, the aftermath of the High Court ruling in Myriad highlights enduring difficulties in securing an appropriate balance of public and private interests. IP Australia, shortly after the High Court judgment was handed down, submitted draft amendments to its patent examination guidelines in light of the decision. These amendments took a narrow reading of the *D'Arcy* decision, holding that some isolated DNA (such as naturally occurring isolated regulatory DNA) would remain patent eligible where it "did not merely represent information coding for a polypeptide."[454] There was significant push back against this interpretation, including from those who had brought the challenge against the BRCA patents.[455] IP Australia published amended guidelines which did not apply the decision so narrowly although Rimmer notes that there may still be litigation concerning whether the guidelines accurately reflect the High Court's decision.[456] This illustrates the one of the limits of legislative guidance and reliance on judicial discretion to secure an appropriate balance between public and private interests in patent law. Once a judgment has been handed down it is up to the patent offices to apply the decision into day-to-day patent practice which, as discussed in Chapter 2, tends to tilt toward the patent holder.

Subsequent cases applying *D'Arcy* have avoided applying the six-step test laid out by the High Court by finding that the invention claimed cannot be considered a "new class of claims".[457] In some cases, the Federal Courts have shown hostility to engaging with the additional questions, particularly where they may engage questions of policy. In *Gilead Sciences Pty Ltd v Idenix Pharmaceuticals LLC* Jagot J determined a case involving an infringement suit, with a counter suit for revocation of a Hepatitis C medication Sofosbuvir. Jagot J held that the issue was not a 'new claim' so as to engage questions 3 to 6 as outlined in *D'Arcy* and held that these questions were directed to one of policy.[458] This was echoed in *Meat and Livestock Australia Limited v Cargill, Inc* where it was held that a claim for a method of identifying certain bovine traits from nucleic acid samples were not a 'new class' and did not therefore justify engaging question the

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454 IP Australia, Commissioners Proposed Revised Examination Practice (2015) available at <https://www.ipaustralia.gov.au/sites/g/files/net856/f/20151208_proposed_practice_note_consultation.pdf> last accessed 16/09/2019.

455 Rimmer, M. 'An Exorbitant Monopoly' *supra* n.372 at 80-84.

456 *Ibid*.

457 Nicol, Nielsen & Dawkins, *supra* n.413. See *Commission of Patents v RPL Central* (2015) 238 FCR 27 which held that a computer programme for assessing competency relative to a recognised standard qualification was not a "new class" at 115.

458 *Gilead Sciences Pty Ltd v Idenix Pharmaceuticals LLC* (2016) 117 IPR 252 at 658.

'policy' questions.[459] Here, Beach J was also critical of the additional questions under *D'Arcy* arguing that they were policy decisions and noting the lack of clarity in how the questions inter-relate, and how much weighting should be afforded to each.[460] D'Arcy had to reach the High Court before Myriad's patents were found invalid: an opportunity rarely available. This raises the question of why such challenges are rarely utilised. This question is explored further in the empirical part of this thesis.

5.5 Conclusion

The analysis of the Australian litigation on the Myriad patents has revealed that superficially, Australia should present a jurisdiction where public, 'outsider' challenges to patents can thrive. However, there are similar barriers to gene patent challenges in the form of narrow defined rules based on technical criteria and a tilt in favour of patent holders in the interpretation of key concepts by the lower courts.

459 Despite this, the judge did theorise on the likely outcome of their consideration, concluding that they would not prevent the method from being patentable subject matter: *Meat and Livestock Australia Limited v Cargill, Inc* (2018) 354 ALR 95 at para 391.

460 *Ibid* at para. 391.

Chapter 6: Empirical Methodology

6.1 Introduction

The empirical arm of this study contributes to answering the research question 'what are the obstacles to public interest groups challenging gene patents?' The preceding chapters identified legal barriers such as standing and the judicial interpretation of standards for patentability. The empirical study complements the comparative, doctrinal study in Chapters 3 – 5. It does so by presenting the findings from interviews conducted with individuals who were involved in BRCA patent litigation in each of the jurisdictions studied. The study is composed of semi-structured, qualitative interviews with researchers, scientists, legal professionals, and policy professionals who were involved as plaintiffs, experts, and legal representatives in the BRCA challenges. The aim of the interviews is to investigate the experience and perception of the obstacles which the participants had to overcome in order to gain a deeper understanding of the difficulties faced by public interest challenges to patents. Prior to the beginning of the study, ethical approval was sought and granted from the University of Bristol Law School's Research Ethics Committee. The application for ethics approval contained information about the methodological choices detailed in this chapter and is available in Appendix 1.

Despite the eventual success of the challengers against Myriad's BRCA patents, there has been limited empirical attention paid to why such challenges are often unsuccessful.[461] This empirical study aims to fill this gap by identifying and analysing the reasons why public interest litigation rarely occurs and even more rarely successful. This chapter sets out the methodology, along with the rationale and specifics of the method utilised before detailing the findings from the interviews in Chapter 8, along with a discussion of the implications of the interviews in Chapter 9.

6.2 Previous Empirical Studies

There is no dearth of empirical studies following the Myriad decisions, although many of these studies focus on the impact of the Myriad decision such as whether the cost of diagnostic testing was made more affordable or testing more widely available.[462] Other studies have examined the impact on patenting behaviour as a result of the litigation in *AMP v Myriad* in the US and *D'Arcy v*

461 As noted in earlier chapters there are some exceptions including, notably, Parthasarathy's Patent Politics *supra* n.102.

462 Nicol, Nielsen & Dawkins, *supra* n.413; Cook-Deegan, R and Niehaus, A. 'After Myriad: Genetic Testing in the Wake of Recent Supreme Court Decisions about Gene Patents' (2014) Current Genetic Medicine Reports 2(4): 223-241.

Myriad in Australia.[463] Some utilise documentary methods to analyse why Myriad's BRCA patents attracted such significant policy and media attention, when other companies held similar patents which restricted access to diagnostic testing for different genetic diseases.[464] This research is different and focuses on those who brought the challenges against the BRCA patents. Some empirical studies do focus on those individuals and organisations, notably Parthasarathy's *Patent Politics,* discussed in Chapter 2. Parthasarathy interviewed over 100 government officials, patent lawyers, patent holders, and civil society groups to understand how the political culture of the US and Europe shaped how each jurisdiction dealt with controversial questions of patentability in the life sciences. However, there has been little empirical research into why such challenges are rare. The interviews conducted as part of this research are specifically directed at gaining a deeper understanding of the difficulties faced by individuals and groups when attempting to invalidate patents on behalf of the public.

6.2.1 Elite Interviewees

Some of the methodological decisions were shaped by the definition of the participants as elite interviewees. There is no definitive definition of an 'elite' interviewee although indicators such as job title class, education levels, skills, or the relational difference between the interviewer

463 Liddicoat, J. *et al* 'The effects of Myriad and Mayo on Molecular Test Development in the US and Europe: Interviews from the Frontline' (2019) Vanderbilt Journal of Entertainment and Technology Law 22 4(5): 785-837; Aboy, M. *et al.* 'Myriad's Impact on Gene Patents' (2016) Nature Biotechnology 34(11): 1119-1123; Guerrini, C *et. al.* 'Constraints on gene patent protection fuel secrecy concerns: a qualitative study' (2017) Journal of Law and the Biosciences 4(3): 542-564. The US empirical studies often analyse the impact of *Myriad* alongside the Supreme Court decision in *Mayo Collaborative Services v Prometheus Laboratories Inc* 566 U.S. (2012) which held that patents claiming the relationship between metabolite levels and the appropriate amount of medication to prescribe to a patient were unpatentable as a law of nature. See C M Holman 'Patent Eligibility Post-Myriad: A Reinvigorated Judicial Wildcard of Uncertain Effect' (2014) George Washington Law Review 82(6): 1796 (where Holman is particularly critical of the *Myriad* and *Mayo* decisions lack of clarity concerning the Supreme Courts aims and the impact this has had on attempts of the lowers courts in determining patent eligibility), C W Genheimer 'A Myriad of Solutions - A Guide for Biotech Companies in Response to the Myriad and Mayo Decisions' (2015) Elon Law Review 7(1): 431, J L Fox 'Industry reels as Prometheus falls and Myriad faces further review' (2012) Nature Biotechnology 30: 373 (written after the *Myriad* case was referred back to the Federal Circuit for consideration in light of *Mayo* and highlighting opinions that these decisions upset rational, well-reasoned existing patent law), M Shikora '*Mayo* and *Myriad,* and a muddled Analysis: Do Recent Changes to the Patentable Subject Matter Doctrine Threaten Patent Protections for Epigenetic Based Inventions? (2018) Minnesota Law Review 102(5): 2229-2264 (noting the controversy of these decisions comes, in part, from an entire industry built on a legal right to patentability).

464 Baldwin, A. and Cook-Deegan, R. 'Constructing Narratives of Heroism and Villainy: Case Study of Myriad's BRACAnalysis compared to Genetech's Herceptin' (2013) Genome Medicine 5(1): 1-14; Contreras, J. 'Narratives Of Gene Patenting' (2015) Florida State University Law Review 43(4): 1133-1200.

and participant can be considered.[465] In this research, the participants were all highly educated - most to doctoral level - and included senior scientists and geneticists, heads of organisations, and experienced lawyers.[466] Some of the participants were also media trained, and have been interviewed previously. Elite interviewees have been found to prefer semi-structured interviews[467], the option for telephone interviews[468], and the opportunity for views mentioned in the research to be attributed to them.[469] The discussion of the methodological choices are therefore shaped, in part, by the definition of the interviewees as 'elite'.

6.3 Methodology

6.3.1 Semi-Structured Interviews

Interviews can cover a range of methodological approaches[470] and are "probably the most widely employed method in qualitative research".[471] This research consists of data from 12 semi-structured interviews. Semi-structured interviews cover a wide range of interview techniques, but are predominantly typified by:

> *"a context in which the interviewer has a series of questions that are in the general form of an interview schedule but is able to vary the sequence of questions. The questions are frequently somewhat more general…[than] typically found in a structured interview schedule…the interviewer usually has some latitude to ask further questions in response to what are seen as significant replies".*[472]

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465 See Harvey, W. 'Strategies for Conducting Elite Interviews' (2011) Qualitative Research 11(4): 431 at 443 and Harvey, W. 'Methodological Approaches for Interviewing Elites' (2010) Geography Compass 4(3): 193. There are difficulties with defining elites, even with these guidelines. Job titles can often be misleading and vary geographically, class and skills sometimes fail to capture all individuals who may be classes as elites, and the relational aspect rests on the assumption that an elite interviewee would translate the interviewer's perceived power difference in an interview setting.

466 Harvey identifies 'elite' participants as being highly skilled and professionally competent and hold "hold important social networks, social capital, and strategic positions within social structures because they are better able to exert influence" see Harvey, *Ibid.*

467 *Ibid*. Harvey observes that it is "generally advised…to avoid asking elites close-ended questions because they do not like to be confined to a restricted set of answers".

468 Stephens, N. 'Collecting Data from Elites and Ultra Elites: Telephone and Face-to-Face Interviews with Macroeconomists' (2007) Qualitative Research 7(2): 203

469 See Harvey, 'Methodological Approaches', *supra* n 465.

470 These include quantitative interviews, focus groups, structured interviews, semi-structured interviews, unstructured interviews, and interviews which take place as part of ethnographic studies as well as more subject specific interviews such as clinical interviews. See Hopf, C. 'Qualitative Interviews: An Overview' in Flick, U., von Kardoff, E., and Steinke, I. 'A Companion to Qualitative Research' (Sage Publications 2004)

471 Bryman, A. 'Social Research Methods'(4th ed., OUP 2012) at 469.

472 *Ibid* at 418.

Semi-structured interviews were chosen as the preferred method for this study because they are particularly useful where surveys or closed questions are unlikely to yield the depth of response needed to answer the research question. For example, where "examining unchartered territory with unknown but potentially momentous issues and [you] need maximum latitude to spot useful leads and pursue them."[473] The flexible, iterative nature of semi-structured interviews and the ability to probe interesting leads meant that questions arising from the comparative research could be followed, as well as facilitating the identification and exploration of other barriers not identifiable from the doctrinal analysis.

6.3.2 The Interview Schedule

It is typical in semi-structured interviews for an interview schedule to be designed and utilised. This ensures that particular themes or points are discussed whilst providing flexibility to respond iteratively to points of interest raised by the interviewee's responses. This also enabled themes which arose in the comparative analysis of the Myriad challenge to be interrogated further. The interview schedule was guided by Kvale's work in *InterViews* which recommends nine types of questions useful in semi-structured interviewing.[474] These are: introductory, follow-up, probing, specifying, direct, indirect, structuring, silence, and interrupting questions. The initial schedule included nine questions, with different types of Kvale's questions utilised. Two additional questions were added following reflection on earlier interviews, which is explored in more detail below. Following Kvale's guidance, the schedule began with an 'introducing' or 'opening' question aimed at eliciting how the participant became involved in the BRCA challenges, and provided an opportunity to tell their 'story' of involvement before progressing to more specific questions. The interview schedule (available at Appendix 2) then went on to ask a variety of questions linked with answering the research question, and informed by the background literature presented in the earlier chapters. The schedule included 'broad' questions with a series of 'probing' questions underneath each 'broad' question. Probes are "neutral questions, phrases, sounds, and even gestures to encourage participants to elaborate on their answers and explain why or how."[475] An example of this use of broad questions and probes in the interview is:

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473 Adams, W. 'Conducting Semi-Structured Interviews' in Newcomer, K. Hatry, H. and Wholey, J. *Handbook of Practical Programme Evaluation* (Jossey-Bass 2015).

474 Kvale, S. and Brinkmann, S. *Interviews: Learning the Craft of Qualitative Research Interviewing* (Sage Publications 2008) at 132-153.

475 Mack, et al. 'Qualitative Research Methods: A Data Collector's Field Guide' (2005) Family Health International at 43.

'Were you familiar with the EPO opposition procedure prior to becoming involved in the challenges to Myriad's gene patents?'

'If yes, where did this knowledge come from? Did you receive any formal training in the opposition procedure?'

'If no, did you become aware of it? How did you become aware of it?'

These 'probing' questions were designed to give direction to the interview, and to ensure the interview stayed relevant to the research questions. This approach was helpful for guiding the interview, however the schedule was not intended to be prescriptive. This meant that the questions were not always asked in the same order for each participant. There is some criticism of this approach. Methodologically, there is some research which argues that the subsequent answers are shaped by the previous questions and answers given. Varying the questions therefore risks having an impact on replies, which can undermine the validity of the response.[476] More practically, there is a risk that changing the order of the questions or 'leapfrogging' across the interview schedule can result in questions or themes being missed.

However, flexibility in the order of the questions is beneficial. Themes which arise in response to one question can be probed without the need to wait until it is asked at a point later in the interview. Waiting until the question arises in the schedule runs the risk that the interviewee may feel they have already answered the question and will not repeat themselves or expand upon their earlier point. Being able to respond to the interviewee's answers can also contribute to the rapport and conversational nature of the interview as it demonstrates active listening by the interviewer.[477] The methodological benefits of flexibility in the interview schedule outweighs these risks. As Bryman notes: there is no clear empirical consensus on the so-called "question order effect" by finding that "few if any consistent effects on people's responses that derive from asking questions at different points in a questionnaire or interview schedule have been unveiled."[478] In the interviews carried out for this research, many participants raised points of interest in response to the introductory question – such as immediately mentioning difficulties they faced when bringing patent challenges. The flexibility of the schedule meant that these issues could be explored based on the interviewee's responses, rather than the schedule, making the conversation flow more easily and allowing a deeper proving of the answers. Practically, to ensure all the questions of the interview schedule were asked, individual

476 Bryman, *supra* n.471 at 221.

477 *Ibid* at 218.

478 *Ibid* at 220.

schedules were printed for each interviewee and the questions were ticked off as they were asked to avoid missing any as a result of moving about the interview schedule.

This flexibility in interview structure also meant that interesting themes which arose in earlier interviews could then be probed in later interviews. As noted above, two additional questions were added following reflection on the earlier interviews which identified that exploring how participants became aware of the gene patents and exploring who undertook the strategic decisions in the patent challenges was an interesting theme which may relate to barriers to bringing the challenges. Given this, two questions were added to the later interview schedules to include:

> *"How did you become aware of Myriad's gene patents?" and;*
> *"Who made the strategic decisions concerning the opposition/litigation?" and, linked with this question, "to what extent were you involved in making these decisions?"*

Two of Kvale's question types were not built into the interview schedule but were utilised in the process of managing the interview itself. Kvale recommends using 'structuring' questions (such as "I would now like to introduce another topic") to move the interview on to another area and 'silence' to allow the interviewee opportunity to "reflect on and amplify" their answer.[479] The structuring questions were helpful in keeping the interview relevant, particularly where there was a short time frame in which to carry out the interview.[480] As outlined below, many of those interviewed were busy scientists, researchers, and legal professionals and therefore could usually only offer an hour of their time. In one interview, for example, there was a lengthy discussion concerning the science of the BRCA genes, with minimal mention of the patents. Utilising 'structured' questions enabled a redirection of the interview to focus on the challenges to the BRCA patents themselves, with the remainder of the interview dedicated to exploring the issues faced in challenging patents.

The use of silence in interviews can be useful to ensure participants have enough time to reflect on their answer and provide more detail to the question. As Kvale and Brinkmann note:

> *"Rather than making the interview a cross-examination by continually firing off questions, the research interviewer can take a lead from therapists in employing silence to further the interview, following the adage 'silence is golden'. By allowing pauses in the conversation, the*

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479 Kvale & Brinkmann, *supra* n.474 at 139.

480 This is particularly relevant for elite interviews, who may only have a short time period available for interviewing. Harvey notes that, in his experience, many of the elite participants could only offer half an hour to an hour of their time, and this time was rigidly observed. In several of the interviews in this research the time frames were rigidly observed as only an hour was set aside for the meeting, and the participant had another appointment directly afterward. See Harvey, 'Strategies' , *supra* n..465.

subjects have ample time to associate and reflect and then break the silence themselves with significant information."[481]

Silence is typically one of the most difficult techniques for researchers to grasp – particularly where the researcher is relatively inexperienced at interview techniques. Utilising silence is a balancing act: too little does not provide the participant with sufficient space for reflection and too much can potentially limit the answers provided. Harvey argues that "creating long silences can potentially produce an overly awkward atmosphere so much that respondents feel uncomfortable elaborating on their answers and therefore are also less willing to disclose certain types of information".[482] The use of phones and video-conferencing in these interviews, explored further below, increased this difficulty as the silence was sometimes difficult to interpret where there was a lack of non-verbal communication. For example, in one interview, the interviewee interpreted the silence as an indication that the line had been disconnected. Despite the confusion, the misunderstanding did not detract from the flow of the interview. Most of those interviewed frequently utilised phone and video conferencing and were therefore experienced with technological hiccups which may sometimes result from their use. The interview picked up quickly following the minor disruption. Silence was used in all of the interviews, and was successful in eliciting further responses in most instances.

Finally, several steps were taken to ensure consistency in the interviews. Each interview schedule had a 'explanatory' note underneath each questions to reiterate why it was being asked. For example:

2. What factors went in to deciding whether to pursue the challenge via the opposition proceedings? (Understanding what drives engagement with the EPO opposition proceedings and whether these are individual, institutional or resource driven).

This was helpful when, in some instances, the interviewee asked for clarification or the question was not understood. Being aware of the intention behind the question ensured that the questions could be reframed and having the details outlined meant that any nerves – particularly in light of interviewing elites and the inexperience of the researcher – were allayed and taken into consideration to ensure the interview went as smoothly as possible.

6.3.3 Limitations of semi-structured interviews

There are drawbacks with any methodological approach. One of the main criticisms of semi-structured interviews is the potential for researcher bias in the design of the interview

481 Kvale, S. 'Conducting an Interview' (2007) The SAGE Qualitative Research Kit at 61.

482 Harvey, 'Strategies', *supra* n.465 at 438.

questions (and follow up questions in the interview itself) and in the data analysis. The issues of bias in analysis are discussed in the next chapter. For the design of the research questions and the interview, there is a risk of leading the participant. That is asking questions – and subsequent follow-up questions – may "be worded in such a way to influence participants response…that lead participants to a particular line of thinking."[483] The risk of leading questions is that they "convey [the researchers] value judgment and biases, imposing a perspective on participants."[484] In this research, to avoid this bias the interview questions are designed as open-ended, with probes designed to encourage participants to expand on their answers or confirm understanding.

6.4 Sampling

The purpose of sampling was to identify a representative group of those involved in challenging Myriad's BRCA patents across three jurisdictions. Sampling was intended to ensure representation on two fronts: representation of all three jurisdictions and a range of professions or backgrounds for those involved (e.g. scientists, researchers, etc). Interviewing individuals from different professions was important to understand whether perceptions of obstacles were shared or varied. The population of those who participated in the challenges to the BRCA patents run into the hundreds: interviewing all members of this population was therefore practically beyond the scope of this research. The next section outlines the sampling technique utilised in this research.

6.4.1 Purposive Sampling

Purposive sampling was used to ensure representation across the three jurisdictions of the range of individuals involved in litigating the patents. The aim was to sample "participants in a strategic way so that those sampled are relevant to the research questions that are posed."[485] Random sampling would not have yielded appropriate participants to answer the research question. Furthermore, some barriers had been identified in the comparative analysis and a strategic approach facilitated further probing of these in the interviews.

Purposive sampling also has the advantage that it can be combined with other sampling techniques.[486] As detailed below, whilst a number of potential interviewees were initially identified, snowball sampling subsequently enable identification of further interviewees.

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483 Mack, *et al. supra* n.475 at 63.

484 *Ibid*.

485 Bryman, *Social Research Methods*, *supra* n.472 at 418.

486 *Ibid* at 427.

Snowball sampling is defined as a technique for identifying participants where "one subject gives the researcher the name of another subject, who in turn provides the name of a third, and so on" and is particularly useful when making contact with a network of individuals who are likely to know each other.[487] Such an approach is also useful for providing access to networks of individuals who may be reluctant to be interviewed without a prior introduction from someone they know and trust.[488]

6.4.1.1 Drawbacks to the sampling approach used

Utilising a purposive and snowball sample facilitated access to a range of professionals or 'elite' participants, including scientists, researchers, policy advocates and legal professionals involved in the challenges, as detailed below. However, there is one group that was not represented in the sample. No individual patients or women who has been adversely affected (whether potentially or not) by Myriad's patents were interviewed as part of this research. This was, in part, driven by practicalities. Whilst scientist, researcher, and organizational contact information is largely available and disclosed on the internet in the form of institutional emails, personal information is not as readily available. When asked if they could recommend anyone else to interview, none of the interviewees mentioned the patient plaintiffs nor provided any contact information to reach out to them. This represents one of the drawbacks with the sampling technique used. Purposive sampling was useful for identifying representative participants of various groups in this study. But it assumes that those interviewed are a homogenous group with similar characteristics and a close social network.[489] Those outside this network can be missed in this sampling technique. There was evidence of this occurring here: scientists were more likely to recommend other scientists involved in the challenges when asked about who else to interview, for example. This was because rather than being one group, those interviewed were several groups, coalescing around a single issue: challenging the BRCA patents. This theme of disparate groups also arose in the findings, discussed in the next chapter.

Notwithstanding the patients' absence from the interviews their absence does not undermine the robustness of the sample. Whilst patients themselves were not interviewed, some of the

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487 Vogt, W. *Dictionary of Statistics and Methodology: A Nontechnical Guide for Social Sciences* (3rd ed. Sage Publications 2005)

488 Ostrander, in her article addressing strategies and techniques for interviewing elites, states that building trust with elite interviewees is vital at the outset to gain access and build rapport. Introductions were intended to begin building this trust. See Ostrander, S A. '"Surely you're not in this to just be helpful" Access, Rapport, and Interviews in Three Studies of Elites' (1993) Journal of Contemporary Ethnography 22(1): 7.

489 Atkinson, R. and Flint, J. 'Accessing Hidden and Hard-To-Reach Populations: Snowball Research Strategies' (2001) Social Research Update 33(1): 1-4.

patient organisations who were involved in the BRCA patent challenges were and so patient experience was partially represented in this way. Furthermore, purposive and snowball sampling techniques do not require each subset of a population to be interviewed as the data gathered under these techniques are usually not broadly generalizable. As such, the sample aims to analyse a particular social phenomena rather than make broad claims attributable to the entire population. To ensure methodological rigour in such research does not require a statistical significance, but instead transparency in the decisions made about the sample and the analysis of the data gathered. It also means that the claims made should not overreach or make generalisations beyond that which is supported beyond the data gathered. Both this chapter and chapter 7 provide this transparency. This chapter next explains how the participants were recruited for this research.

6.4.2 Recruiting Participants

Potential interviewees were identified from reviewing the documents relating to the Myriad litigation in Australia and the US, and the opposition the EPO. A list of names, professions and email addresses was collated from the EPO opposition documents and the US and Australian court documents. A list was generated including activists, scientists, researchers, patent attorneys and lawyers, non-patent legal specialists, policy experts, and professional organisations. Whilst most names were identified in the opposition and litigation literature, one interviewee was identified following a conference on European Patent policy at an early stage of the empirical process.

Following the identification of potential interviewees emails were sent outlining the research and asking if the recipient would be interested in participating as an interviewee. These cold emails[490] included what to expect from participation in the interviews, information about the confidentiality of their data and interview responses, as well as details covering how the interview data will be stored in line with University guidelines. These emails were individualised, including a brief section on why they the participant had been contacted. To improve the likelihood of a positive response the initial email and briefing note asked for an hour of the interviewees time to complete the interview. This was done as the participants are likely to be busy (as current scientists, researchers, and legal professionals), and they may have only been able to spare an hour to participate.[491] Most interviews lasted more than the anticipated hour, with three lasting between thirty and forty-five minutes. In some instances,

490 A 'cold' email is defined as a communication sent to a participant with whom no previous contact had been made.

491 Giving an estimated time for completion of the interview is particularly important for those interviewed as 'elite' - see Harvey, 'Strategies', *supra* n.465.

individual names were not readily available - for example, where institutions or organisations had been listed as an opponent, but without a readily apparent key contact. In this instance, institutions were contacted via the email address on their website with a message asking for details to be forwarded to anyone who could assist.

Twenty-five emails were sent to twenty individuals, and five organisations. Twelve individuals agreed to the interviews, with one individual declining to be interviewed. Where no response was received from the initial email communication, a follow-up email was sent to ask first, if the initial email had been received and secondly, reiterating that the participants could ask for any further information about the project before agreeing to be interviewed. One organisation responded with information and answered questions via email, but those who were involved in the BRCA challenges on behalf of the organisation were not available for interview. The positive response rate (defined as contact which subsequently led to interview data) was therefore 48%. This includes six scientists, three non-patent legal professionals, one policy specialist, and one interviewee who was both a scientist and non-patent legal professional. Geographically, five interviews were from individuals involved in the oppositions at the EPO, four were involved in the Australian litigation, and three were involved in the US litigation. There is some crossover in professional characteristics and jurisdiction in the sample. In particular, some scientists were also involved in professional organisations. There was also evidence that some individuals were involved in the challenges in multiple jurisdictions by filing third party observations or amicus briefs, or by providing information and advice to those challenging the BRCA patents in other countries. As such, the characterisation of each participant is made according to their main job and the jurisdiction in which the individual was predominantly involved in challenging Myriad's patents.

At the end of each interview, each participant was asked if they could recommend anyone else involved in the BRCA patent challenges who would be relevant to the research question and may be willing to be interviewed. Four interviewees recommended six individuals to interview. In five of these instances the individual named had already been identified as a potential interviewee from the review of the literature. This demonstrates that the database of names provides a robust methodological approach for identifying individuals and groups involved in gene patent challenges.

6.4.2.1 Saturation

Determining how much data is enough data is difficult in any empirical research.[492] In this research, this decision was reached at theoretical saturation: that is the point at which no new data is gathered from the interviews, but continued data collection merely affirms what was earlier gathered.[493] In this research, such saturation was reached at interview nine, with nearly all new 'codes' generated at this stage.[494]

6.5 Interview Format

Twelve interviews took place between November 2018 and August 2019. These were semi-structured and took place on a one-to-one basis totalling over fourteen hours of interviews. The approach to interviewing aimed to provide flexibility to the format of the interview. The initial outreach email gave participants the flexibility to choose whether to participate in the interview face-to-face, via video-calling, or by phone call. This decision was made for practical reasons: both to recognise the time commitment required for interviews, the geographical constraints, and to maximise the likelihood of agreement to being interviewed. This flexibility also worked particularly well as a result of different time zones; some interviewees asked for interviews to take place early in the morning, or late in the evening UK time. Interviews through phone calls or video conference meant that these could take place from home and increased the time available for interviews making it easier to recruit participants and arrange interviews.[495]

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492 For a discussion on this see: Baker, S. and Edwards, R. 'How Many Qualitative Interviews Is Enough? Expert Voices and Early Career Reflections on Sampling and Cases in Qualitative Research' (2012) National Centre for Research Methods; van Rijnsoever, F. '(I Can't Get No) Saturation: A simulation and guidelines for sample sizes in qualitative research' (2017) PLoSOne 12(7); Sim, J. *et. al.* 'Can Sample Size in Qualitative Research Be Determined *a priori*?' (2018) International Journal of Social Research Methodology 21(5): 619-634; Bryman, *Social Research Methods, supra* n.472.

493 A National Centre for Research Methods review into the question of what number represents sufficient interviews in social science research succinctly summarises the optimal number as: "it depends". Most submissions conclude that, beyond practical limits, the optimal number is linked to data saturation. Such 'saturation' approaches are sometimes criticised as being a "largely interpretivist endeavour" by the researcher (van Rijnsoever, *supra* n.492)) and hard to identify as a fluid principle that changes day by day throughout the research (Becker, H. in Baker, S. and Edwards, R. 'How Many Qualitative Interviews Is Enough?). However, as van Rijnsoever points out researchers in a range of subject areas have recognised that the balance of such subjectivity is transparency in the decision-making process.

494 See Section 6.7 for more details on how the interview data was 'coded'.

495 This reflects the experience of other researchers who have engaged in research taking place over the phone or over video conferencing software, such as Skype. In each of these studies the researchers found that video or phone calls yielded good rapport as well as valuable and reliable data whilst resolving issues faced by financial or geographical restraints. See, for example, Deakin, H. and Wakefield, K. 'Skype Interviewing: Reflections of Two PhD Researchers' (2014) Qualitative Research 14(5): 603, Stephens, *supra* n.468, Ostrander, *supra* n.488.

One participant chose to meet face-to-face, three chose to video call, and five chose to speak on the phone. Although speaking on the phone and through video conferencing software provided increased access and recruitment of participants, this type of interviewing is sometimes viewed as inferior to face-to-face interviews: the latter of which is sometimes still viewed as the "gold standard" of qualitative interviews.[496] There are practical and methodological limitations to video or phone interviews. Interviewing using Wi-Fi or phone lines can lead to interruptions from the internet or phone signal cutting out, or from disturbances or distractions where the interviewer and participant are taking the call. There are further concerns that a lack of non-verbal cues, embarrassment of being 'on video' in video calls may impact the quality and validity of data accumulated in non-face-to-face interviews.[497] Similarly, a lack of access to contextual body movements may impact how the data is articulated. Stephens, recounting his experience interviewing macroeconomists, observed that the lack of non-verbal cues in telephone elite interviews contributed to a difficulty in understanding phrases without hand gestures (for example, the phrase 'a pile this high' without gestures may be hard to translate).[498] In this research some of the limitations of video and phone interviews did arise. In one interview there were ongoing issues with internet connectivity which resulted in an interview taking place on Skype 'dropping' three times during the ninety-minute long video call. A practical difficulty also arose as a result of incompatible software: one interviewee only used Apple's 'Facetime' for video calls, which was not available on either personal or University computers. Beyond the practical and methodological drawbacks, there is also a critique that utilising different formats can impact the quality of the research data gathered. Those interviews done face-to-face and over video call may provide more data in the form of non-verbal communications. There is also the potential that the same person may have provided different answers depending on how they were interviewed.

Despite some of the recognised issues arising, there was a minimal impact on the interview itself. Issues arising from technological dropouts or embarrassment did not arise: most

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496 Deakin & Wakefield, *Ibid*. Deakin and Wakefield observe that "after many decades of the use of interviews within qualitative research, such discussions surrounding the face-to-face interview can often feel uncontested, and online interviews are presented as second choice or alternative when this 'gold standard' of interviewing is not possible at 604; However, see: Holt, A. 'Using the Telephone for Narrative Interviewing: A Research Note' (2010) Qualitative Research 10(1): 113-121 who argues that telephone research is a strong methodological approach as long as the interview context is properly considered; Irvine, A. 'Using Phone Interviews' (2010) National Centre for Research Methods Realities Toolkit #14 and Novick, G. 'Is There a Bias Against Telephone Interviews in Qualitative Research?' (2008) 31(4): 391-398 which both argue that there needs to be more research into the question of whether face-to-face interviewing remains the 'gold standard'.

497 Deakin & Wakefield, *Ibid*.

498 Stephens, *supra* n.468.

participants frequently used video conferencing and phone calls in their professional and personal lives and were therefore comfortable utilising such mechanisms and were familiar with handling technological hiccups.[499] The issues of a mismatch in software was resolved by accessing an Apple device to carry out the interview. This also led to a change in the initial email from referring solely to 'Skype' to include other video calling mechanisms to increase opportunities for a positive response. The contemporaneous video calls allowed for the interpretation of visual cues and the phone conversations had similar hallmarks to the video calls; namely, laughter and detailed responses. There were some interruptions – from visitors, phone calls, and smart home devices – but these were temporary and did not interrupt the flow of the interview itself. In relation to the quality of the interview data, there is empirical evidence that there are minimal differences between responses given in face-to-face interviews and in telephone interviews and between face-to-face and video interviews.[500] In this research, there were similar hallmarks across all three types of interview: rapport – as demonstrated through lengthy answers and responses, laughter, and interviews which lasted longer than an hour – was evidenced across all three formats of interview. There was also no difference in the length or detail of responses in any of the formats suggesting that there was minimal impact of the format of interview in the answers given.

499 Following the WHO declaration of the Coronavirus pandemic in January 2020 and the pivot to predominantly online mechanisms of working and socialising there is an increasing recognition that there is an ethical consideration necessary in asking participants to engage in video calls. The interviews here took place prior to WHO declaration and, as such, has not examined such ethical questions. For a brief discussion of these issues see Jowett, A. 'Carrying Out Qualitative Research Under Lockdown - Practical and Ethical Considerations' (2020) LSE Blog available at < https://blogs.lse.ac.uk/impactofsocialsciences/2020/04/20/carrying-out-qualitative-research-under-lockdown-practical-and-ethical-considerations/> accessed 20/06/21.

500 Sturges and Hanrahan, in their study exploring visitors and correctional officers' perceptions of visiting inmates, found that there was little difference in the responses between interviews conducted face-to-face and by phone, although emphasised that this depended on the research question and the participants being interviewed: Sturges, J. and Hanrahan, K. 'Comparing Telephone and Face-To-Face Qualitative Interviewing: A Research Note' (2004) Qualitative Research 4(1): 107-118; Weller, S. 'The Potentials and Pitfalls of Using Skype For Qualitative (Longitudinal) Interviews' (2015) National Centre for Research Methods available at <http://eprints.ncrm.ac.uk/3757/1/Susie%20Weller.pdf> whose research looked at using Skype to mobile calls and Skype video calls for carrying out longitudinal interviews and analysed face-to-face interviews with Skype interviews on the grounds of rapport and content, concluding that as long as there was a feeling of co-presence in the interviews, there was little difference in rapport and content - with the exception of traumatic or sensitive events. Bryman also notes that in his research that telephone interviews "generated detailed and considered replies of the kind typically sought by qualitative interviewers": Bryman, *Social Research Methods*, *supra* n.472 at 488. Saarijarvi and Bratt argue that the impact of the declaration of the Coronavirus pandemic in 2020 might increase the interest in using different methods, see Saarijarvi, S. & Bratt, E. 'When Face-To-Face Interviews Are Not Possible: Tips and Tricks for Video, Telephone, Online Chat, and Email Interviews in Qualitative Research' (2021) European Journal of Cardiovascular Nursing 20: 392-396.

Despite these concerns, the benefit to accessing elite interviewees, and accessing interviewees from across the world outweighed the drawbacks caused by connectivity issues or a lack of contextual information. This chapter now outlines the ethical considerations which underpinned the design of the interview and the treatment and storage of the data gathered through the research.

6.6 Ethical Considerations

The methodological choices and design of the interview schedule were developed in accordance with ethical principles including confidentiality, informed consent, and privacy. The next section details how these ethical principles shaped the interview design.

Prior to beginning the data collection, ethical approval was sought and granted from the University of Bristol Law School ethics committee. This approval was granted following an internal ethics application, which included several appendices including a risk assessment, copies of the briefing note sent to participants to during recruitment, and a consent form. The briefing note outlined the research providing: information about the researcher, the proposed title of the research, a brief background to the study, when participating in the research would involve, how the research data would be used and stored, as well as information about funding and contact information for both the researcher and supervisors.[501] The consent form included both a consent to the interview, as well as a separate section seeking consent to recording the interview, and an additional section for waiving anonymity, if the participant chose to do so.[502] The ethics application, and the principles taken into account when designing this study, reflect three key aspects of ethical research: confidentiality, consent, and privacy. These principles reflect both the Research Council UK's Governance of Good Research Conduct, and the Socio-Legal Studies Association Re-Statement of Research Ethics.[503]

6.6.1 Confidentiality

Protection from harm is a key ethical principle for all research. Harm often covers physical or mental harm but can also extend to reputational damage and adverse impact on their employment, which is particularly relevant to this research. It was anticipated that interviewees

501 A copy of the briefing note is available in Appendix 3.

502 A copy of the consent form is available in Appendix 4.

503 Statement of Principles of Ethical Research Practice, Socio-Legal Studies Association available at http://www.slsa.ac.uk/images/slsadownloads/ethicalstatement/slsa%20ethics%20statement%20_final_%5B1%5D.pdf, Research Councils UK 'RCUK Policy and Guidelines on Governance of Good Research Conduct' (2013) available at https://www.ukri.org/files/legacy/reviews/grc/rcuk-grp-policy-and-guidelines-updated-apr-17-2-pdf/. See also, Bryman, *supra* n.471 Chapter 6.

may be willing to give statements or make observations which may have not been known publicly, or may make statements at odds with other members of their communities, or with their employer's policies. This was particularly relevant in this research as several interviewees may have opposed the Myriad's patents despite their University or employer's position being pro-patent, or generally supportive of gene patenting. Vital to ensuring confidentiality in this research was therefore guaranteeing anonymity. Participants were given the option to waive anonymity, although none chose to do so. At times, the interviewees sought confirmation that the statements made was not attributable to them and so the commitment to confidentiality of the data was emphasised at various points of the interview process. As such, all interview data was anonymised. Identifying information was removed from the record keeping and replaced with a numerical identifier. The transcripts, and associated notes, had identifying information (such as workplaces) removed. The general location (i.e. Europe) and broad categorisation of career were left in the data (i.e. scientists, legal professional). This is because such information is relevant to the interpretation of the interview data and research findings. Where this information was likely to lead to the identification of the interviewee, it was removed. Finally, all contextual data about gender, professional associations, employment details, or any other details which may have led to identification of the participant were removed in the write-up of the interview findings.

6.6.2 Informed Consent

This research was conducted overtly and so informed consent was sought and gained from all participants in this research. Informed consent and the avoidance of deception are key principles of all good research. This involves ensuring that participants are provided with all the necessary information regarding the aims and nature of the research to ensure that they are able to make a free and informed choice about participation. Such information was provided in several ways. The briefing note, as approved by Bristol Research Ethics Committee (see Appendix 3), outlined the purpose of the research, what to expect from participation, researcher information, and information about data storage. This information also included funder details and details of future data use.[504] At the beginning of each interview the details of the briefing note were outlined, with an opportunity for participant's to raise any questions or concerns.

504 Mack's list of information vital to informed consent does not include funder details, not how the data may be used in the future. Bryman, the UKRC guidelines, and the Socio-Legal Studies Association guidelines however recognise that details of the funder are vital to gaining informed consent. This is particularly relevant in this research as, due to its funding by the ESRC, there is an expectation that the research data will be uploaded to the UK Data Archive for future use in secondary data analysis. As such, information about the funder, and the potential for future use of the data was provided to all participants in the briefing note and the consent form.

Verbal and written consent was sought for both participation in the interview, and digital recording. However, gaining verbal and written consent was not always achieved contemporaneously. Although verbal consent was gained at the beginning of each interview, written consent was sometimes received at a later point. This was due to the practicalities of the interviews: many did not take place face-to-face.

6.6.3 Privacy

The protection of participant's privacy is vital to any research project. There was no requirement for individuals to be identified in this research as their identity was not central to answering the research questions posed. There is, therefore, nothing to be gained from revealing their identity. Participant's privacy was also protected by ensuring the confidentiality of the data, and of the participant information discussed above. During the research names, professions, and contextual information were gathered from the participants. Measures were put in place to ensure the confidentiality of this information, and to ensure the participant's privacy were protected. Through the research, the control of all data – both the digital data and that stored in hard copy form – was retained by the researcher. Individual names and contact information were kept separate from transcripts, which were anonymised. Digital recordings of the interviews were taken on an encrypted Dictaphone and were subsequently transferred to an encrypted, password protected file as soon as possible. Once transcribed, interview transcripts were stored in a separate, password protected file location and were encrypted. These files are only accessible via a University PC or via a VPN on a personal laptop. The interviews also generated hard copy data including observations, reflections, and issues worth exploring further in the interview. These hard copy notes were stored in a locked drawer in a secured University room. This ensured the participant's privacy was protected as far as possible.

Some experience context is required when exploring the interview findings. For example, some of the barriers identified to bringing gene patent challenges impacted scientists differently to those with legal expertise. As such, in some circumstances, the broad class of the participant is noted (such as 'scientist' and 'legal professional'). Where this information would likely lead to the participant being identified, it was not included.

6.7 Coding and Thematic Analysis

The interviews were recorded using an encrypted recording device, before being transcribed in Microsoft Word. A criticism of interview transcripts are that transcribing can 'flatten' the data, and remove the context – pauses, hesitations and laughter – which can illuminate rapport or

hesitation.[505] In this research, the initial transcripts included as much context as possible, including pauses, hesitations, and laughter that arose in the interviews. To provide further context, notes were jotted down reflecting on the interview. Bryman observes that participants may 'open up' at the end of the interviews, and therefore advises to keep a recording device active whilst wrapping up.[506] In the face-to-face interview, the conversation with the participant continued whilst exiting the building and some interesting insights were mentioned but not recorded. To capture this information as quickly as possible, verbal notes were taken on the recording device as soon as possible. Each interview therefore generated a digital file, a transcription of this file, and researcher notes. This approach "very rapidly [generated] a large, cumbersome database because of its reliance on prose".[507] Thematic analysis was used to tackle this thicket of data. Thematic analysis is defined as "a method for identifying, analysing and reporting patterns (themes) within data. It minimally organises and describes your data in (rich) detail".[508] A theme is defined as "something important about the data in relation to the research question and represents some level of patterned response or meaning within the dataset."[509] Thematic analysis as a technique for data analysis is widely used, yet poorly defined and demarcated due to the flexibility of the approach.[510] Thematic analysis is not wed to a specific theoretical framework, and so can be used within different frameworks, and to do different things within them. Whilst this flexibility means that thematic analysis is appropriate to a number of research projects, it also means that vital to a good thematic analysis is an acknowledgment of the researcher's theoretical position in relation to the research, as well as detailing the decisions made in the final report. This section details these decisions in relation to this research project.

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505 For a discussion on how transcription can remove this context see Hammersley, M. 'Can We Re-Use Qualitative Data Via Secondary Analysis? Notes on Some Terminological and Substantive Issues (2010) Sociological Research Online 15(1): 5 -7.

506 Bryman *supra* n.471 at 487.

507 This cumbersome database may "[leave] researchers struggling to find a path through the thicket of prose" see Bryman, *ibid* at 565.

508 Braun, V. and Clark, V. "Using Thematic Analysis in Psychology" (2006) Qualitative Research in Psychology 3(2): 77 at 6.

509 *Ibid* at 83.

510 See Braun & Clark, *ibid*; and Bryman, *Social Research Methods*, *supra* n.471 at 578-579. Braun and Clark's seminal article on using thematic analysis was critical of the lack of clear guidance in using thematic analysis and attempted to rectify this gap by providing an "outline of the theory, application, and evaluation of thematic analysis" (at 4). In 2014 Braun and Clark published an article exploring how thematic analysis can help health and wellbeing researchers and found that - despite the uptake of thematic analysis following their article - the technique still struggles at times with unclear boundaries yet still presents "a toolkit for researchers who want to do robust, and even sophisticated analysis of qualitative data", see Braun, W. and Clark, V. 'What Can "Thematic Analysis" Offer Health and Well-Being Researchers" (2014) International Journal of Qualitative Study on Health and Wellbeing 9(10).

This analysis was initiated following each interview with notes on particular themes or emerging patterns of as they arose. A brief summary of key themes, findings and initial thoughts were collated following each interview. Data analysis thus began and took place throughout the collection stage, rather than after data collection had been completed. This is in line with a thematic analysis approach whereby data collection and analysis are not rigidly demarcated.[511] Thematic analysis has been theorized as typically involving six 'phases' which were mirrored in this research: familiarisation with the data, generating initial codes, searching for themes, reviewing themes, defining and naming themes, and producing the report.[512] The phases are not siloed: the researcher will likely move back and forth between phases during analysis in a process of iteration, rather than progressing through each stage in isolation.[513] Similarly, in this study, the data was 'coded' by reading and re-reading the interview transcripts and associated notes, searching for "data…that appears to be interesting ….[and] the most basic segment, or element of the raw data or information that can be assessed in a meaningful way regarding the phenomenon".[514] The data was subsequently grouped, before being reviewed for common themes. This stage was iterative. Some codes fitted into several themes and, as the themes began to emerge, some codes no longer contributed to the overall theme and were therefore moved. This analysis thus resulted from an iterative approach which "involves a constant moving back and forth between the entire data set, the coded extracts that you are analysing, and the analysis of the data that you are producing".[515]

Forty 'codes' were identified, which were grounded into eight broad themes. These themes were then narrowed further into three broad themes: socio-economic costs, legal rules, and institutional / cultural networks. For example, one code was initially 'no legal training' which became part of the narrow theme 'lack of technical, legal knowledge' which constituted part of the broad theme institutional / cultural networks. The data was reviewed further and the analysis refined to ensure that the themes conformed with coherent patterns internally (i.e. within the theme) and externally (i.e. in relation to the data set as a whole).

511 As Braun and Clark note, thematic analysis requires moving back and forth between the data collection and analysis stages, and the actual process analysis begins with the analyst begins to notice and look for patterns and meanings in the data and finding "themes…the investigators identify before, during and after the analysis" see Braun & Clark, *supra* n.508 at 15.

512 *Ibid* at 35 (Table 1).

513 *Ibid.*

514 *Ibid* at 18.

515 *Ibid* at 85.

6.8 Limitations

The findings and analysis are based on a relatively small sample of interviews making it difficult to make generalisations to the wider population. This research is also based on a case study specifically exploring the difficulties faced by the participants in the *Myriad* case litigation.[516] However, there is still benefits to studying opposition and challenges in this way. Although the interview sample was modest, theoretical saturation was reached during the interviews. This indicates that the findings are likely to be representative of a wider population of individuals and organisations who seek to challenge patents and their experiences when attempting to do so. Furthermore, as discussed in more detail in the next chapter, the findings can be potentially applied across different categories of patents. The hybridised nature of science and law and the 'insider'/'outsider' socio-cultural divides, could carry over across many categories of patents beyond gene patents. Equally, the legal and extra-legal barriers faced by NGOs and public society coalitions voicing concerns about the impact of patents on access to diagnostics, treatment, and clinical research are likely to continue playing out in the patent offices and courts search for a balance between the interests of patent holders & for-profit organizations and the wider interests of the public in current controversies over, equitable access to vaccines.[517]

6.9 Conclusion

This chapter has explained the rationale for the choice of methodological approach used in the empirical arm of this study and its limitations. Semi-structured interviews and purposive sampling were used because they allowed flexibility in the exploration of the participants experience in litigating against the validity of the BRCA patents. A thematic analysis was used to identify and refine emerging themes throughout data collection. The findings and final overarching themes and sub-themes are set out in the next chapter.

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516 Liddicoat, J. *et al.* 'Are the gene-patent storm clouds dissipating? A global snapshot' (2015) Nature Biotechnology 33: 347-352 which argues that, whilst not completed dissipated, gene patents are a predominantly North American problem, and argues that attention is potentially best now directed at "the next wave of biotechnology patents."

517 The issue of access to vaccines has been brought into sharp relief as a result of the coronavirus pandemic and evidence of inequitable vaccine access for developing countries. See, for example, Gurgula, O. 'Drug prices, patents and access to life saving medicines: changes are urgently needed in the Covid-19 era' (2021) Forthcoming in the European Intellectual Property Law Review Available at SSRN: https://ssrn.com/abstract=3780630 or http://dx.doi.org/10.2139/ssrn.3780630; t'Hoen, E. 'Protect Against Market Exclusivity in Fight Against Covid-19' (2020) Nature Medicine 26(6): 813-814.

Chapter 7: Interview Findings

7.1 Introduction

This chapter presents the findings of the semi-structured interviews. This chapter is split into three parts which structure the findings around three emerging main themes and seven sub-themes. The first part reveals the procedural costs to applicants of challenging the validity of patents at the EPO and in national courts. It identifies the cumulative costs notwithstanding the legal and expert advice given on a pro bono basis. Secondly, this chapter shows how significant gaps in understanding between science, law, and patents limit the ability for groups to bring patent challenges. These gaps mean that the challenges had to be mediated through patent specialists, who acted as gate keepers to the diffusion of this knowledge. Thirdly, this chapter reveals the institutional and cultural barriers which the litigations had to overcome including the insular nature of the patent system. Each section is further broken down into subthemes, explained further below.

- Part I – Social and Economic Costs

Part I details the social and economic costs to bringing gene patent challenges. Three subthemes emerged from the interviews. First, the economic costs include the high cost of the administrative, legal, and expert fees. Secondly, whilst the use of pro-bono work facilitated the challenges, the reliance on such work is precarious. The final sub theme identified was that there are professional risks to becoming involved in the opposition and litigation.

- Part II – Legal Rules

Part II discusses the barriers presented by navigating the legal rules surrounding patents. Two subthemes emerge from this analysis. First, the difficulties navigating the procedural process for challenging patents and the reliance on specialist assistance to do so. Secondly, there is a significant gap between law and science and how this applies to patents. This gap presents significant difficulties for navigating the layers of expertise required to invalidate patents.

- Part III – Institutional and Cultural Networks

Part III identifies and discusses the barriers arising institutional and cultural networks. This is split into three subthemes. First are those barriers arising prior to the challenge beginning. These include the awareness of gene patents and finding legal advice. The second subtheme is that of the patent club. This identifies the close relationship between patent professionals and norms within patent practice as barriers to bringing gene patent challenges. Finally, this chapter discusses the difficulties in forming a counter network to balance the insular network.

7.2 Socio-Economic Costs

All of the interviewees were asked what they perceive as the biggest barrier to bringing gene patent challenges. Seven interviewees, covering all three jurisdictions, stated that it related to money. The cost of gene patent challenges includes : administrative costs (filing fees and Court fees), legal fees (the costs incurred by their own solicitors and barristers), expert fees, and adverse costs (the liability for Myriad's costs, if they were successful). This section breaks down the responses concerning costs into two sections. The first discusses the barrier of costs faced during the opposition and litigation (that is, the administrative costs, legal and expert fees). The second discusses costs post-opposition or litigation, namely the potential for adverse costs. To provide context to this discussion, it is worth briefly outlining the comparative costs of filing for litigation in the US and Australia versus filing for opposition at the EPO. The EPO opposition process has the lowest costs associated with challenging patents, with estimates of the total cost of the challenge at between $65,000 - $650,000 USD.[518] The costs for litigating in both Australia and the US are estimated at upwards of $1 million USD.[519] These numbers are likely to be conservative: most analysis of costs only includes figures up to the decision at first instance.[520]

7.2.1 Administrative, Legal, and Expert Fees

The cost of challenging patents was an issue both in the opposition procedures at the EPO and the litigation in national courts. When asked if they had any difficulties paying for the opposition Interviewee 4 said that:

> *"Sure. You know, I spent a lot of time trying to get that money. So…there has been and again I don't know the numbers by heart but for the first round was our department in our university who paid the bills….And then, I had paid several rounds for each new opposition*

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518 Rotstein, F. and Dent, C. 'Third Party Patent Challenges in Europe, The United States, and Australia: A Comparative Analysis' (2009) The Journal of World Intellectual Property 12(5): 467-499. This does not include the cost of potentially then litigating the European Patent in national courts. None of the Myriad patents were litigated in national courts are therefore this issue is not considered further here. However, for a consideration of litigating patents in England and Wales see McDonagh, L. and Helmers, C. 'Patent Litigating in England and Wales' (2013) Civil Justice Quarterly 32(2): 369-384.

519 See Rotstein & Dent, *ibid*; American Intellectual Property Law Association, '2017 Report of the Economic Survey' (August 2017) available at < https://www.aipla.org/detail/journal-issue/economic-survey-2017> (accessed 16/3/2020).

520 Estimating the total cost is also subject to a number of different factors involved in opposition and litigation. Helmers notes that estimating costs needs to take into consideration a wide variety of procedural issues, such as the extent of pre-trial discovery, the role of expert witnesses, and the length and complexity of the trials. See Helmers, C. 'The Economic Analysis of Patent Litigation Data' (2018) Economic Research Working Paper No.48 at 7.

because there had been…four oppositions eventually, something like that… We had as many oppositions as there were patents…

I've told myself I should have kept notes day after day. So yes, I have had hard times to collect money. It was all gifts from genetic institutes, from genetic societies so I needed legal entities to be able to pay and support."

Although not all of those involved in the EPO challenge agreed with this analysis. Interviewee 6, responding to the same question, said that "*No, it was not a problem. First, because, and the difference with the US, the opposition…[we] don't need a lot of money for the oppositions."* The reason for the 'affordability' of the opposition process was not as the process itself is cheap – the opposition cost hundreds of thousands of Euros – but is more affordable in comparison to the cost of litigating in the US. This is evidenced by the quote above, which considers US challenges to require 'a lot of money'. Another respondent pointed out that:

"…and I instantly also realised that because if you want to launch a court case in the US you have to think twice because you are talking millions and millions in costs. As in our case, the opposition for all the patents taken together has cost us a few hundreds of thousands of Euros. Way below one million. So I could understand and I was kind of unhappy about the fact that in the US even if you think something is definitely wrong, you still need an awful lot of money to get it right." (Interviewee 4)

Although the cost of litigation in the US was frequently used by those involved in the challenges in Europe and Australia as a touchpoint of how expensive patent litigation can be, cost was not an issue in the US litigation as the ACLU were able to fund the litigation. However, those involved in the US opposition did note that, without the ACLU, there would have been no challenge. Organisations, such as the Public Patent Foundation and the College of American Pathologists, who supported the ACLU's actions against Myriad, did not have the money to file for challenges against Myriad.

The lack of organisational money to bring patent challenges was echoed in the interviews with those involved in the Australia litigation. Interviewee 1 that that their challenge in the Australian Courts was done on the *"smell of an oily rag…[we] had no money. It was all basically good will on the part of everyone involved".* The reliance on the 'good will' of all parties to bring the case was echoed in the other interviews with those involved in the Australia litigation. Despite a significant number of parties doing the case for free, there were still significant costs in bringing the case to the Australian High Court. To be able to meet these costs the Australian challengers had to seek out legal aid. Interviewee 7 notes that;

> *"Just in terms of funding…we had a limited grant of legal aid from the Commonwealth Government actually, strangely enough, I mean legal aid is virtually unavailable in Australia for civil litigation but there's a sort of, public interest exception that the Federal Attorney General's staff administers and they made a limited grant of legal aid which covered some of the various expenses and costs and I think covered the cost of the witnesses expenses that we incurred."*

In Europe, the nature of the challenge meant that there was no body from which to seek legal aid. As such, individuals who spearheaded the challenges had to seek money from a range of sources. This took a substantial amount of time and effort;

> *"So I was collecting money from other opposition centres but this was small money because there is no such funds available in big amounts. Then I extended my call to the other European genetics societies and again, I don't have the figures on how much was paid by whom it went too fast, it went too irregular. But actually we have been able to pay all the bills. I had a very hard time to find money."* (Interviewee 4).

Interviewee 5 echoed this finding, recalling that they worked both within their organisation and reached out to other bodies and organisations for a grant to support the European challenges. The important role of individuals and organisations spearheading the challenges and bringing various groups together is discussed in more detail below.

Whilst the cost of challenging the patents was a barrier in itself a looming issue for the claimants in the US and Australia was the potential for an adverse costs judgment against the litigants. Both the US and Australia have a "loser pays" system where the party who were ultimately unsuccessful in the suit are responsible for the costs of the successful party. These costs are significant.[521]The risk of losing and being subject to an adverse costs order was therefore a significant barrier to bringing the challenge and prevented some groups and individuals both from being able to challenge the patent in Court, and from being a party to the litigation. This risk limited organisations and individuals in different ways.

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521 The American Intellectual Property Law Association (AIPLA) estimated in 2010 that the average costs accrued in US patent litigation is around $3 million, see WIPO Magazine 'IP Litigation Costs: Special Edition' Feb 2010. <https://www.wipo.int/export/sites/www/wipo_magazine/en/pdf/2010/wipo_pub_121_2010_01.pdf >. In Australia, Rotstein and Dent estimated that the average costs in patent litigation is between $530,000-$700,000 USD. These figures are based on litigation concluding after a decision in the first instance and do not take into consideration the costs of appealing the case, nor of the case progressing to the highest appellate court in the respective jurisdictions. These costs also vary according to the complexity of the case, the experts involved, and pre-trial actions. Rotstein & Dent, *supra* n.518.

Charitable and not-for-profit organisations were prevented from exposing their organisations to a substantial financial risk under their governance charters. There were a range of charities and not-for-profit organisations which vocally opposed Myriad's BRCA patents but did not initiate any legal challenge to the validity of said patents. This research found that this was, in part, as a result of corporate charters which prevented these organisations from engaging in risky financial actions. Interviewee 5 said that they were aware of a UK charity which considered getting involved in the US litigation but were unable to do so as they "*lived off putting pennies in charity boxes so there was no way they could use that to justify hiring US patent attorneys to challenge Myriad in the US".* Similarly, Interviewee 8 mentioned that many of the NGOs or not-for-profit organisations in the US could not get involved in the litigation as their constitutions or charters for best practice would not permit the organisations involvement due to the financial risks of litigation. In Australia, Interviewee 1, recalled their discussions with a charity who considered challenging Myriad's patents, and stated that:

> "*We had long talks and in the end they decided that they couldn't risk being the plaintiffs in a legal action because they were bound by their charter and their charter restricted their ability to be able to take that kind of a risk which [included] taking on the risk that if they lost they would have to pay substantial legal costs to Myriad."*

Interviewee 12 – a policy advocate – confirmed that, the charity they were employed by at the time were eager to become involved in the patent challenges but their not-for-profit status and costs risks meant they could not be a plaintiff or assist in any substantive way with the litigation.

The interviews with those who took part in the challenges in Australia also identified that the high costs limited the individuals who would be willing to be a plaintiff in the litigation. Interviewee 11 in Australia commented that, originally, a research assistant was being considered as a lead plaintiff but they decided not to proceed due to the potential financial impact on them personally. Interviewee 1 also noted that whoever became the plaintiff in the Australian litigation would need to risk bankruptcy in the event that the case was unsuccessful;

> *"So, even though she [D'Arcy] wasn't having to pay for any of the legal costs because it was all being done pro bono. There was always a risk that she [might] be ordered to pay the legal costs of Myriad Genetics. So she had to be prepared to go bankrupt if she couldn't afford to pay and then we're talking patent cases, we're talking hundreds of thousands of dollars, probably millions of dollars. And Jones Day were the lawyers acting for Myriad and they're not inexpensive and they also employed QCs as well. So, the legal costs were mounting."*

In the US, the funding provided by the ACLU meant that the risk of a potential cost order was mitigated. But, the risk of adverse costs was a factor in why other organisations – such as the Public Patent Foundation – had not filed the challenge previously, nor could pursue the challenge itself (Interviewee 8). In the US, finding a suitable plaintiff is already a difficult task, as a result of restrictions on standing.[522] The limitations on the involvement of charities and not-for-profit organisations as a result of their charters mean this selection of plaintiffs more complex and difficult. When discussing the potential for future challenges, Interviewee 8 also mentioned that the main groups who had previously been involved in bringing legal challenges to patents – notably, the Public Patent Foundation – were now essentially defunct due to a lack of funding. This is reflected on the Public Patent Foundation's website which has not been updated since 2015.[523]

An adverse costs order was not mentioned in the interviews with those involved with the challenges at the EPO.[524] However, there was a broader concern mentioned by two interviewees that Myriad would, instead, "scoop" their laboratories and negotiate with national governments to outsource BRCA testing. As one interviewee noted;

> *"We were afraid that at some point that Myriad would go one level up to the national governments in some of those countries. Especially in France. And negotiate with the Minister of Health. And then say okay we offer the test for this or this price. And look at those laboratories in France. They're slow, they're not giving a good service, etc. and so at a certain moment [we] were really afraid that this would scoop the whole discussion. The French government would say 'you know we don't support them anymore, we have a contract with Myriad for the…'"*

The interviews demonstrate the significant barrier as a result of the costs and financial risks in bringing patent oppositions and patent litigation. The effect of these costs limits who can bring challenges against patents.

7.2.2 The Precarity of Pro Bono Work

What is clear from the above is that the challengers in each jurisdiction had a different approach to handling the substantial cost involved in seeking invalidation of Myriad's BRCA patents. In the US, the ACLU covered the costs of the litigation and so did not have to spend time and

522 See Section 4.3

523 See Public Patent Foundation website available at <http://www.pubpat.org/> . Their latest news section was last updated in March 2015. Although, there is no referencing to the Foundation closing or ceasing its advocacy efforts.

524 Costs as a result of opposition proceedings are governed by Art.104 EPC and Rules 88 and 122 Implementing Regulations to the Convention on the Grant of European Patents.

resources finding money and individuals to support the case. In the European challenges, some money was provided by the organisations of which the individuals spearheading the challenge were a part of, but none of the work was done pro bono. Interviewee 4 explains that;

> *"I don't know the numbers by heart but for the first round was our department in our university who paid the bills. Um, so our patent attorneys we had paid them their fees so it was not pro bono, at all."*

Whereas Interviewee 5 notes that, initially, their organisation supported the challenge through funding and they eventually were able to secure financial support from the national government;

> *"The most important is to pay for the patent attorney. So the [organisation] paid for it. And we have, later, help from the [government ministry]. So, it was not really a problem. It was the most important to have some funding at the beginning just to begin. And it is in the interest of the structures like the [organisation]."*

A risk to the opposition in the European context was consequently that they would run out of money to pay their patent attorneys, patent lawyers, and fees at some point during the proceedings. In contrast, the experts and legal professionals involved in the Australian litigation were mostly contracted to work on a *pro bono* basis. This presented a double-edged sword for the Australian litigation. The work being done *pro bono* was vital for the challenges to proceed as limited funds meant that it would have been unaffordable otherwise. This is shown by Interviewee 1:

> *"And so I then met with the team and we put together the lawyers that would be involved and it was agreed that I would act as the technical advisor that the lawyers would be Morris Blackburn. So Morris Blackburn agreed to do the case pro bono and then we appointed a number of barristers and one of them was [counsel]who kindly agreed to do the case pro bono. And then there were a couple of technical experts that we had to get and they also agreed to help pro bono and so consequently the team was put together [.....] It was all basically good will on the part of everyone involved and we then started the proceedings and [that] was how it happened.*[525]

However, relying on the good will of those involved resulted in an insecurity to the challenge. If any of those who had given their time, resources, and expertise for free decided not to proceed

525 Not all of the respondents involved in the Australian litigation concurred that the experts became involved without payment. Interviewee 11 noted that one of the costs that had to be covered was expert fees, which included travel costs. Despite this, they both agreed that the majority of the legal work was undertaken *pro bono.*

any further, the challenge would have stopped in its tracks. This was identified as a serious concern by Interviewee 1:

> *"Well it could have happened that any one of those barristers who had freely agreed to do this pro-bono might have dropped out. It might have been that Morris Blackburn might have decided they didn't want to do this anymore. So there were enormous hurdles at various stages along through the litigation that could have seen the litigation stop dead at the full federal court stage."*

This uncertainty manifested when Cancer Voices Australia – initially a plaintiff in the litigation – withdrew prior to the High Court proceedings. All three interviewees involved in the Australia litigation commented that Cancer Voices withdrawing was concerning for the future of the litigation, particularly as they did not give much notice that they were intending to do so. When asked if Cancer Voices withdrawing presented any difficulty, Interviewee 7 commented:

> *"It would have if we didn't have Yvonne [D'Arcy] as a second string to our bow the whole case would have been discontinued. We would have had to start again. So, luckily, we had two applicants and so, no, it didn't create any difficulties whatsoever. It was just odd that…I don't know if it was a communication breakdown but all of sudden one day they're there and the next day they're discontinued."*

This demonstrates that there is a fragility to bringing claims through a reliance on work done *pro bono*.

7.2.3 Professional Risks

Beyond financial risks, there were professional risks to becoming involved in the challenges for some of the plaintiffs. The interviews found that there was tension between those who intended to oppose or litigate against Myriad's patents and their employers or colleagues who disagreed with this action. This was because either they were involved in patenting biotechnologies themselves or they disagreed with the argument that the BRCA patents were causing harm. There was therefore a perceived risk to their careers and reputations of those interviewed. In some cases, this initially prevented their involvement in the challenges. Interviewee 9, a US geneticist, was working at a University in the late nineties and received a cease a desist letter from Myriad, which they wished to legally challenge. However, they spoke with the University legal team who advised against taking the action , in part due to the fact that the University was involved in patenting other biotechnologies. This tension between the desire to challenge the patent and an employer or colleagues involved in and supportive of patenting is present in other jurisdictions. Interviewee 6, a European scientist, said that:

"at the beginning I didn't have the support of all of my colleagues in France. Some of my colleagues thought that it would be very interesting to have some collaboration with Myriad Genetics."

Other interviewees put this tension in more stark terms:

*"I had one call, not a geneticist, but a researcher who warned me and said 'hey guy, what are you doing?' he phoned and said you are killing the system. And I was young then and I thanked him for the information, and I told him to shut up!"(*Interviewee 4)

This final quote demonstrates that those interviewed did eventually engage with the challenges in spite of the potential professional risks. However, it suggests that there may be others who would have been reluctant to become involved in opposing the patents if it went against the position of their employers or other colleagues.

This research shows that there are significant socio-economic costs to bringing patent challenges. These costs prevented challengers from becoming involved in the opposition or litigation. These costs also meant that the challenges in Europe and Australia had to spend a significant time pooling money from various sources, and relied extensively on the good will of others to pursue the challenge. The reliance on good will, as well as the dependency on pro bono work, made the challengers fragile and at risk of faltering. Costs limited the pool of available plaintiffs, and nearly prevented the Australian challenge from progressing. This section also identifies that there were professional risks to those willing to challenge Myriad's BRCA patents. This risk arose from a tension between colleagues and employers who utilised patents and the challengers. The increasing privatisation of University research through patents is only likely to increase this tension in the future.[526]

7.3 Legal Rules

This part discusses the legal rules which the challengers have to navigate to bring patent challenges. This is broken down into two subheadings: navigating procedural process (including the time frames of challenges, the strict application of the EPC, and standing) and the expert gap between law and science.

526 There is an increasing global drive to increase technology and knowledge transfer between universities and industry through the commercialisation of university research. This has led to a explosion in university patents see Henderson, R. et al. 'Universities as a source of commercial technology: A detailed analysis of University Patenting, 1965-1988' (1998) 80(1): 119-127 which demonstrates the significant growth in University patenting. For a more recent analysis, see Plomer, A. *Patents, Human Rights and Access to Science* (Edward Elgar 2015) at 10-13.

7.3.1 Navigating Procedural Processes

7.3.1.1 Challenge Time Frames

Oppositions at the EPO and litigation in national courts present complex procedural process which require navigation to mount successful challenges to patent validity. The EPO time limit of nine months post publication of the invention posed a difficulty for those not familiar with the patent system.[527] This short time frame meant there was significant pressure on the individuals and organisations bringing the challenges to find the patent, understand its claims, establish grounds of opposition, and file the appropriate paperwork;

> "*Of course, the opposition procedure of nine months put quite some pressure on us to get the parties together. We started relatively late to working on this so I'm still grateful to the people from the different offices that worked like crazy on this*" (Interview 4)

> "*You have nine months, of course it is* only *for nine months, the time."* (Interview 6)

In the US there are no time limits to file for invalidation proceedings against a granted patent. This meant that the decision to invalidate Myriad's BRCA patents in the US took place only two years prior to the expiration of the patent.[528] This was, in part due to the time it took for the ACLU to prepare the case before filing proceedings in the District Court;

> *"We had a science advisor at the time who was not an attorney but she looked at different science policy issues that were concerned with civil liberties and one of the ones she identified for us was around gene patenting. So, we began to investigate the issue and, you know, it's a novel issue for us. The ACLU had never done any patent work so it was one we studied for a couple of years before bringing the litigation which, for our purposes, is a long time to spend on something." (Interview 8)*

In Australia, the lack of enforcement by GTG meant the preparation for litigation did not begin until sometime into the life of the patent. [529] The initial lack of enforcement meant that Maurice Blackburn initially did not become involved in the BRCA patent challenges as it was not viewed as a social justice issue whilst the patents were not causing overt public health impact (Interviewee 9). When they did become involved, it took a significant amount of time to identify

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527 Art.99 EPC states "within nine months from the publication of the mention of the grant of the European patent, any person may give notice to the European Patent Office of opposition to the European patent granted."

528 The Supreme Court decision invalidating the US BRCA patent was handed down on 13th June 2013. US Patent 5747282 (claiming the isolated BRCA1 gene) expired in June 2015; US Patent 5693473 (claiming the mutations in the BRCA1 gene) expired in December 2014; US Patent 5837492 (claiming the BRCA2 gene) expired in December 2015.

529 For a discussion of the reasons for the later litigation in Australia see Section 5.2.

plaintiffs, understand the patent, and determine a litigation strategy. This meant that the High Court decision invalidating Myriad's patents was handed down two months after the patent had expired.[530] This meant that Myriad's Australian BRCA patent remained legally valid and enforceable for the life of its grant.

The lengthy time frames for litigating the validity of patents stems not just from the time it takes to learn the information and determine a patent strategy. It also results from the fact that challengers have to pursue the cases to the highest courts. As Interviewee 1 notes, discussing the effectiveness of the challenges:

> *"We have to seriously look at all of these issues and deal with it otherwise we're going to continue to create these sort of problems and it's only going to be the most tenacious, well-funded or incredibly lucky litigants that pursue a case all the way to the highest level, to the UK Supreme Court or the High Court of Australia, the US Supreme Court, that will ultimately see the law corrected in the way it should be. Well, we know, that is the most inefficient, expensive and ridiculous way to get the law right. We need to get it right in a much less expensive, lower level and until that happens we're going to have many examples of bad law remaining…because the High Courts have never got their hands on the particular patents in issue."*

The discussion of the law being 'corrected' here refers to viewing gene patents as informational in content, rather than chemical or structural. Chapters 3 – 5 show that the success of the challenges was, in part, due to the ability of the challengers to reach the highest courts. But this has implications for the public interest whilst the patents remain valid.

7.3.1.2 The Strict Application of the EPC

Those interviewed who were involved in the European opposition were surprised about what arguments they could and could not make before the OD and TBA. The interviewees experienced difficulties in understanding the arguments which could be advanced against the BRCA patents, referring to frequent 'mis-steps' they made throughout the litigation. This was particularly true of those arguments which challenged the EPC itself:

> "*Well, for me, as an outsider the most frustrating thing was that we had to play this technical game on priority date and typing errors. And that the EPO did not change its mind because according to the EPC they had the full rights to patent those genes. And they actually, they told us, we can't do this – we'd have to go to the politicians and it's a political*

[530] The High Court decision in *D'Arcy v Myriad Genetics* was handed down on 7th October 2015. Myriad's Australian BRCA1 Patent AUS686004 expired in August 2015.

*thing to change the EPC. It's not the EPO. So, they made clear to us that we should not attack the EPC in Court." (*Interview 4).

The same interviewee expressed surprise that the EPO appeared to operate in a vacuum, and lacked an awareness of how diagnostics worked in practice:

"…some of the [board members] allowed us to talk off the record and, at least explore what difference places were and what different opinions were. Because they knew EPC but they had no clue on how diagnostics was being offered…And I think when we explained to them how we offered diagnostics, this was an eye opener for them as well. And, of course, by no means did the patent attorneys at Myriad ever go that way. They also quickly said 'this is ours, we've done it and we are the best'. So I think that information, the fact that even if we were not allowed to cite them about any of these cases, which is normally true at least we had that interaction to say 'this is my world, this is how I see it'."

This quote highlights how arguments about the practical implications of the invention and its impact on diagnostics are side-lined. The interviewee went on to comment about how he learned to play within the rules of the EPO:

"*So eventually I knew that, in the opposition and in the EPO when we were there I had to follow other rules that outside I could make statements. And initially I made statements that upset the EPO. I remember one early on I said that you are…they are not telling the truth. And I was just saying these shouldn't be patented and so they felt attacked. Eventually I became more neutral. Not neutral but just learnt the lesson that I should not attack within the patent office things which were not to be dealt with in the patent office.*

They didn't like the argument within the patent court case or within the room so they were not very happy when we said this is wrong and so on and so forth."

Understanding what could and could not be argued before the EPO required the intervention of patent specialists. Interviewee 5 noted that there needed to be a "good scientist, a good lawyer, and a good communicator…I decided to be the good scientist!".

7.3.1.3 Standing

Chapter 4 identified standing as a barrier which prevented nearly all of the plaintiffs in the US challenge from proceeding. The sampling approach specifically aimed to identify and interview those involved in the US challenges to analyse whether standing was perceived as significant barrier. The interview data supports the analysis in Chapter 4, and shows that standing was a concern for the challengers. Interviewee 8, who was involved in identifying and recruiting participants, talked extensively about the difficulties faced by the doctrine:

> *"We definitely knew that was going to be an issue so I was concerned about that. We thought we were only solid ground because we had the scientists who had been directly threatened by Myriad and so, you know, as long as we had those folks we felt confident in our ability to move forward with the case. I, even with the more cramped understanding of standing that the federal circuit has, I still found that other plaintiffs had standing, in particular some of the associations should clearly have had standing."*

Whilst the standing doctrine itself was difficult to overcome, the interviewee highlighted that it was more significantly problematic due to the way in which the Federal Circuit – a specialist patent court – viewed and applied the law of standing;

> *"But I also think it's another example where you can see that, in the context of patent law, the traditional legal concepts are not applied in the same way. And they should be. And so I do think organisational standing should have been recognised in our case even with the more limited understanding of who has standing. And they weren't. But we definitely anticipated it would be an issue and we deliberately crafted the litigation to have a number of plaintiffs, some of whom we were very confident would have standing and others we were less sure of." (Interview 8)*

The challengers, therefore, needed to understand and navigate how standing is specifically applied by the US Federal Circuit in patent law. As discussed in Chapter 4, it was the Federal Circuit's narrow interpretation of the standing doctrine which was nearly fatal to the US challenges.[531] Identifying plaintiffs to bring patent challenges is therefore problematised by the unexpected applications of legal doctrine. This theme of patent norms is returned to later in the chapter.

These excepts also shows that the ACLU successfully progressed through the litigation, in part, by drawing on extensive networks to facilitate overcoming the barrier of standing. Building these networks and accessing this broad range of plaintiffs took time. Although standing was not an issue in Australia or Europe, this theme of drawing on a broad network to support the challenges is echoed in these jurisdictions: Maurice Blackburn in Australia relied on a network of NGOs and public interest organisations to identify plaintiffs and the European challenges draw upon linked professional organisations, such as the European Society of Human Genetics, to bring together a diverse array of individuals. This raises the question of: what happens if the individuals or organisations who wish to challenge the patents do not have these networks? This is explored further in Chapter 8.

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[531] Section 4.3.2

7.3.2 The Expert Gap Between Law and Science

Challenging patents over biological material requires an understanding of three interlocking aspects: the science of genetics, patent law, and how the legal criteria for the grant of a patent applies to the science. This legal criteria is neither purely technical nor purely legal, but is instead a hybridisation which requires "an evaluation of the technical aspects of the claim and application of a legal threshold which must be met."[532]This research has found that navigating these layers was nearly impossible for the challengers as a result of gaps in understanding about patents, law, and science.

7.3.2.1 Lack of Patent Law Knowledge

Those interviewed had some of this knowledge but lacked in others – i.e. the scientists were experts in genetics and therefore understood the science, but rarely understood the legal aspects required to mount an effective challenge. This data revealed that many of the challengers had little to no knowledge about patent law prior to becoming involved in the challenges. In the US, this lack of legal knowledge precluded a challenge to the validity of the BRCA patent despite activism in other areas. Interviewee 9, a geneticist in the US, had previously been involved in policy attempts to change patent law as it related to isolated genes. However, there was no discussion about a legal challenge to the validity of the patent because she knew nothing about the law. Other interviewees also highlighted this lack of patent knowledge. Interviewee 4, talking about their experiences of challenging patents at the EPO, began with no knowledge about the grant and opposition of patents:

> "*So, I was like a freshman on the legal side of patenting. I knew genes could be patented somehow somewhere. But I had no clue about the legal situation at all. I had no clue that there was a European Biotech Directive and this kind of things and that there was a European patent."*

They went on to say that they believed challenging the patent would be relatively straightforward. They argued that the science would support that genes could not be patented, and that they could make strong arguments about the impact on public health. This idealism, however, was quickly quashed:

> *"I think initially I was very idealistic…. But then regularly, as we went, I learned that I somehow became more technical, more thinking in terms of patents. Not putting myself on*

532 Plomer, A. 'The EPO as patent law-maker in Europe' (2019) European Law Journal 25(1): 57 at 65.

the other side but understanding what it was all about. And knowing where these lines were, where we had to stay."

These observations reflect the initial response from ACLU lawyers. When the issue of gene patenting was initially raised, there was a reported disbelief that such patents were legal.[533] In Australia, the lawyers involved in challenging Myriad's patents also lacked the specific knowledge needed to litigate the validity of the patents, although the expertise in class actions made them more comfortable learning patent law:

"I wasn't familiar with patent law…although I wasn't put off by not knowing much about it. Although I recognise that [others] probably would be" (Interviewee 11)

Those involved in the challenges inevitably gained some knowledge about patent law, and many of the interviewees talking about their increased awareness and understanding of patents and the patentability criteria. However, the ability to effectively learn and understand patent law was limited as their role in the process was marginalised by the patent specialists who were needed to navigate the challenges. This specialist assistance was needed at all stages. To understand what could and could not be granted one interviewee reached out to their University Law department and Technology Transfer Office (TTO) to understand not only what had been granted, but the options available to challenge them.[534] Whilst these offices were not able to assist with the actual opposition they did subsequently recommend patent attorneys who were able to do so. However, once patent attorneys became involved, the Interviewee's role was marginalised to where they were "just" responsible for the science and money;

"*So we had discussions with this patent attorney, explained the case, and they accepted to go for it and then assist us. So, from then on, they were the players and I was just the one who was kind of providing data, contacting people, searching for money to pay the lawyers. And then this is how it went."*

In the US, Interviewee 9 & 10 – both geneticists involved as plaintiffs in *AMP v Myriad* - said that their roles were marginalised to being responsible for the science only, and their involvement

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533 Simoncelli, T. 'Should you be able to patent a human gene?' transcript of TEDX Talk (2017) available at <https://www.ted.com/talks/tania_simoncelli_should_you_be_able_to_patent_a_human_gene/transcript>. In this talk, Tania Simoncelli recounts approaching ACLU lawyer Chris Hansen about issues at the intersection of law and science and mentioning gene patents, to which Hansen responds "You're telling me that the US government has been issue patents on parts of the human body? That can't be right".

534 University Technology Transfer Offices (TTOs) are concerned with commercially licencing University owned IP rights to third parties, often businesses. There is, therefore, a question about whether such offices can provide appropriate levels of advice for patent challenges. This is discussed later in the chapter.

was limited to the beginning of the process. One interviewee also noted that their role as plaintiff did not allow them to attend the hearing at the Supreme Court;

> *"I wasn't really involved to a large extent. I gave a deposition to [the ACLU] but I wanted to focus on my work and so I left the legal stuff to them. I did go to the Supreme Court hearing, but I waited outside in line as a member of the public and, luckily, was one of the fifty to get in!" (Interviewee 9).*

When the cases reached the hearing stage, the role of the challengers remained limited. One participant went to correct a scientific point in the course of the EPO hearings, but was interrupted by legal points, and did not speak for the hearing as a whole:

> "*I didn't speak in the whole course of this thing. You know, I was literally about to say something. Because, on our side of the table there were some growing concerns with some angle that Myriad would take, and they didn't know how to deal with it and so I said 'well, let me have a go…I'll see what I can say' and literally I had the microphone and had opened my mouth and the judges got in before me and brought up some point. Some legal point which then took over the conversation. And then I never said anything." (Interviewee 5)*

The other challengers involved in the EPO opposition echoed similar statements that once the hearings began, their involvement was limited. This marginalisation throughout the process meant that those involved in the challenges – despite gaining some knowledge of the legal process – did not become familiar with the layers of knowledge required to challenge patents more generally. As outlined above, the scientists and researchers involved in challenging the patents in the US were only involved at the beginning of the process. Interviewee 10, a US geneticist, stated that they learned some things about US patent law but this was limited, and their focus was on explaining the science to the ACLU. In Europe, similar comments were made about learning some aspects of patent law, but still not understanding others:

> *"And this was eventually where I learned how it was dealt with and how I learnt the basics. And I think I must have read pieces of the EPC to get an idea of what was in the Biotech Directive. I'm pretty sure I had been reading the Biotech Directive to get a background on it. But I know…for specific recitals it was the patent attorneys that told me about this and this recital goes with this recital and I had no clue and there is one thing which I still don't understand it's the not the patents but the ones that are coming after them…what do you call them?"* (Interviewee 4)

This shows that, whilst some of the patent challengers did learn about the process for challenging patents, the diffusion of knowledge was limited. This was, in part, due to the side-lining of various plaintiffs once patent specialists became involved.

7.3.2.2 Clash between patents and science

Complicating this process of understanding and navigating the substantive patent law was a disconnect between the science, and how patent law is applied to that science. The scientists interviewed were all geneticists, and familiar with the science behind Myriad's BRCA patents. Many of those involved were experts in diagnostics, as well as internationally respected names in their fields. However, the application of this science to the grant of Myriad's patents did not accurately reflect their understanding of the science behind the isolation of the BRCA genes. This is perhaps best seen by the interpretation of Myriad's BRCA1 patent claim by the EPO. Recalling their attendance at the EPO hearings in Munich, Interviewee 5 expressed surprise that Myriad was unsuccessful due to minor typing errors despite it clearly being the BRCA1 gene that had been claimed:

> *"…the judges turned to him to say 'how would you like to comment?' he looked up as if surprised and said 'but it is not the gene'. What he means is, there are these seven sequence errors and the judges actually agreed with him, and the judges went back to the Myriad lawyer who actually got quite upset. You know, she was, in a scientific way right and she was upset about this rather rigid interpretation that a few sequence errors could mean that they'd got the wrong gene. There was no gene that looked like the gene with the sequence errors. The gene was BRCA1 with a few sequence errors. So she then gave another presentation and she talked for twenty minutes about how it had to be the right gene. She was correct and the judges did listen patiently, and they turned to our side of the table and asked [our representative] who had similarly been occupying himself with other things and he said 'but it is not the right gene. It is not the right sequence.' And so, this went on a little while. And indeed, twist remarkable twist of fate, I don't know how they made this error. They didn't even get the mutations that they had based the discovery on. So they came out of it with nothing." (Interviewee 5).*

The interviewee went on to say that the EPO, in adhering a literal interpretation of the EPC, failed to accurately reflect the reality that what was claimed could only be the BRCA1 gene:

> *"They were behaving very much according to a fixed formula which was 'if there's an error, if there was a difference in the sequence of the molecule and if it's a different molecule then you can't take a patent on it'. It was a rigid argument which was not strongly embedded in science as the Myriad lawyer was trying to inform them. But it was a formulation, a way of working themselves through the decisions they had to make."*

In Australia, Interviewee 7 expressed surprise that Myriad were able to mount an argument on the basis of structural and chemical differences between isolated DNA and naturally occurring DNA, which they did not believe had scientific merit;

> *"Well, the second problem we experienced which took us by surprise was the nature of the defence which Myriad ran which we thought didn't have merit but they came up with plausible arguments and plausible experts to the effect that the isolated DNA was chemically, functionally, and structurally different they said from naturally occurring DNA. We thought that was nonsense, but they had a plausible argument.." (Interviewee 7)*

There were further gaps identified between the legal professionals and scientists who brought the challenges. A theme through the interviews was that legal specialists who did not have a patent background could not understand and articulate the nuances of science to mount a successful challenge. Interviewee 1, discussing how the Australian challenges were unsuccessful prior to the High Court argued that the specialist nature of patent law meant that it could not be effectively argued by non-patent specialists;

> *"I just felt that the lawyers that were representing her…weren't actually up to the job…They're not patent lawyers. They didn't really have a grasp of the technicalities and, of course, the end result was very poor."*

The difficulty in arguing the technicalities of sciences was also noted by Interviewee 10. Interviewee 10 was a plaintiff in the US litigation and attended the Supreme Court hearing as a member of the public. They observed that the ACLU lawyers struggled to articulate the science of genetics and commented that the arguments put forward were 'muddied'. This, they commented, was particularly true concerning the arguments focused on cDNA.

This section has shown that there are significant gaps between scientists and lawyers in their understanding of genetics and law. Patent specialist involvement was a doubled edged sword. Their involvement was necessary to the success of the challenge, but also acted as a gatekeeper to knowledge about the patent claims. This role limits the ability of challenges to build up the knowledge of patent law to challenge future patents.

7.4 Institutional and Cultural Networks

The final part of this chapter discusses the finding that there were institutional and cultural networks which limited the ability of the challengers to bring gene patent challenges. This section is split into three sub-sections: barriers faced prior to the beginning of the opposition or litigation, the patent club, and outsider coalitions.

7.4.1 Pre-Challenge Barriers

7.4.1.1 Awareness of gene patents

To begin any patent challenge, the challengers first need to be aware of the patent to challenge. As such, one of the first questions asked the participants how they became aware of the BRCA patents. There were a range of ways those interviewed learned about the BRCA patents, including through conversations with professional contacts or through academic conferences:

> *"The story is that in early in 2001 it was my colleague…who gave me a call and said 'do you know that the breast cancer gene has been patented?' And my answer was double. First, I didn't know and second, I had no clue that genes could be patented." (Interviewee 4)*

> *"And so most of us came for the meeting of the American Society of Human Genetics and just before this meeting we responded to the invitation of Myriad…[they] explained that the BRCA1 and 2 genes were not patented but there was instruction at the European Patent Office and they were waiting for the decision on whether they would be granted a patent or not and they had good information they will get the patent…" (Interviewee 6)*

> *"at that farewell party [for a colleague] I was seated next to a patent lawyer. And in the course of the evening I got to talking to him about this issue of the patenting of genes and decided that I thought this was an issue that I was interested in." (Interviewee 7*

Some of the interviewees were aware of the patents through previous professional work or other academic collaborations.[535] In the US, the ACLU were aware of the BRCA patents through its in-house science advisor.[536] None of those interviewed found out about Myriad's patents by searching for them in patent databases or through patent newsletters even though, for those scientists and researchers interviewed, they were at risk of infringing the patents through their ongoing research and diagnostics.

Once those interviewed became aware of the BRCA patents, they were faced with further challenges. Finding the patent and understanding what had been granted required intervention and assistance by patent specialists. One participant noted that it took some time working with a patent attorney[537] to understand the content of what Myriad was claiming:

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535 The detail on this is left intentionally vague. Further information on this point has been redacted to protect the identity of the interviewee.

536 See Section 4.2.1.

537 In Europe, patent attorneys are those who have a degree-usually in a STEM subject-who have taken additional qualifying exams concerning patent law, but who do not usually have a law degree. Their role is to draft patents, give advice, and communicate with patent offices. Patent attorneys usually cannot argue before national courts but can-if they have qualified as a European Patent Attorney-

"What bothered us more…I grasped with [the patent attorney's help]…the idea that there was a distinction between the gene patent and the diagnostic patent. And from a diagnostics stand point, actually, most of us in laboratories were upset because there was no novelty. So for quite some time we looked at this one but then we found, together with the lawyers or attorneys, it was clear that this would be very difficult to attack…" [Interviewee 4]

Learning about the grant of the patents was not through patent databases, but through social and professional networks. Once the challengers were aware that a patent had been granted, specialist assistance was needed to decipher the content of the patent claims.

7.4.1.2 Finding Legal Advice

A second key theme which arose when discussing how the patent challenges began was the difficulty in finding legal advice to facilitate the challenges against Myriad's patents. This was broadly for two reasons. Many of the patent specialists approached to provide legal advice viewed the challenge as futile either because it was not worth the financial risk or because the ingrained practice of granting patents over isolated DNA meant that the decision was unlikely to result in substantive changes to the law. As one interviewee noted:

"I remember one of our attorneys saying 'I don't understand why for such small money you go through such a big deal. They were saying it's not even worth it." (Interviewee 4)

In the Australia context, one interviewee commented that it took a long time for Maurice Blackburn – the law firm who represented Cancer Voices and D'Arcy – to agree to take on the case. This was, in part, due to the fact that the prospect of success was "just to the side of the middle" meaning it was only marginally likely to successfully invalidate the patent (Interviewee 7).

Part of this difficulty in accessing legal advice is the relatively close-knit world of patent practice and industry. Asking a practitioner to argue against patentability may have been asking them to act against their professional interests. Most patent challenges are between two commercial

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argue before the EPO (although there are some exceptions: in the UK, for example, patent attorneys have the right to represent clients before the IPEC). Arguments before national courts require the instruction of legally qualified representatives-for example, solicitors and barriers who specialist in IP in the UK. This is similar in Australia wherein patent attorneys hold a degree or postgraduate qualification in the sciences, engineering, or mathematics and then pass additional qualifying exams to provide advice, draft and apply for patents on behalf of clients but specialist solicitors or barriers are needed to argue before the Australian Courts. In the US, there is a similar distinction albeit with slightly different nomenclature. Patent agents can gain a licence from the USPTO to advise and file patent prosecutions on behalf of clients, but cannot go to court. Patent lawyers or patent attorneys are those with a law degree and have passed the Bar who can represent clients in litigation. Some of those interviewed use the term patent lawyer or patent attorney interchangeably. This is kept verbatim in the examples, but highlighted when they refer to different professions.

entities. The rarity of public interest challenges makes it unlikely to find a patent specialist whose business solely involves challenging the validity of patents on behalf of the public. Those cases also tend to concern invalidating individual patents or infringement disputes, rather than seeking to narrow patentable subject matter. This meant that the patent specialists who were instructed were perceived as having to be quite strategic. As one interviewee at the EPO noted:

> "*even if our own patent attorneys were ready whenever we were together to think about this and say 'how shall the law be changed and what should happen' they knew what lawyers they had to play within the lines. And, of course, from their business side yeah, one day, they defend a patent, the next day they attack a patent so they need to play it right. Otherwise they have no customers anymore."* (Interviewee 4)

This awareness – that the patent specialists may be making representations which potentially went against their interests – was noted by Interviewee 11 in Australia who remarked that:

> "*We were lucky that [counsel] was already wealthy and close to retiring! He didn't care that the pharma and biotech companies would no longer instruct him.*"

In the US, the ACLU used their own in-house counsel to argue against the patent rather than instructing specialist legal advisors to argue before the courts. As such, they did not have the same difficulties as those at the EPO or in Australia. However, one Interviewee did note that accessing legal advice was likely to be tricky in the US. Seeking advice from patent attorneys (those involved in drafting and prosecuting patents) would have been unlikely to result in a recommendation to challenge the patent :

> *"If anyone went to seek legal advice on this they would likely go to a patent lawyer who would tell them that these patents were fine…You know, those folks would not have advised anybody to challenge those patents."* (Interview 8)

Part of the difficulty in finding legal advice was that the patent specialists took a view of the law which aligned with patent holder interests.

The ACLU using their own in-house counsel was, however, beset with its own difficulties. Learning patent law took time – several years, in fact, whilst Myriad's patent remained valid and enforced. This learning process was complicated further by, as one interviewee observed, the belief that patent law was different and 'special' compared to other areas of law, and therefore applied legal rules and principles differently. This is explored further below.

7.4.2 The Patent Club

There is further evidence of the insular nature of the patent profession throughout the interviews. This insular nature left many of the challengers with a belief that they were 'outsiders' to the system: In Europe, one interviewee commented that:

> *"Well, for me, as an outsider the most frustrating thing was that we had to play this technical game on priority date and typing errors."* (Interviewee 4)

This language of being an 'outsider' to the patent system can also be seen in the interviews in Australia:

> *"Taking the case on had challenges as an outsider to the patent system Although I am used to dealing with cases in areas of law I'm not familiar with." (Interviewee 11)*

This 'outsider' status is compounded further by hostility to the groups who attempted to invalidate Myriad's patents. Interview 8 commented that they gave a presentation about their validity arguments to a meeting of the US Patent Bar which was "*met with belligerence*". In Australia, Interview 1 recalled a similar experience speaking with patent specialists;

> *"I've been thrown out of patent conferences because I came to ask a legitimate question and made a legitimate point but because it grated on the orthodox position that everyone in the room believed in which was that you could patent anything under the sun…invented by man. They were very hostile. And they still are. So there's a huge hostility to people like myself within the patent profession."*

This section discusses this insular nature in more detail and analyses where this perspective comes from.

7.4.2.1 The relationship between the Courts and PTOs

A common theme that arose from the interviews was that there was a perception of a pro-patent holder bias from the specialist patent courts. This was because the judiciary had often previously worked with pharmaceutical companies and biotechnology companies. Advocating against the pro-patent assumptions of these justice was difficult. All those interviewed who were involved in the Australian litigation were particularly concerned about Justice Bennett, who was previously a barrister for Roche and sat on the Full Federal Circuit hearing in *D'Arcy v Myriad:* Interview 1 commented that:

> *"One of those judges was Justice Bennett…who once acted for Roche. She was also the chair of the Australian Law Reform Commission when it dealt with this whole issue of gene patents. And she had a very well-known particular position…And so consequently it was no*

surprise when eventually the full court handed down its decision unanimously that five judges of the full federal court decided that it was also patentable to patent the genetic mutations for BRCA 1 and 2."

Interviewee 7, stated similar concerns about the close relationship between industry and the patent bar, nothing that it was "*particularly hard arguing in front of Judges who [have] a background in Intellectual Property because they tend to be protective of patentees and pro-patent.*" They went on to say that he understood this was largely due to the day-to-day practice of IP professionals being focused on commercial activities, or infringement proceedings. At the EPO, interviewees were surprised that they would argue to invalidate patents against those who had initially granted them. This led to a similar perception of bias. Interview 4 observed "*but it always gives you the feeling that there will be some bias because the patent office has granted the patent and now has to change its mind eventually".* The same interviewee observed that: "*the judges are not independent because they belong to the EPO. But, again, I'm not arguing against them because the examiners and the opposition and the appeal boards, they are fantastic people".*

The effect of this close-knit relationship meant that it was vital that, in the US and Australia, the cases reached the higher courts. These courts did not have the close relationships at the lower courts, and were more generalist. This meant that they did not apply patent norms as seen in earlier decisions. This section now explores the evidence of these patent norms.

7.4.2.2 Patent Norms

This struggle to reach generalist courts was, in part, due to the lack of technical understanding and the procedural barriers presented. This research found that it was also due to norms within patent law. This led to the law being applied differently in the patent context than it would have been in other areas of law (such as contract, for example). This was most clearly summarised by Interview 8, discussing how the US Federal Court applied the standing doctrine: "*But I also think it's another example where you can see that, in the context of patent law, the traditional legal concepts are not applied in the same way…and they should be."*

Interview 7, discussing learning patent law, noted that this area was arcane and full of norms and conventional wisdom, which were hard to learn externally to the system. The interviewee went on to say that one aspect of this conventional wisdom was that the specialised Courts viewed themselves as uniquely placed to protect patents from attempts to 'weaken' patent protection. This meant that the courts read patents very broadly and applied exceptions to patentability very narrowly. This assumption that patents required as broad and extensive protection as possible contribute to a particular way of thinking about patents: that is, patents

are purely economic tools, divorced from broader social and political considerations, and should be construed to protect patent holders above all else.

This particular way of thinking about patents was described by those interviewed in various ways as 'ingrained', 'faulty', 'insular', and 'isolated'. Challenging these assumptions was a barrier to successful arguments against Myriad's patents. Interviewee 7, a class action lawyer in Australia, noted that he was particularly surprised that Myriad's patents had not been challenged prior to 2015 as there was a clear informational distinction between isolated DNA and DNA found in nature. This position, however, was particularly difficult to communicate to their opponents and particularly to the specialized Federal Court in Australia. Interview 1 provided an argument for why this may have been the case; namely that the distinction between isolated DNA and naturally occurring DNA was a semantic one, which has become ingrained throughout the patent profession, and which circulated in the narrow pools of people to create a particular way of seeing patents;

"*And so this whole position developed which justified the distinction, which I thought was completely semantical that an isolated bit of DNA was not naturally occurring because it was a purified form, it was a form that did not exist in nature. And that's essentially the line that the patent offices around the world accepted as the way they could justify getting around the patentable subject matter restriction on such things as discoveries of nature. So whether it was the European patent office, the Australian patent office, the American patent office that's what they did. And so they started granting things over these materials and that really started in the 80s, but it just sort of continued on and then we go from parts of humans, to things that cause disease (such as the BRCA deficiencies) and it was very difficult to try and convince patent attorneys and lawyers that this was just not an acceptable, justified, or rational even distinction….*

So, you know when you've practiced in a particular field and you actually believe the law is the way they believe it to be and of course they become judges. It's not that they're doing anything dishonest but they bring that ingrained knowledge and that bias with them to the bench."

This 'ingrained' knowledge was disconnected from how more generalist legal professionals understood the law, as well as from how the average person would approach the issue. Interviewee 11 commented that;

> *"There is a disconnect between the law and the 'punter' in the streets perceptions about the law…[patent attorneys] told us we were wrong, and that they were never going to win. The other people we spoke with were shocked and surprised that this was the legal position in Australia."*

It was therefore essential that the challengers were able to get their case to non-patent specialist courts, namely the High Court, in Australia, and the Supreme Court in the US where the lawyers came from a variety of legal backgrounds and were not subject to the same way of thinking about patent law. Similarly, in the US, Interview 8, commented that one of the biggest difficulties they had to overcome was particularized way of thinking about the patent system, including an insular way of thinking about the patent system which favoured strengthening patent holder rights and an exclusion of social, moral, and ethical arguments against patents. This bias took place from the beginning of the challenge – finding legal advice – all the way through the litigation.

7.4.3 Outsider Coalitions

A final theme that that arose through the interviews was that successfully invalidating and narrowing Myriad's BRCA patents took coalitions of patients, scientists, lawyers and researchers to achieve:

> *"To launch a [challenge] you need to have someone who knows very well the law, and you need also a good communicator, and you need a good scientist. So I chose to be the good scientist! I worked with journalists, with lawyers and also with sociologists and scientists. I consulted many people."* (Interviewee 6)

Whilst these different individuals and organisations all had similar concerns about the BRCA patents they had not communicated with one another or joined forced to try and challenge the patents. In some circumstances, they were not aware of the other. In this sense, these individuals and groups were siloed from one another. Interviewee 8, in the US, emphasised this point stating that:

> *"You know, in some part, I think it's because these people were siloed. I also think that we don't have that strong a history in terms of patient advocacy groups working in close alignment with scientific organisations and I think there's been some critique about the scientific community and how they get – or don't get – involved in advocacy in the United States. ..There had been some efforts early on and by some very prominent people but it had not been sustained and I think part of it was because they hadn't built up that larger coalition…"*

This was similar to Australia, where there were a range of patient groups, NGOs, and professional organisations who did not communicate with one another or collaborate to prior to the challenge. There was an immense effort involved in bringing the groups together. Interviewee 12, a policy advocate, commented that they spent a long time forming alliances and

coalescing the various interests so that they were all "singing from the same hymn sheet." This was the same in Europe, where the opposition was organised by key individuals. Bringing these various groups together took a significant amount of time, resources, and networks. After the BRCA successes these coalitions largely dissipated. Some of the organisations central to bringing the challenges together ceased to exist. PubPat, a vital organisation at the head of the US challenges, is no longer active.[531] This temporary nature is one of the barriers to challenging patents going forward.

7.5 Conclusion

This chapter has presented the findings of the semi-structured interviews carried out with those involved in the challenges to Myriad's patents. The main finding of these interviews is that challenging patents on behalf of the public at large is beset by a number of barriers. These barriers include the cumulative cost of challenging patents, as well as an insular culture created by the technical nature of patents, procedural barriers, and a 'patent club'. The next chapter discusses the implication of these findings in relation to the wider literature.

Chapter 8: Opening the Insular System

8.1 Introduction

There are a number of key findings arising from the doctrinal and empirical analysis. This chapter discusses these findings and situates them within the broader literature identified throughout this thesis. Whilst there is variance across the three jurisdictions studied, this research has identified cross cutting themes and findings which are discussed here. Some of the discussion, however, does centre on barriers in one jurisdiction (for example, standing in the US). The first section discusses the barriers specific to one jurisdiction, before moving on to do discuss the broader themes and lessons learned.

The findings detailed in the previous chapter indicate that the combined effect of socio-economic, legal and institutional/cultural barriers creates an insular system which shields patent holders from public challenges. Equally, this research shows that litigation presents an opportunity to pierce through this insular patent system. This is shown by the courts willingness to reassert the public interest at the heart of the patent bargain, and the judgments of two supreme courts that the BRCA did not meet the legal requirements for an invention. Oppositions at the EPO, whilst not asserting the public interest in the way the courts did, also significantly limited the impact of the BRCA patents. These challenges can therefore play an important role representing the public in the patent system. Bringing a successful challenge required a coalition of individuals, organisations, and legal and scientific experts – all of which were willing to collaborate but had not previously been brought together to challenge patents. This chapter draws out the main lessons to be learnt from the analysis of the findings. It identifies areas to pursue to facilitate public patent challenges in the future. The analysis is split into three parts: lifting legal barriers, bridging institutional and cultural networks, and socio-economic costs.

8.2 I - Lifting Legal Barriers

This research identifies a number of legal barriers to bringing gene patent challenges. The interviews were designed to specifically probe legal barriers which had been identified in the doctrinal analysis. For example, the judicial application and interpretation of "harm" and "all the circumstances" was shown in Chapter 4 as a significant barrier to the US challenges.[538] The interviews add empirical weight to this analysis, with the US interviewees highlighting the difficulties with the unpredictable application and interpretation of the doctrine, particularly by

[538] See Section 4.2.2.

the Federal Circuit Court. The interviews identify a number of other legal barriers the challengers face, including the time limits to bringing an opposition at the EPO, and the strict application of the EPC. This chapter discusses suggestions for lifting legal barriers to facilitate public patent challenges.

8.2.1 Opposition Time Limits

The nine-month time limit for oppositions the EPO has not attracted significant attention in the literature. However, this time limit was highlighted by the European challengers as a barrier to opposing the BRCA patents. The interviews show that nine months was a tight time frame for the scientists and researchers to progress through the stages of an opposition. To oppose a patent, challengers have to: know that a patent had been granted, seek specialist patent advice, then gather the funds and resources to file the opposition. The time limit was tighter still for public interest groups as they had to spend a significant period of time coalescing various interests, resources, and funds to pursue the challenge.

The nine-month time frame rests appears to rest on the assumption that the publication of patents will be sufficient to make the public aware that a patent has been granted. The preparatory material for the Munich Diplomatic Conference for setting up the EPO in 1973 argued that a six-month period for opposition was sufficient as the public would also know about the patent as a result of the publication requirements under Article 93 EPC.[539] This research shows that publication by patent offices has little to do with how and when the public become aware of the grant of a patent. The challengers did not learn about patents through publication, but through professional networks. This research also shows that the challengers needed expert patent help to decipher what Myriad was claiming, even where they were specialists in genetics.[540] The requirement for specialist intervention adds further pressure to the 9 month time limit. Those who deal with patents on a daily basis, and are already aware of the substantive patentability criteria and exclusions to patentability, are likely to find this nine-month time limit significantly easier to manage. The time limit therefore represents a set of assumptions about who will be challenging patents that belies the fact that, procedurally under the EPC, "any person" can oppose patents.[541] In this way, it echoes Parthasarathy's argument that:

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539 Preparatory documents drawn up for the Munich Diplomatic Conference for the setting up of a European System for the Grant of Patent 1973.

540 This is explored further in Section 8.4.3.

541 Section 3.2.1.1.

> *"Our understandings of what the scope of the patent system is, what questions are relevant, who should participate and how they should do so, and what role patent systems should play in the governance of emerging science and technology are not set in stone but are shaped by politics and society."*[542]

Given the difficulties posed by the nine-month time limit, a longer time frame for submitting patent oppositions could facilitate future challenges. The nine-month time period within the EPC was reached as a compromise: a longer time period was recommended during the EPC working group discussions.[543] Extending the time limit for oppositions gives the public space to find out about the granted patent, to call on experts to establish the contours of the patent, and provides ample opportunity to prepare an opposition case properly. This benefits the public in providing an opportunity to grasp the detail of the patent and prepare well-thought-out oppositions. It would also benefit patent offices by acting as an additional layer of inspection which may provide a check against invalid patents. As one interviewee noted:

> *"So the European Patent Office has a second analysis of the patents for nothing [laughs]. You see? So I think it's a good thing."* [Interviewee 6]

Patent offices are under intense pressure with an increasing backlog of cases. It has been argued that this contributes to patents of questionable validity being granted.[544] Oppositions with sufficient time to review the material and prepare thoughtful submissions and arguments may be a helping hand to a stretched system. One criticism of this recommendation is that it may introduce uncertainty for patent holders. [545] However, this assumes that once this nine-month period has passed the patents will not be challenged for validity. As discussed in Section 3.2.1

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542 Parthasarathy *supra* n102. 193.

543 Preparatory documents drawn up for the Munich Diplomatic Conference for the setting up of a European System for the Grant of Patent 1973.

544 Jaffe, A. and Lerner, J. *Innovation and Its Discontents: How Our Broken Patent System is Endangering Innovation and Progress and What to Do About It* (Princeton University Press 2004).

545 The argument that changes can introduce uncertainty for patent holders is commonly deployed as a reason patent law cannot be reformed or interpreted differently. Section 4.4.2.2 discusses how this argument was used to fuel proposed challenged to patenting in the US. Judge Moore, in *AMP v Myriad* 689 F.3d 1303(Fed Cir 2012) held that courts should be "particularly wary of expanding the judicial exception to patentable subject matter where both settled expectations and extensive property rights are involved" (at 1343). In the UK, Lord Neuberger relied on a similar argument in *Human Genome Sciences Inc v Eli Lilly* in which Lord Neuberger relied upon a submission from the BioIndustry Association that "the requirements of clarity and certainty in this area of law are emphasised…" Kumar notes that the argument for settled expectations is particularly problematic for public interest challenges. She notes that "patent challenges are extremely expensive. After a bad patent issues, a public interest group may need to wait to make sure that the patent poses a real risk to the public welfare and would then need to find the funds to cover the high cost of litigation and find suitable plaintiffs who could survive a standing challenge. By the time such a case made it to the Federal Circuit, expectations may be settled, making it that much harder to get the patent (or class of patents) invalidated. Kumar, S. 'Standing against Bad Patents' (2017) Berkeley Technology Law Journal 32(1): 87-136.

patents granted by the EPO are a 'bundle' of national patents. As such, they remain subject to validity proceedings in national courts.[546] Lengthening the time frame for EPO opposition procedures is therefore unlikely to introduce significant further uncertainty. However, given the complex and interlinking nature of the barriers identified, lengthening the time frames in isolation to other reforms is unlikely to facilitate future patent challenges.

8.2.2 Standing

Both the doctrinal analysis of the US litigation and the interviews show that standing is a significant barrier to public interest challenges to gene patents in the US. Some US commentators have doubted the wisdom of lifting restrictions on standing as a way to facilitate further challenges.[547] The findings here do not support this assessment. Rather, this research adds support to studies which argue that the current US approach to standing requires reform to facilitate public interest challenges. Such studies recognise the importance of such litigation to balancing private and public interests in the patent system. Burstein, for example, argues that a wider approach to standing would "help to ensure that patents serve not just private interests but those of the public more broadly."[548] Kumar echoes this finding, emphasising that third party challenges are vital as a balance against private interests:

> "*Without the safeguard of third party standing, the right to litigate against agencies would generally be limited to regulated parties whose interests may run counter to the interests of the general public."*[549]

Parthasarathy also suggests that to improve the representation of the public in the patent system, a reform of standing would be beneficial. She states that: "*…given US support for public-*

546 Art. 2(2) EPC.

547 There is an argument that post-grant challenges introduced by the America Invents Act 2011 is sufficient to facilitate further challenges. However, as Kumar notes: appeals s still progress to the Federal Circuit Court, meaning that challengers would still have to overcome the limited standing doctrine. See Kumar, S. 'Standing against Bad Patents' (2017) Berkeley Technology Law Journal 32(1): 87-136.

548 Burstein, M. J. 'Rethinking Standing in Patent Challenges' (2015) 83 George Washington Law Review 83(2): 498 – 553

549 Kumar, *supra* n.547. Kumar reviews the impact of the America Invents Act 2011 which allows challenges to patents in the USPTO's Patent Trial and Appeal Board as a mechanism for public interest challenges, but notes that the appeal of PTAB decisions go to the Federal Circuit. This presents two issues. First, the semi-specialist nature of the Federal Circuit makes it susceptible for regulatory capture by interested parties and secondly, challengers have to prove standing under the Declaratory Judgment Act. Kumar argues that the current framework under the Declaratory Judgment Act is therefore "too limited to be an effective tool for fully protecting third-party rights, given that is focus is on protecting direct competitors" (at 92).

interest litigation, it might require an explicit expansion of legal-standing requirements or institutional support of public-interest cases".[550]

Removing, or lowering, the procedural requirement of standing could facilitate challenges to problematic patents to be brought by the public without the need to specify a specific injury directly traceable to the claimed patent.[551] Such facilitation would mean that organisations would similarly not have to spend significant time and money looking for the 'perfect' plaintiff to base their case around. Some critics argue that standing is necessary to ensure the court make determinations of "cases and controversies" rather than determining questions of policy.[552] However, Sunstein, in an empirical review of US Supreme Court, cases found that the proliferation of standing rules is a relatively recent phenomena, exploding in the mid-eighties following a judicial turn to restraint in decision making.[553]

Standing rules are often argued as necessary to stop a deluge of spurious lawsuits which could overload the courts and beleaguer patent holders with endless litigation.[554] There is a risk that this, in turn, could exacerbate one of the issues identified in this research. Myriad's US and Australian patents were valid for all, or nearly all, of the lifetime of the grant. However, as discussed in chapter five, Australia does not have limitations on standing in patent cases and the courts are not inundated with patent lawsuits.[555] Furthermore, the reform of standing does not necessarily mean the removal of all procedural limits. Instead, it could facilitate public interest claims.

Whilst there is therefore scope to reform standing to facilitate public interest claims, this research has shown that this alone would not be sufficient. There are wider extra-legal and socio-economic, institutional and cultural considerations which require further attention.

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550 Parthasarathy, *supra* n.102 at p.197.

551 There is some variance in the terms used between this research and the studies discussed in this section. The term 'problematic' patent is used here to mean a patent which causes public harm as a result of limited access (in the Myriad case to diagnostics and research). Kumar uses the terminology 'bad' patents. Despite the difference in terminology both this research and Kumar's studies are referring to similar issues arising with patents. Kumar refers to bad patents as being those which cause higher costs, a lack of access to goods and services, and impeded research – mirroring the issues here of problematic patents. Kumar, *supra* n.547at 101-104.

552 There is an argument that post-grant challenges introduced by the America Invents Act 2011 is sufficient to facilitate further challenges. However, as Kumar notes: appeals s still progress to the Federal Circuit Court, meaning that challengers would still have to overcome the limited standing doctrine. See Kumar, *ibid*.

553 Sunstein *supra* n.251.

554 This position is most forcefully argued by Scalia, A. 'The Doctrine of Standing as an Essential Element of the Separation of Powers' (1983) Suffolk University Law Review 17(4): 881-900.

555 Section 5.2.2. By contrast, public interest challenges are rare. "*The Cancer Voices case is unusual, not only because the limited nature of the challenge to the Myriad patent, but also because of the parties to the case."* Van Zimmeren, *et al. supra* n.12.

Standing reform alone is therefore unlikely to facilitate further public interest challenges. More wide scale changes are needed to overcome the complex, interlocking nature of the barriers identified. This chapter now moves to discuss Part II, analysing the gap between experts.

8.3 II - Bridging Institutional Cultures: The Gap Between Experts

Challenging patents over biological material requires an understanding of three interlocking aspects: the science of genetics, patent law, and how the legal criteria for the grant of a patent apply to the science. A key finding of this research is that navigating these layers of knowledge created a significant hurdle to bringing gene patent challenges. This was as a result of gaps in understanding between scientists, lawyers, and the application of patent law. This section discusses where these gaps were found, and how this finding builds on the current literature.

This research shows that there is a gap between what scientists and researchers understand as science and the scientific standards applied by patent offices. For the scientists and researchers involved in the challenges, their conception of what counts as novel or an 'invention' in science and genetics did not reflect the very low standards applied in patent law. This disconnect is evidenced through the comparative analysis discussing the dispute over whether the isolated BRCA genes were a product of nature or not. It is also shown in the discussion about the errors in the typing sequence which, despite clearly being the BRCA gene claimed, was denied patent protection. This was described as not reflective of reality.

There were further gaps identified between non-patent legal specialists and the application of patent law. A repeated theme through the interviews is that patent law is viewed as 'special' by those who practice it and therefore can take a different approach to applying legal standards. This is shown, for example, by the interviewees in the discussion of standing.[556] This meant that navigating the processes and procedures for challenging patents was difficult and, much like the scientists above, required the intervention of patent specialists.

Non-patent specialists were hampered in other ways. This research showed that the highly specialised nature of genetics and how it was applied by patent law was difficult to grasp. This led to frustration in some of the interviews that the lawyers were not able to grasp the science. The Australian legal team were described by one interviewee as 'poor' and a plaintiff in the US described the ACLU's attempt to argue about cDNA before the Supreme Court as 'muddied'.

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556 Burstein makes a similar comment arguing that: ""Patent standing" is just standing. There is no justification for treating patent standing differently from any other justiciability problem. And the application of traditional standing principles to patent challenges yields a broader concept of standing than the courts addressing the issue currently contemplate. Burstein *supra* n.548.

All of the above meant that patent specialists were essential for navigating the layers of technocratic knowledge relating to the grant of patents. This research shows that once patent specialists became involved, many of the challengers were side-lined. Scientist plaintiffs in the US were involved at the beginning of the litigation and provided witness evidence, but were then largely absent. This was similar in the EPO where one interviewee noted that, once patent attorneys were instructed, they were limited to 'just' doing the science. This has implications for future patent challenges. The involvement of patent specialists was therefore a double-edged sword: both facilitating the current challenge whilst limiting future challenges by acting as gatekeepers to the knowledge needed for future challenges.

These findings are consistent with other studies that found navigating patent practice is not possible without specialist intervention.[557] Overcoming these barriers required the formation of coalitions of outsiders to bring a successful challenge. This research therefore adds empirical weight to Drahos' argument of the need for a counter network to reclaim the social contract and act on behalf of the public interest and his argument that "the only way to counter the power of one network is with another network."[558] Drahos argues that the effectiveness of the outsider network requires them to "have the technocratic skill to confront the insider network."[559] This research adds support to this requirement. Furthermore, these findings may help explain why 'outsiders' to the patent system have such difficulty learning patent rules. This research shows that becoming familiar with patents and the legal processes for challenging their validity is not just a case of learning the technocratic rules. Rather, it requires overcoming significant differences in understanding between different groups. These differences go to fundamental aspects of the patent, such as the science claimed as Myriad's 'invention'.

8.3.1 Insular Networks

This research has shown that the culmination of the barriers identified creates an insular network. The contributing elements to this network are: the technical and specialist nature of patents putting challenges beyond the reach of the public; the highly specialised nature of the legal rules which defied normal legal practices; the complexity of the procedural steps for challenging patents; the close nature of the relationship between members of the judiciary and

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557 Maxey argues that a broad interpretation of the standing requirements would 'open the floodgates' for patent litigation. In an in-depth review arguing that the District Court erred in its interpretation of standing, Maxey argues that "If the court upholds this analysis, then it would be easy for any party to invalidate any of the USPTO's policies that allow a patent to be issued and provides the patent holder the ability to enforce exclusive rights." Maxey, J. 'A Myriad of Misunderstanding Standing' (2011) West Virginia Law Review 113: 1033-1071 at 1060.

558 Drahos, *supra* n.33 at 290.

559 *Ibid*

the patent industry; the strict application of 'technical' patent standards which was viewed as divorced from reality; and the requirement of mediation by patent specialists who have close links with industry to navigate these steps.

The cumulative effect of these barriers is the perception of an insular network which is biased toward patent holders. This network also works to shield patent holders from public interest challenges. Bringing these challenges requires overcoming formidable barriers, which individual organisations or members of the public themselves are unlikely to achieve. Overcoming this insular network required the creation of a counter network.

8.3.2 Creating A Counter Network

Recommendations to address the gap between the public and private in the patent system often argue for democratization through increased public participation in various aspects of patent regulation.[560] This research shows that another effective mechanism for redressing this gap is opposition and litigation. This does, however, require the formation of a 'counter network.'

There is evidence that, vital to a successful public interest challenge, is a coalition of diverse parties with different skills but with a similar goal of protecting the public interest in the grant of patents. The gaps in expertise and costs involved show the difficulties with a single party bringing a patent challenge. Navigating the layers of legal and extra-legal barriers identified was possible due to the range of funding, expertise, and skills brought by various groups. This coalition could be therefore be considered a form of what Drahos called the 'outsider governance network':-

> "*The future of the patent social contract depends on the formation of an outsider governance network. There are many outsiders – government departments such as health departments and environment departments, competition law authorities, civil society organizations, technology movements interested in patent-free innovation…science researchers who still subscribe to public-good values, university administrators…companies on the receiving end of patent bullying and litigation, indigenous groups fighting biopiracy,*

[560] Parthasarathy recommends increasing the public involvement to challenge the presumption inherent in the US and European patent systems that favours scientific knowledge to the exclusion of other knowledge that may be relevant to create a system of innovation that maximise social benefit. See Parthasarathy *Patent Politics*, *supra,* n.102 at 199-200. Sideri argues in favour of a reconceptualising neutral regulators at the EPO to regulators who are "practically wise". This would mean they would be empowered to take into consideration a variety of different perspectives including those from the public through increased links to public bioethics committees. She argues that, vitally, this needs to take place in a forum where judgments have not yet been formed to create an "ongoing social dialogue concerning how we understand the relationship between us and the society in which we want to live" (p177) see Sideri 'Bioproperty, Biomedicine, and Deliberative Governance: Patents as Discourse on Life' (2014)

farmer groups opposed to patent locks on seed varieties, and many others. There are many more outsiders than insider beneficiaries of the patent system." [561]

Though this research concurs with Drahos' argument of the importance of such counter networks to upholding the public interest, it finds that there are significant difficulties in their formation and maintenance. Building these coalitions required bringing together a diverse array of stakeholders to overcome the barriers identified. This took a significant amount of time and resources. The various 'outsiders' to the patent system were siloed and needed operationalizing to pursue the challenges.

The siloed effect of the various organisations was highlighted most explicitly in the US interviews. All of the plaintiffs involved in the ACLU case had been attempting to raise awareness about the effects of the BRCA patents but had limited interaction with each other despite having similar concerns over Myriad's private ownership of the genes. Breaking these organisations out of their silos required both building trust in the ACLU that they would be successful and breaking down communication barriers. It also required a level of financial shielding. In providing financial support, the ACLU gave a level of protection against fees which would bankrupt their organisations. The Australian example provides a contrast to this position: interested plaintiffs did not become involved due to the personal financial risk involved.

One solution would be to replicate the work of organisations such as the ACLU, through for example a funded NGO, as an entity aimed directly at patent advocacy. One of the difficulties with this suggestion is that there have already been dedicated organisations with this goal. PubPat , for example, is a non-profit organisation set up to "represent the public's interest against undeserved patents and unsound patent policy."[562] The aim of the organisation is to encourage vigorous debate in the patent system and increase public scrutiny. PubPat was actively involved in challenging high profile patents and its model of education and advocacy surrounding patents was commended by Rimmer as:

"*as a novel institution in the patent framework…such a model can play a productive role in challenging the validity of high-profile patents; working as amicus curiae in significant court cases; and also promoting patent law reform*. "[563]

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561 Drahos, *supra* n.33 at 291.

562 See 'About Us' - http://www.pubpat.org/

563 Rimmer, M. 'Patent Busting: The Public Patent Foundation, Gene Patents and the Seed Wars' in Lawson, C. and Sanderson, J. 'The Intellectual Property and Food Project' (2014) Routledge: London.

Rimmer suggests that such an organisation should be emulated in other areas of IP, including trademarks and copyright. However, PubPat faced similar issues to those identified in this research. The organisation were denied standing when challenging stem cell patents[564] and are now largely dormant.[565]

Lessons could be learned from other areas of IP where there have been successful attempts to create 'counter' networks to challenge private rights which cause social harms. The open source software, movement, for example has successfully organised to advocate for open access to software codes that should be free to modify, copy, or redistribute as they please. The Open Source Initiative (OSI) for example, have successfully created a centralised international organisation lobbying for broad licences over software to be open source.[566] With regards to patents, Medicins Sans Frontieres and other NGOs worked with intergovernmental organisations to highlight the problem of patents over medicines and lobby on behalf of AIDS sufferers to ensure antiretroviral medication was affordably available to those most impacted by the virus.[567] Comparative research with the other areas identified may provide insights into how such organisations are formed and maintained.

This chapter now moves to discuss Part III of the findings and analyse the socio-economic barriers identified in this research.

8.4 III – Socio-Economic costs

8.4.1 Make Legal Aid Available for Patent Challenges

This research shows that there are socio-economic limitations to bringing gene patent challenges. These pose a significant barrier to opposition and litigation. Most of the interviews identified the cost of the challenges and access to funds as one of the biggest issues they faced. This supports Drahos argument that "few can afford the costly battlegrounds of courts."[568]

However, the issue of cost in bringing patent claims is a dense and complex issue and this research has shown that it has deeper implications than just affordability. The high cost of patent litigation and opposition prevents patients, certain charities, and advocacy organisations from becoming involved in challenges. Not only does this preclude interested parties from

564 *Consumer Watchdog v Wisconsin Alumni Research Foundation* 753 F.3d 1258 (2014).

565 PubPat's website has not been updated since 2015 & Interviewee 8 observed that they believed the organisation were no longer active due to a lack of funds.

566 See https://opensource.org/history

567 T'Hoen, E. 'TRIPS, pharmaceutical patents, and access to essential medicines: a long way from Seattle to Doha.' (2002) Chicago Journal of International Law 3(1): 27-47.

568 Drahos, The Global Governance of Knowledge, *supra n.33* at 291.

challenging patents but can also narrow the pool of potential financial contributors and the available plaintiffs. Relying on work done pro-bono does not necessarily alleviate these concerns. Whilst work done using people's good will or pro bono facilitated the Myriad challenges, they also introduced an additional layer of precarity to bringing patent challenges. As several of the interviewees noted: the goodwill could have run out at any time.

Some of the literature recognises the cost of litigation is poses a limitation to public interest challenges. The ability for public interest groups to challenge patents due to the excessive costs was noted in the ALRC report *Genes and Ingenuity* and was emphasised as particularly relevant because of the nature of genetic research*:*

> *"The high cost of litigation, and its impact on access to justice, is a recurrent concern in civil proceedings. However, the issue has special importance in challenging or enforcing gene patents because of the significant role of universities and not-for-profit organisations in genetic research in Australia."*[569]

The ALRC's recommendation to remedy the issue of cost is to "that courts

exercising jurisdiction under the Patents Act should continue to develop their practices

and procedures for dealing with patent matters in order to promote the just, efficient and cost-effective resolution of patent disputes."[570] The recommendation of low cost procedures for patent disputes was also recommended by Drahos as a way of enabling a counter network of outsiders to scrutinise patents.[571] Low cost procedures may be beneficial, however it is not clear in the research how much mechanisms will operate. This research highlights that some groups are limited to becoming involved in patent challenges as a result of their charters. It therefore remains to be seen what form such low cost mechanisms can take to overcome this limitation. Legal aid may be an alternative option.

The legal challenge in Australia was successful, in part, as a result of an award of funds to law firm Maurice Blackburn by the Commonwealth Government. This award was particularly important to facilitate reaching the Australian High Court, which this research shows was vital to the success of the challenges. Legal aid is rarely available in Australia but was granted in this instance due to the public importance arising from the grant of gene patents. A similar system

569 ALRC, *Genes and Ingenuity, supra* n.339 at 18.

570 *Ibid.*

571 Drahos, The Global Governance of Knowledge *supra* n.33 at 292.

could be employed in the US or in other jurisdictions, and be made available for challenges at the EPO.[572]

A key question to answer is: how does this get funded? Governments are unlikely to provide public money to fund patent litigation in national courts. As Drahos notes, patents do not determine elections and consequently political representatives are unlikely to be incentivised to make fund available.[573] However, funds could be provided through fines or levies on patent holders whose patents or licencing practices are subsequently found to be invalid and causing social harm. A panel of members of the public including NGO representatives, scientists, researchers, and patients could determine what patents were mostly significantly undermining the social contract and determine where funds could be allocated.[574]

This research has found that legal aid – whilst not sufficient to overcome all the barriers identified here – is a useful mechanism for facilitating public patent challenges. This chapter now moves on to discuss the implications of another key barrier identified: the lack of accessible patent information.

8.4.2 Facilitating Public Access To Patents

The first step to challenging a patent is to become aware that one has been granted. Individuals or organisations have to know that a patent has been granted, be able to find that patent claim, and then be able to understand the scientific and legal terms contained within the patent application. The theoretical framing and the interview data identified barriers at all stages of accessing this patent information. At each stage, patent specialists were needed to assist in locating and deciphering the claims in Myriad's applications. The lack of accessible patent grant information has been studied, with a particular focus on the way patent claims are drafted.[575] This section discusses ways in which public access to patents can be facilitated.

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572 It is worth noting that the proposed Agreement on a Unified Patent Court (UPC) puts forward provisions for legal aid to facilitate patent challenges and ensure access to justice. Article 71(1) states that "A party who is a natural person and who is unable to meet the costs of the proceedings, either wholly or in part, may at any time apply for legal aid." Rule 375(1) of the UPC Draft Rules of Procedure holds that the aim of providing legal aid is to "ensure effective access to justice."

573 See Drahos, *Global Governance of Knowledge, supra* at n. 33at 289.

574 This would mirror the approach of PubPat in determining where best to challenge patents: "The Public Patent Foundation carefully selects the patents that it is challenging. According to *Science*, Ravicher 'supervises a handful of volunteer scientists, occasional grad students, and legal interns as they search for potential flaws in big-name patents'. He particularly targets the patents that he believes 'are causing the most harm' see Rimmer, Patent Busting, *supra* at 563.

575 Freilich, *supra* n.69

8.4.3 Patent Databases

This research found that both establishing what patents covered the BRCA gene and deciphering those patents was a hurdle to beginning the challenges. Patent attorneys or patent search specialists were needed to find the Myriad patents and details of the claims in fee-paying patent databases. One necessary step to overcome this hurdle is to optimize free, public patent databases such as ESPACENET or WIPO's Patentscope. To make accessing patent information easier for the public there needs to be easily searchable and up-to date databases. This should be designed in collaboration with a diverse cohort of members of the public including scientists, researchers, NGOS, professional organisations, and lay people to determine the most appropriate and useful form optimisation should take. There seems to be the capability for search engines and online systems to be optimised for patent searches, and for these systems to have the capacity for alerts to manage the flow of information coming from the patent system. As Drahos states: "the algorithms that run Google and Wikipedia would seem to suggest that we can achieve global levels of transparency for patent and invention information".[576]

Whilst optimising databases is undoubtedly important to facilitating public access to information[577], this research found that the challengers did not learn about patents through such databases. A more important issue is making the information within the patent more readable. The interview findings highlighted that those involved in the challenges needed specialist patent support to decipher the information contained within the patents, even where those reading the patents were scientists and geneticists themselves.

8.4.4 Making patent claims readable

Patent claims are written to demarcate the boundaries of a claimed invention. Such claims are often written in dense legal jargon commonly referred to as 'patentese'.[578] These claims serve a dual purpose: they are both a technical document, outlining the details of the invention claimed for disclosure purposes, and a legal document, detailing the contours and boundaries of legal

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576 Drahos, *Global Governance of Knowledge, supra* n.33 at 301.

577 There are attempts to index and improve patent search engine optimisation. Drahos identifies The Lens as one such attempt. (Drahos, *ibid* at 302) The Lens is a free Australian based online patent search facility, providing a comprehensive picture of patents granted by the EPO, USPTO, AusPTO. However, The Lens has incomplete data and aims to collate "95% of the worlds patent information in the next two years". A more effective system would be to induce the organisations with access to the complete and raw patent data to develop these systems. This would mean finding a way to encourage (or force) patent offices to develop effective search systems to benefit the public more generally and not just its own users. See The Lens, <https://www.lens.org/lens/bio/patseqdata#/globe/> (last accessed 08/08/21).

578 Rakoff, J. 'Down with Patentese' (2011) Fordham Intellectual Property Media and Entertainment Law Journal 21: 839.

protection. However, such obfuscatory language can make patents difficult to read for specialists in the subject matter claimed in the invention, and almost impenetrable for members of the public to read. To facilitate public access to patent information there needs to be a readable, accessible format of patent claims.

One potential recommendation is to build on Fromer's 'layered' suggestion for improving the disclosure function in patents.[579] Fromer argues that patents have two layers, with two distinct audiences: the legal layer (aimed at defining the legal boundaries of the claim) and the technical layer (aimed at communicating the invention to a technical expert). She theorises that disclosure failure stems from an entanglement of these layers, muddying each perspective: lawyers may struggle to understand the contours of protection claimed through the technical language of the subject matter claimed and technical specialists may fail to see adequate disclosure as a result of the 'patentese' deployed. To remedy this, patent claims could be written in two layers and marked so as to address and direct the distinct audiences to the most appropriate information. The findings of this research suggest that there could be an additional 'lay' layer to the patents. This 'lay' layer could be directed at providing key information for members of the public. This would not remove any technical or legal information but could be constructed in a similar manner to an executive summary. This would strip back the dense and complex information without removing the legal and technical detail required for patent protection. Information contained within this summary could include details such as a jargon free description of the claim, along with the anticipated applications of the invention, the names of the inventors, and disclosures of any public funding. Further empirical studies exploring this could help determine whether such an approach would be a viable option to increasing access to patent information.

A 'lay' layer does not necessarily solve the issue of overcoming the substantive barriers, discussed in this chapter. However, it may go some way to clarifying the information contained within patent claims making them easier to locate and easier to read. Members of the public would be able scan an outline to see whether it may or may not be problematic (rather than having to seek specialist advise simply to understand what is being claimed). Forcing inventors and patent attorneys to clearly spell out the claimed invention and intended uses may also lead to clearer patent claims. Simplifying legal jargon to make it more publicly accessible is not new: there have been attempts to strip back legal jargon and make the law more understandable to the public in various aspects of UK law.[580] There is no reason why patent laws should not also

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579 Fromer, J.C. 'Patent Disclosure' (2009) Iowa Law Review 94(2): 539-606.

580 The Office of Parliamentary Counsel, for example, works with the UK government to ensure clarity and public accessibility to UK law.

attempt to achieve this standard. As one interviewee pointed out: "patent law likes to think it's special and should be treated differently. But there is really no reason why it should."

8.5 Conclusions

The comparative analysis of the Myriad challenges in Chapters 3 -5 shows that litigation and opposition does provide an opportunity to reassert the public interest in the patent bargain. The successful narrowing of Myriad's European patents at the EPO, and the invalidation of the Australia and US patents were driven by the public interest. The reasoning of the US Supreme Court and Australian High Court specifically drew upon the patent bargain, emphasising the need for balance between the public interest and the private rights granted to patent holders. However, the litigation had to reach the highest appellate courts to reaffirm this public interest. Challengers were faced with a variety of barriers to doing so including: narrow interpretations of the doctrine of standing,[581] short time limits for opposition,[582] and the judicial interpretation of patentability standards to favour patent holders.[583]

This chapter builds on the doctrinal research to show that the challengers have to overcome formidable barriers to bringing patent challenges including; socio-economic, legal, and institutional/cultural barriers. These barriers create an insular network, shielding patent holders from patent challenges. This network can only be overcome by a counter network of outsiders. However, this research shows that building this counter network is faced with difficulties. Those networks which coalesced around the Myriad challenges have now largely dispersed.

8.5.1 The Public as the Ultimate Outsider

This research suggests that the ultimate 'outsiders' to the patent system is the public. The interviews suggest that there is a disconnect between public understanding of patents and how the patent system works in practice. Interviewee 11 observed that there was a disconnect between how the 'punter' in the street understood patents and their function in practice. This echoes the public outrage at the grant of patents over the isolated BRCA patents. This research has shown that members of the public sit outside the social and professional networks of the 'outsiders' interviewed here. The purposive sampling approach, for example, used in this research did not reach the BRCA patients. It is also hard to see how a member of the public, without access to the networks identified here, would be able to overcome the variety of

581 See Section 4.3.

582 See Section 3.2.1.

583 See Sections 3.3 and 5.4.1.

barriers identified. The role of public interest groups is therefore of fundamental importance to protecting the public interest.

Chapter 9: Conclusion

"We, all of us, share a duty to ensure that the common property of the human genome is used freely for the common good of the whole human race."[584]

9.1 Introduction: Answering the Research Question

This thesis asks: what are the barriers faced by the public in seeking to challenge the validity of gene patents standing in the way of public access to diagnosis and treatment? It concludes that there are a number of legal and extra legal barriers, and that these constitute a formidable obstacle to overcome to bring a successful challenge to the validity of a patent.

In answering this question, this thesis utilises a hybrid method, combining comparative doctrinal legal analysis with an empirical investigation. The comparative doctrinal analysis focuses on the litigation relating to Myriad's BRCA patents as a case study to identify whether aspects of patent law present specific obstacles to public interest challenges. This litigation was chosen as it provides a rare opportunity to investigate the obstacles faced by challengers in different jurisdictions. It also facilitates an analysis of how the obstacles were ultimately overcome through the invalidation of the patents by the US Supreme Court and Australian High Court, and the narrowing of patents at the EPO. The empirical investigation interviewed individuals who were involved in the challenges to the BRCA patents to gain a deeper understanding of the wider, extra-legal spectrum of obstacles. The overall approach to the doctrinal and empirical arms of the study was theoretically informed by the socio-legal perspective articulated by Drahos in the research he conducted on patent offices and their clients. This study draws upon and describes several key concepts of his research, including: the social contract, the insider/outsider network, and counter cultures and networks. The discussion of the legal and extra-legal factors standing in the way of public challenges to patents detailed in this study reveal the explanatory and normative force of these concepts.

This concluding chapter summarises the key findings of this research, followed by implications for future patent challenges. This chapter then identifies areas for further research.

584 New York Times, 'Text of the White House Statements on the Human Genome Project' (2000) available at <https://archive.nytimes.com/www.nytimes.com/library/national/science/062700sci-genome-text.html > last accessed 18/07/21.

9.2 Summary of Findings

Chapter One introduced the research, setting out the social and political background to the Myriad litigation. It situated the thesis in the wider literature, and identified the gap this research aimed to fill, namely by carrying out a systematic review of the barriers faced by the public when challenging the BRCA gene patents. This chapter then discussed how the hybrid methodology would be used to address the research question: what are the barriers faced by the public in seeking to challenge the validity of gene patents standing in the way of public access to diagnosis and treatment? The socio-legal approach to the research was also set out.

Chapter Two reviewed the main justifications of the monopolies granted to patent holders, focusing on judicially endorsed claims that patent law represents a social contract or bargain between the patent holder and the public. The discussion showed that key elements of the so-called social contract are tilted in the favour of the patent holder. This includes, for instance, the concept of 'disclosure' and the idea that courts are engaged in a balancing of private and public interests in the interpretation of the patentability criteria. The chapter illustrates the gap between the mainstream 'social contract' narrative and the reality of the hedging of patent law in favour of patent holders. It concluded with Drahos' critique and reformulation of the idea of patent law as a social contract to redress the balance between patent holders and the public. This theoretical framework was used to illuminate the doctrinal analysis of patent law (chapters three – five) and the key findings emerging from the interviews (chapters six and seven).

Chapter Three examined the opposition to Myriad's European BRCA patents, focusing on the opposition procedure and the EPO's interpretation of the patentability criteria and its exceptions. This discussion showed that, whilst 'any person' can oppose a European patent, there is significantly limited scope to argue against the validity of a patent on public interest grounds. This chapter demonstrates that this limited scope stems from the absence of a definition of invention, leaving challengers to argue that the BRCA patents fell within explicitly recognised exceptions. These exceptions are interpreted and applied narrowly, leaving no space to successfully argue the access concerns which drove the challenges. The chapter illustrated the gap between the socio-economic concerns which drove the challenge and the technical patentability grounds upon which Myriad's patents were ultimately narrowed. It concluded by demonstrating this gap through an analysis of the TBA's decision which held that the access arguments were related to patenting generally, as opposed to the question of validity. This analysis showed that the decisions side-line access concerns, and discussed implications for future public interest challenges.

Chapter Four examined the litigation against Myriad's US patents, focusing on the judicial application of standing and the court's interpretation of the patentability criteria. It began with an analysis of the standing doctrine, and showed that this presented a significant limitation to public challenges. A narrow consideration of 'harm', for example, was shown to be almost fatal to the ACLU challenge by excluding plaintiffs whose injury arose from a lack of access to diagnostics or research. The analysis of the interpretation of the patentability criteria showed that reaching the Supreme Court was essential to the success of the challenge. The Court's application of the product of nature exception facilitated a reassertion of the public interest in granting patents, which was absent from the lower courts. However, the chapter highlighted that the socio-economic concerns argued by the ACLU were largely missing from the reasoning of the decision. The chapter concluded by discussing contemporary challenges to the product of nature doctrine, highlighting the fragile nature of the judicially created exceptions.

Chapter Five analysed the litigation against the Australian BRCA patents, focussing on the judicial interpretation of the statutory definition of an invention. The chapter showed that the retention of this definition facilitated a judicial consideration of the balance between patent holders and the public interest. The flexibility specifically gave challengers scope to argue that controversial patents did not meet the eligibility criteria, and contrasted this position with that in Europe and the US. The analysis of the Australian Myriad litigation showed that, whilst the definition gives courts scope to consider a range of socio-economic arguments about the grant of patents, only the High Court engaged with these issues. This echoes the finding in Chapter Four that reaching the highest courts was essential to the success of the challenge. The chapter concluded by highlighting the enduring difficulties in finding the balance between private and public interests by showing that Australian courts have been reluctant to engage with the tests laid down by the High Court in *D'Arcy v Myriad*. This analysis showed the difficulties in relying on legislative guidance and judicial discretion to secure an appropriate balance between private interests and public interests in patent law.

Chapters Three to Five identified the difficulties faced by public challengers stemming from the interpretation of what constitutions an invention and the exceptions to patentability, as defined in statutes and treaties. These chapters also show that there are difficulties posed as a result of the judicial interpretation of the procedural rules which govern these challenges. This includes, for example, the interpretation of standing. The empirical investigation builds on the findings in the comparative chapters to gain a deeper understanding of the barriers faced when challenging patents. Chapter Six discussed the empirical methodology, including: the use of semi-structured interviews, the use and limitations of purposive sampling, the design of the interviews, the

ethical considerations which underpin this research, and the approach to the analysis of the interview data gathered. The limitations of this research were also discussed.

Chapter Seven discussed the key findings arising from the semi-structured interviews. The analysis of the interviews showed that successfully litigating a challenge to the highest courts meant that challengers will encounter formidable barriers. This is as a result of a number of legal and extra-legal barriers. First, this chapter showed that the cumulative cost of challenges places the opposition and litigation out of reach for many members of the public and organisations. The professional risks to becoming involved in challenges limited this involvement further. Secondly, this chapter showed that the legal rules were interpreted and applied to favour patent holders. The interpretation of the procedural processes worked against the challengers and the socio-economic access arguments which drove the challenges. The judicial application of standing and the limited scope to argue access concerns and the 'real life' impact on diagnostics were examples of this. Thirdly, the chapter showed that specialist hybrid nature of patents put understanding patents and arguing against their validity out of reach of the challengers. Challengers were unable to navigate the specialist nature of patents without assistance from a patent expert. This limited the ability to gain knowledge about patent law for future challenges.

Chapter Eight focussed on the implications of the interview findings and discussed recommendations to facilitate public interest challenges. This chapter shows that reforms such as improving the accessibility of patent information and providing legal aid would go some way to facilitate public interest challenges but are, by themselves, not enough. This chapter also showed that other recommendations for reform – such as the suggestions to reform standing – are also insufficient to increase public interest challenges. This chapter also showed that the barriers identified creates an insular system in which patent holders are shielded from public interest challenges. Successfully navigating the myriad barriers presented by costs, resources, legal, and institutional factors required the formation of an outsider network. This analysis shows that this outsider network took an extensive amount of time, effort, and resource to form. This chapter concludes by discussing the fragility of such outsider networks by showing that the successful coalition for the Myriad challenges have now largely dispersed. Chapter nine summarises and concludes this research.

This thesis makes a significant and original contribution to knowledge surrounding patent challenges and the social contract. It does so by, for the first time, systematically interrogating the barriers faced by public interest challenges to patents. This is also the first empirical analysis of these barriers. This research is original in its use of a theoretically informed, mixed doctrinal and empirical study. This comparative, socio-legal lens has revealed how the

application and interpretation of legal rules is tilted to favour the patent holder. This research also shows that there is significant divergence in the judicial application of these legal rules. Furthermore, this research highlights a number of extra-legal institutional, and cultural rules standing in the way of public interest challenges to the validity of controversial patents. The cumulative effect of this has implications for the social contract and future patent challenges, which is explored next.

9.3 Implications for the Social Contract

Chapter two showed that there is a gap between the commonly cited social contract and patent systems which are tilted to favour patent holders, obfuscating the public interest. This research has analysed whether public interest challenges to patents present an opportunity to redress this balance. It concludes that they can. The analysis of the Myriad challenges shows that litigation presents an opportunity to reassert the public interest at the heart of the social contract and pierce through the insular patent system. This research has found that the highest appellate courts are willing to reassert the public interest in making determinations of patent validity. Notwithstanding the lack of reliance on the access issues which drove the concerns. patent oppositions at the EPO can also present an opportunity to redress the balance. The challengers were successful in significantly narrowing Myriad's European BRCA patents and lessening the impact on access to diagnostics and research.

However, pursuing these cases is obstructed by the formidable barriers identified in this thesis. Whilst the judiciary asserted the public interest in its reasoning, this research shows that there are contemporary challenges which might limit the impact of these decisions. This is shown, for example, through the lack of judicial engagement with the public policy dimensions of the Australian High Court's decision in Myriad[585] and the legislative attempts to restrict judicially recognised exceptions to patentability in the US.[586] Whilst litigation can present a solution to enforcing the public interest in patents, this research finds that there are limitations.

Drahos argues that, to reclaim the social contract, a coalition of outsiders is required;

> "*What is needed to counter the power of one network is with another network. The outsider network needs to have the technocratic skill to confront the insider network. Confrontation has to be constant and detailed*."[587]

585 See Section 5.4.3.

586 See Section 4.4.2.2.

587 Drahos, *Global Governance of Knowledge*, *supra* n.114 at 290.

This research adds empirical weight to the need for a powerful counter network: the challenges to Myriad's patents were only successful as a result of the networks of scientist, researchers, patients, NGOs, and legal professionals which were formed. This research, however, has identified difficulties with the formation and maintenance of such a network. This includes the lack of technocratic knowledge required to navigate patents laws, and the dissipation of the networks which coalesced for the challenges to Myriad's patents.

The dissipation of these networks may not be seen as problematic: the acute concerns about access as they relate to gene patents may have passed.[588] However, there remain concerns that the 'tilt' toward the patent holder is causing harm to the public interest in other areas. The patenting of the coronavirus vaccine raises similar concerns about the appropriate balance between private rights and the public interest discussed in this research. Whilst there have been attempts to ensure an equitable distribution of patented coronavirus vaccines, there remain significant inequalities in vaccine access.[589] Attempts to remedy this gap have yet to be successful.[590] Developments in the field of genome editing also pose questions about patient and researcher access to transformative technologies. CRISPR – a gene editing technology – has the potential to cure chronic illness and eradicate hereditary disease.[591] The grant of patents over such a transformative technology has sparked concern about the potential block to ongoing research.[592] Furthermore, there are concerns that the high cost of gene editing, maintained in part by patents, puts access out of reach of many patients and can negatively impact public

588 Liddicoat, J. *et al.* 'Are the gene-patent storm clouds dissipating?' *supra* n.516.

589 For a discussion of the vaccine inequality and the IP issues involved see Parthasarathy, S. 'Policy Memo: Ensuring Global Access to Covid-19 Vaccines' Gerald Ford School of Government Policy Memo. One proposed remedy to these issues is a temporary waiver on patent rights, see Thambisetty, S. *et al.* 'The TRIPS Intellectual Property Waiver Proposal: Creating the Right Incentives in Patent Law and Politics to end the COVID-19 Pandemic' (2021) LSE Legal Studies Working Paper No. 06/21 although this approach has been criticised as being failing to address other issues causing vaccine inequality, such as limits on manufacturing capabilities, see Reddy, P. and Pai, Y. 'What's the point of continuing a discussion on the unworkable TRIPS Covid-19 Waiver proposal?' (2021) IPKat Blog available at <https://ipkitten.blogspot.com/2021/07/whats-point-of-continuing-discussion-on.html> last accessed 03.8.21.

590 COVAX, for example, is a multilateral agreement intended to ensure that the developing countries were able to access vaccines for 20% of its population. However, the programme has been beset with difficulties, missing its vaccination targets. See Mueller, B and Robbins, R. 'Where A Vast Global Vaccination Programme Went Wrong' (2021) The New York Times available at <https://www.nytimes.com/2021/08/02/world/europe/covax-covid-vaccine-problems-africa.html?> last accessed 02/08/21.

591 Matthews, D. 'Access to CRISPR Genome Editing Technologies: Patents, human rights and the public interest' (2020) Queen Mary University of London Legal Studies Research Paper No.332/2020 at 1. CRISPR is an acronym for 'clustered regulatory interspaced short palindromic repeats'.

592 Matthews, *Ibid.* CRISPR technology has also been the subject of a patent dispute between the technology's creators, see Sherkow, J. 'Who owns gene editing? Patents in the Time of CRISPR' (2016) Biochemist 38: 26-29.

health.[593] These concerns mirror many of those raised in the Myriad challenges. There are developments in other fields. The Earth BioGenome Project aims to complete genomic sequencing of "everything in the world".[594] The organisation's Ethics, Legal, and Social Committee notes that attempts to patent the findings arising from the project are likely to be controversial. Issues such as bio-colonialism in the patenting of indigenous remedies and blocks to ongoing research are identified as ongoing challenges.[595] The study of public interest challenges to patents therefore remains significant. There remains scope for future litigation on behalf of the public interest. In light of these findings, this chapter now identifies areas for further research.

9.4 Looking Forward: Further Areas of Research

This research has focused on biotechnological inventions, and those who challenged gene patents in Europe, the US, and Australia. In light of the findings, this section recommends areas for further research:

9.4.1 Further comparative studies

This research has focused on biotechnological inventions and patents in the US, Australia and Europe. This means there is scope for research which seeks to understand barriers to public interest challenges involving different technologies and in different jurisdictions. Such research should include:

- Comparative research into the judicial interpretation of the social contract in other jurisdictions to gain a deeper understanding of the facilitation (or lack therefore) of public interest challenges. This could also include an analysis of patent decisions by other legal organisations;
- Comparative research on different categories of invention to analyse similarities and differences in barriers to patent challenges. This could include, for example, an analysis of whether the difficulties posed by the highly specialised nature of gene patents are comparable across other types of invention;

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593 *Ibid.* See also Sherkow, J. 'CRISPR, Patents, and the Public Health' (2017) Yale Journal of Biology and Medicine 90(4): 667-672.

594 Earth BioGenome project available at < https://www.earthbiogenome.org/?> last accessed 02/08/21.

595 Sherkow, J. S. *et al.* "Ethical, Legal, and Social Issues in the Earth BioGenome Project" Report of the Earth BioGenome Project's Ethical, Legal, and Social Issues Committee, March 2021 at 4.

- A large-scale systemic, cross cutting review analysing other jurisdictions and inventions to build on the barriers identified here and explore more deeply the global barriers to patent challenges.

9.4.2 Assessing 'lay' layers to patent claims

One of the recommendations discussed in Chapter 8[596] was the employment of a 'lay' layer to patent claims, aimed at communicating the nature of the invention to a non-patent audience. Empirical research could probe this idea further, to assess the feasibility of this approach and assess whether use of such a mechanism could facilitate disclosure of inventions to the public.

9.4.3 Empirical Research with Patients

As discussed in Chapter 6[597], one of the limits to the sampling technique used was that patient plaintiffs were not interviewed. Evidence from the sampling technique and the interviews suggests that there are interested stakeholders – in this instance, patients – who fall outside the 'outsider' networks which formed to challenge the patents. Further empirical research should be conducted to understand their experience of barriers to patent challenges.

9.4.4 Understanding counter networks

A key finding of this research is the importance of the networks of challengers to bringing a successful challenge. Given the importance of this network to upholding the social contract, there should be further research into this area to provide insights into how these networks form, are maintained, and dispersed. This will add insights into whether such outsider networks are the right approach to upholding the social contract.

9.4.5 Submissions To the Court

Rimmer notes that organisations such as PubPat can also represent the public interest by filing amicus briefs.[598] One point briefly touched upon in this research was the submission of various amicus briefs to the courts in the Myriad challenges. The US litigation received over 40 amicus briefs from a wide range of stakeholders.[599] By contrast, the High Court of Australia only received one intervention from The Institute of Patent and Trade Mark Attorneys of Australia,

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596 See Section 8.4.4.

597 See Section 6.4.1.

598 Rimmer. Patenting Busting, *supra* n.564.

599 For a list of amicus briefs submitted to the US Supreme Court in *AMP v Myriad* see SCOTUSBlog available at <https://www.scotusblog.com/case-files/cases/association-for-molecular-pathology-v-myriad-genetics-inc/> (last accessed 08/08/21).

an industry representative, which the court refused to hear.[600] There is limited research on when public interest groups file amicus briefs. For example, why did the Australia High Court attract so few submissions when the US Supreme Court attracted such a significant number? There is also scope for research to assess whether amicus submissions to the court are an effective mechanism for representing the public interest in patent cases.

9.5 Conclusion

This research has analysed whether there are barriers to bringing public interest challenges to gene patents. It has concluded that, whilst litigation presents an opportunity to assert the public interest in patents, challengers are faced with formidable barriers to doing so. This has significant implications for the social contract at the heart of the justifications for the grant of patents. Notwithstanding the dissipation of concerns surrounding gene patents, this contribution is significant in light of the current debates outlined above. This chapter has also identified further areas of research to further explore the themes identified. This shows that there remains work to be done to reclaim the social contract, and ensure the public interest is protected in the grant of patents.

600 For a list of interventions in *D'Arcy v Myriad* see High Court of Australia available at <https://www.hcourt.gov.au/cases/case_s28-2015> (last accessed 08/08/21).

Appendices

Appendix 1

Application For Ethical Approval to University of Bristol Law School Research Ethics Committee

Law School

Application for Ethical Approval by the Research Ethics Committee

You need to complete this form only if your research involves human participants (this is likely to be the case if you are using any of the following methods interviewing, observation, questionnaires, study of case files relating to individuals). Any such research requires University research ethics approval, which may be granted at the School, Faculty or University level.

Your application will be considered in the first instance by the Law School's Research Ethics Committee (LREC). It aims to provide you with a response within 10 working days. In some cases your application may be referred by the LREC to the Faculty of Social Sciences and Law Research Ethics Committee (FREC).

Please consider the guidance in the 'General Considerations' section (Section 4) in relation to the research that you are proposing to do. Once you have considered the ethical implications of your proposed study, please complete the 'Specific Considerations' section (Section 5).

Not all sections of this form will necessarily apply to your research. Where you consider this to be the case please indicate with 'not applicable'. Elsewhere, the length of your answers should be determined primarily by the potential of your research to pose risks or cause harm to participants (including yourself and, if applicable, your research team) over and above those involved in everyday life. You should reflect carefully on the ethical issues raised by your research; one-word answers to the questions in the 'specific considerations' section will rarely be adequate.

Applications should be made at a point where research plans are reasonably settled, but amendments to approved applications can be submitted to the LREC Chair for consideration.

Research students must discuss their applications with their supervisors before submitting them to the LREC. All student applications must be submitted to the LREC via a student's primary supervisor who must electronically 'sign' the form (Section 6).

In the case of research teams, this form should ideally be completed by the principal investigator. If this is not the case, the completed form should be signed off and submitted by the PI (Section 6).

Please refer to the Guidance document **Completing the Application for Ethical Approval by Research Ethics Committee**, which contains detailed notes about filling in each section of the form, provides advice about legal and ethical issues, and outlines the type of information and degree of detail that the Law School Research Ethics Committee requires to provide guidance and make a decision on your application. You can find this, and other relevant documentation, on Blackboard.

The completed form should be sent electronically to the LREC Chair, Dr Athanasios Psygkas <a.psygkas@bristol.ac.uk>.

Please note that for certain projects (e.g. international research projects) it is essential that you complete the RED registration checklist at:

http://www.bristol.ac.uk/red/research-governance/registration-sponsorship/study-notification.html

Failure to do so will leave you without recourse to the University's insurance coverage for research activities. It is your responsibility to check whether your research requires RED registration.

Research Ethics Application Form

Section 1: Applicant and Project Details (All applicants)

Name(s)	Louise Hatherall
Email address(s)	Louise.hatherall@bristol.ac.uk
Degree Course or Post(s) Held	PhD (Law)
Title of Research Project	Public Interest Challenges to Gene Patents: An analysis of the legal obstacles faced by NGOs and Public Interest Groups
Description of proposed empirical research, indicating: i) why that research requires prior approval by the Law School Research Ethics Committee. ii) why it is necessary to undertake the research in question. iii) Your assessment of any cost/risk to research participants	The proposed empirical research relates to my PhD thesis concerning the engagement of NGOs and public interest groups with the patent system. This research is concerned with understanding the legal obstacles encountered by public interest groups when challenging gene patents. It is specifically interested in genetic patents, as these raise broad and wide-ranging public interest issues such as access for patients to diagnostic tests and treatments. The review of the scholarly literature in the field reveals that NGOs legal challenge to patents is pertinent to the regulation and protection of gene patents (see, for example *AMP v Myriad*, *PubPat v Warf*) but, NGOs face multiple legal obstacles, for instance they need to show that they have standing to sue. The challenges faced by NGOs are understudied, both from a doctrinal and socio-legal perspectives. This research seeks to examine these obstacles from a theoretical, doctrinal and empirical angle. The theory draws on Peter Drahos' 'insider theory' and his extensive empirical study of patent offices showing that there is an 'insider/outsider' system in effect. Patent policies and practices, he argued, are driven both by large and powerful patent offices (such as the UKIPO, USPTO and JPO) and by big businesses, who have a significant voice in determining patent policy. This system means that 'outsiders' – such as NGOs and smaller patent offices – face significant difficulties in challenging gene patents. His study, however, is concerned with patent offices and their clients and how standard setting in the patent system is driven by patent offices clients. It does not explore the obstacles faced by NGOS, patients and other outsiders who seek to utilize the legal system to challenge the patents granted by patent offices. My research thus builds on the concept of an 'insider' system by interviewing 'outsiders' who nonetheless have a key stake in the patent system. This research uses the patent litigation surrounding Myriad Genetics' BRCA1 and BRCA2 patents as a lens to explore obstacles to patent challenges. Litigation took place before the US Supreme Court (*Association of Molecular Pathology v Myriad Genetics Inc),* the Australian High Court (*Yvonne D'Arcy v Myriad Genetics Inc*) and before the European Patent Office Board of Appeal. NGOs and public interest groups were involved in each challenge. These litigations demonstration that there are both national legal obstacles along with international and systemic obstacles to public interest engagement

	with patent challenges. As such, this research is comparative, exploring patent challenges in Europe, the United States and Australia. The aim of the empirical arm of this research is to explore the legal challenges faced by public interest groups through interviews with individuals who have been involved in these challenges. This will be done through semi-structured interviews focussing on the legal obstacles faced when attempting to challenge gene patents. This is the aspect of the research which falls within the LREC purview. I will be collecting personal data, including names and job roles. Those individuals who I will seek to interview will be lawyers, academics, scientists, and those who work with regulators. These individuals will come from NGOs (such as Medicins Sans Frontieres, the Public Patent Foundation and the ACLU), national patent offices (such as the UKIPO, USPTO and EPO) and professional organisations (such as the British Society of Genetic Medicine). It is expected that those interviewed will be highly educated and hold positions of prominence within such organisations, so will be correctly identified as 'elites' for the purpose of interviewing. Given this status I will negotiate anonymity on an ad hoc basis with each interviewee. Any personal data will be anonymized, unless requested otherwise, and will be stored in an encrypted state in the University Research Data Storage Facility. Data stored in this way will be kept for ten years, in line with University of Bristol Policy. Any data that is not anonymized (due to agreement with the participant) will be destroyed on completion of the project. Any data on paper will be shredded and disposed of confidentially once anonymized and encrypted. Any digital data will be overwritten, again, once anonymized and encrypted.

Section 2: Source of Funding (All Applicants)

Is the research funded, in whole or in part, by an organisation external to the University?	YES
Funding Organisation	ESRC
Funding organisation website	http://www.esrc.ac.uk/skills-and-careers/studentships/esrc-students/
Nature of funding awarded, e.g. studentship, project funding, etc.	ESRC 1 + 3 Studentship Award
If the funding is awarded under a particular programme or scheme, please identify.	
Does the Funding Organisation require institutional ethical review?	YES
Does the Funding Organisation have particular ethical review requirements, e.g. the use of an independent reviewer?	No

Section 3: Supervision and Training (Research Students)

Name(s) of proposed/actual supervisor(s)	Aurora Plomer and Andrew Charlesworth
Have you discussed this application with your supervisor?	Yes
Have you received research methods training either at Bristol or elsewhere?	YES
Please indicate the person/body that provided the training	University of Bristol – Research Methods Training as part of my MSc in Socio-Legal Studies
Please briefly indicate the subject matter of that training	I took several modules which contributed to my research methods training: - Introduction to Qualitative Research Methods - Introduction to Quantitative Research Methods - Advanced Socio-Legal Research Methods - Social Legal Theory - Philosophy of Social Science Research Methods
Please provide the date of attendance	Sept 2015 – Sept 2016
Have you attended a research ethics workshop or an equivalent session as part of your research training at Bristol or elsewhere?	YES
Please indicate the person/body that provided the training	University of Bristol – via my MSc
Please provide the date of attendance	20th October 2015 (Philosophy of Social Science Research Methods) 23rd November 2015 (Introduction to Qualitative Research Methods) 18th February 2016 (Advanced Socio-Legal Research Methods)
Date of electronic submission of this form to primary supervisor	13.12.2017

Section 4: General considerations (All Applicants)

Note: Detailed answers are **not** expected in this section. The Research Ethics Committee simply wishes to be assured that you have consulted and considered relevant guidance.

Have you reviewed and addressed the ethical implications of your proposed research in line with the Socio-Legal Studies Association Re-statement of Research Ethics (to which the School of Law subscribes)?	YES
If you are leading a research team, have you taken steps to ensure that each member of that team will have read the SLSA ethical guidance, and be fully aware of the ethical dimensions of this research?	NA
Have you reviewed and addressed the ethical requirements of conducting research at the University of Bristol?	YES
Does your project involve participants who are children or young people?	NO
Have you considered whether you need to apply for a Criminal Record Check?	NA
Does your project involve participants who lack the capacity to consent either permanently or intermittently? If so the LREC is not the appropriate body for which to apply for ethical approval (Guidance Document: Application Process, point 3)	NO
Does your project involve human health-related research? If so the LREC may not be the appropriate body for which to apply for ethical approval (Guidance Document: Application Process, point 3)	NO
Have you reviewed and addressed the University 'advice on research' in the context of data protection legislation?	YES
Does your project involve any research data that you would wish to shield from disclosure under the Freedom of Information Act 2000?	YES
Does any aspect of your research suggest the need for a risk assessment exercise prior to completion of this form (e.g. interviews away from the University)?	YES
Does any aspect of your research suggest that there may be a physical or mental risk to you, or other research team members, carrying out fieldwork with human subjects? See further, the Social Research Association's Code of Practice for the Safety of Social Researchers.	NO

If you have particular questions about any of this guidance that you would like to raise with the Law School Research Ethics Committee, please note them here.	
If you have questions about issues that are not covered in this general section, please note them here.	
If you have found particularly useful materials that you think may be helpful for others in addressing general ethical issues in research projects, please note them here.	

Section 5: Specific considerations (All Applicants)

Note: Detailed answers **are** expected in this section.

Methodology

1. Please indicate your methodology and proposed data collection methods (e.g., survey questionnaire, interview, internet, focus groups, observations, secondary data). Please also indicate whether you have prior relevant research training in, or experience of, those methods.
This research has two arms to answer the research questions: a doctrinal analysis and an empirical study. The doctrinal analysis uses the litigation surrounding Myriad Genetics' BRCA patents as case studies to analyse legal obstacles faced by public interest groups in challenging their patents. This arm analysis the role of amicus curiae briefs and the standing doctrine, and the difficulties these legal processes pose to patent challenges. The second arm of this research is empirical, and aims to understand the obstacles and opportunities for NGOs and public interest groups to challenge gene patents from a socio-legal perspective. Using semi-structured interviews I will interview individuals from organizations who have been involved in gene patent challenges, specifically the Myriad litigations. These include NGOs such as Medicins Sans Frontieres, PubPat; professional organizations such as the UK British Genetics Society and regulators such as the World Intellectual Property Organization (WIPO) and the UKIPO. The aim of these interviews is to understand what barriers – or opportunities – public interest groups face when attempting to bring gene patent challenges. The interview will ask how far public interest groups were able to utilise the patent law system to bring their challenge, where they had difficulties or were stopped completely, and how they managed these difficulties. As these interviews are semi-structured it is expected that there may be some variety in the questions asked due to the iterative nature of such interviews. It is also likely that I will require different interview schedules for different individuals; interviews with the regulators, for example, are likely to differ from those with scientists and lawyers directly involved in such challenges. Interviewing regulators will allow a perspective on the internal machinations of gene patent challenges – and whether they are any perceived barriers from the 'inside' perspective. To set a rough structure for the interviews I will have a set of primary questions centred around the common themes of obstacles to patent challenges, opportunities which are utilised (or under-utilised) and any barriers experienced to bringing legal challenges to gene patents. The aim of this rough structure and grouping will enable the interviews to stay on track, whilst being flexible enough to respond to the issues which arise during interview. I will ask those who I interview if they can introduce me to or identify any other individuals who will be able to contribute to the research. It is envisaged that there will be between 10 and 15 interviews. The full interviews will then be transcribed by myself before being analysed from a grounded theory perspective. The grouping into common themes during the interview will assist with this. These interviews, along with my doctrinal and theoretical aspects, will inform the overall analysis of the thesis.

Additional materials provided for review	YES

Covert & Deceptive Research

2a. Are you using any covert or deceptive methods?	NO

2b. If so, please state what you propose to do and why these methods are justified.

Nature of Research Participants

3a. Please describe the expected characteristics of your research participants.
This research seeks to interview individuals involved in challenging gene patents. This includes those who were involved specifically in the Myriad litigations (American Civil Liberties Union, Marie Curie Institut, British Society for Genetic Medicine), NGOs who have been active and vocal in other patent challenges (Medicins Sans Frontieres, Knowledge Ecology International) and patent system regulators (UKIPO, WIPO, EPO). I would argue that the intended interviewees are accurately defined as elite interviewees. Harvey (2011) argues that the term 'elites' is difficult to define, however expected characteristics are "highly skilled, professionally competent" who hold "important social networks, social capital, and strategic positions within social structures because they are better able to exert influence." He goes on to argue that this term can mean different things in different contexts, and their 'elite' status can fluctuate over time. Here, the term elite is used as the individuals I will seek to interview will be highly educated, hold – or have held – prominent positions in their companies and hold important social & professional networks. It is also expected that the research participants will be media trained, or likely have some experience in being interviewed.

3b. Will your proposed research will involve contact with any of the following groups:	
Children/young people (younger than 18) / Vulnerable adults	NO
Adults or young people who lack the capacity to consent/NHS patients or service users/prisoners (in health related research)	NO

3c. If you answered YES to either of the first two categories in 3b, you will need to consider whether you should apply for a Disclosure and Barring Service check. Please consult the Guidance Document for details. Please outline any particular risks which you think your research might raise for those groups, or for you or your research team, and whether you believe specific measures may be needed to address them. If you believe your research may impact other groups for whom special measures may be needed, please describe the group(s) and any precautionary measures to be taken. If you answered YES to either of the last two categories in 3b, the LREC alone is unlikely to be able to provide ethical clearance for your research. Please consult the Guidance Document for details.

Undue Influence

4a. How will you gain access to the proposed research setting(s)? Are there particular factors, such as power dynamics/relationships of dependency that may place undue influence upon research participants to participate, e.g. influence of gatekeepers or other intermediaries? To what extent does your methodology address such issues?
It is recommended in 'Law School Guidelines for Elite Interviewing' (2010) that potential interviewees should be contacted via letter outlining the parameters of the study. However, I have already been in contact with some key individuals in this area who are happy to be interviewed for my research, and who may make recommendations as to other potential interviewees. These contacts have been made through my attendance at conferences, and by discussing my research with other delegates. As these contacts have arisen naturally through discussing genetic patents and the current literature there was no undue influence exerted to encourage participation. As such, I would argue that there would be no ethical problems in utilising these contacts, despite their deviance from Law School guidelines. However, in recognition that it is vital for any participant to have as much information as possible about the research (and in recognition that breaks in conferences may not provide the ideal location to provide extensive information about research projects) I have drafted a briefing note which outlines the same information as recommended in the Law School guidelines. This note will be sent to individuals who have already indicated their willingness to be interviewed. I also intend to use the 'snowball' technique and ask those who have already agreed to be interviewed whether they can recommend other interviewees. This briefing note could then be forwarded to additional contacts (either by myself or by those contacts I have already made). This note can also be used as a letter to 'cold' contact potential interviewees. The 'snowball' technique is defined at "identifying respondents who are then used to refer researchers on to other respondents" (Atkinson and Flint, 2001). This technique is problematic as it is contradictory to conventional notions of sampling as there is limited control over who is included in the sample. However, it is argued the benefits of this technique outweigh the drawbacks of the method of access. The 'snowball' approach provides the strongest approach as it allows access to an elite network of individuals. Elite interviewees may be reluctant to be interviewed without an introduction, or without a recommendation. Ostrander (1993) argues that building trust with elite interviewees from the outset is a vital part of interviewing elites. As such, introductions via colleagues who can vouch for the integrity of the research will be beneficial. 'Cold' contacting obviously does not have these benefits so the briefing note is important for developing trust and transparency in this research. Due to the time constraints of undertaking doctoral research and the space limitations of the thesis itself, this research does not seek to be representative. As outlined above, there is very limited research undertaken surrounding the question of public interest litigation and patent systems. As such, this research intends to start the conversation rather than provide any definitive and representative answer to the problem posed. The robustness of this research is therefore not hampered by the lack of a strict sampling technique.

4b Will payments or other inducements be offered to research participants	NO

4c. If you answered YES to 4b, please provide details, in particular the rationale for the use of a payment/inducement.

Data Protection

5a. Please describe the nature of the empirical data you expect to collect.
It is expected that this research will collect qualitative interview data. This will be in the form of digital recordings, notes taken during the interview and transcripts of the interviews. The data will consist of their answers to the interview questions, any additional comments or recommendations of future participants and any observations or thoughts I have during the interview. The interview data will be centred around questions concerning any legal obstacles the participants faced in bringing gene patent challenges, how far they were able to utilise the patent system, any specific areas which they experienced difficulties and any alternative routes they used to challenge gene patents. For regulators I will ask for their knowledge of utilising the patent system, any difficulties which are being reviewed and where they get their evidence from for analysing how the patent system runs. I will also ask for their thoughts on areas for improvement in gene patent litigation. Throughout the research I will gather personal data from the participants which makes their data identifiable. This will be anonymized at transcription stage, unless the interviewee wishes to be identified.

5b. Will you be collecting 'personal data' (as per the Data Protection Act 1998)	Yes

5c. If you answered YES to 5b, please indicate your assessment of whether the data collected could be used to support measures or decisions targeted at particular individuals, or might cause substantial distress or damage to a data subject.
There is a minimal risk that this data will cause substantial distress or damage to participants. The personal information will relate to the individuals name, job title and personal views. The audio files and transcripts will not be linked to individuals, unless they have given explicit consent for their name, direct quotes or both to be used in the thesis. The default position will be that there is complete anonymity for participants. Variance to the position will be negotiated with individuals at the beginning of their interview (and clarified at the beginning of any subsequent interviews or communications). Explicit written or verbal consent will be gained to use direct quotes or identifiers and participants will have an opportunity to review their direct quotes in context, with the option to withdraw for up to six months after the interview. This time frame is necessitated by the submission deadline of my PhD.

5d. If you answered YES to 5b, please outline whether personal data will be pseudonymised or anonymized, and if so, at what stages in the research.
The data collected will be anonymized during transcription, unless it has been explicitly agreed otherwise (see 5c. above).

5e. Will you be collecting 'sensitive personal data' (as per the Data Protection Act 1998)	NO

5f. If you answered YES to 5e, in addition to your responses in 5c, please explain briefly why you would describe your research as being 'in the substantial public interest' (Data Protection (Processing of Sensitive Personal Data) Order 2000).

5g. Does your research require you to share personal data of research participants with third parties outside the EEA e.g. researchers in overseas universities?	NO

5h. If you answered YES to 5g, please outline how you have ensured that any personal data transfer is in accordance with the requirements of Principle 8 of the Data Protection Act 1998

Informed Consent

6a. What advance information will you be providing to research participants (or their proxies)? Please provide copies of material to be provided to or, as appropriate, read to, research participants. **If you are not planning to provide advance information, in written or verbal form, please provide a full explanation – see also 2a.**
A briefing note will be sent to all potential research participants outlining the aims of the research and the way in which the data will be used. This briefing note will also outline that I intend to record all interviews, but that this can be negotiated if the interviewee does not want their interview recorded. It will also detail how the interview data will be stored and advise that their data can be withdrawn at any time up to six months after the interview has taken place. Reasons for this will be provided; there will become a point at which it will not be possible to retract their information due to the submission of my thesis. This note will also contain my contact information, in case they wish to discuss any aspect of the research.

Additional materials provided for review	YES
6b. Will you obtain written, or recorded, consent from research participants prior to collecting data from them?	YES

6c. If you answered NO to 6b, please explain why obtaining written, or recorded, consent is undesirable in the context of your research, and outline any additional measures you believe may be necessary to ensure that the rights of research participants are adequately protected.

6d. If you answered YES to 6b, please explain how you will handle withdrawal of consent by research participants. Additionally, if your project is a multi-stage or longitudinal project, please outline how you intend to ensure that research participants will remain adequately informed and whether further grants of consents will, or may be sought.
If the research participant withdraws their consent during the interview then I will end the interview and advise that their data will be destroyed as soon as possible. If a participant chooses to withdraw their consent after the interview but within the timeframes specified all data they have provided will be confidentially destroyed. This will be via "over-writing" for any digital data, and via confidential shredding for hard copies of data.

6e. Please outline any circumstances relating to your research where legal or ethical issues might require you to disclose information pertaining to a research participant without their consent. How has this influenced the guarantees you are offering your intended research participants?
It is not anticipated that there will be a situation in which I will be required to disclose such information.

Data Security and Archiving

7a. In what format do you intend to collect and store your data? Where will it be stored and what security arrangements will be in place to ensure its safe-keeping at the various stages of the research process?
It is intended that the data will be collect in three different ways: digital recordings of the interviews, interview transcripts and personal hard copy notes. During interviews and before transcription digital recordings will be held on an encrypted recording device before being transferred as an encrypted file onto a University of Bristol Computer. This data file will be accessible on my home laptop via a VPN. My laptop is password protected and I am the only person with access to it. Hard copies of my interview notes, or hand-written transcripts of interviewees who do not wish to be recorded, will be kept in a locked filing cabinet at the University of Bristol. This cabinet is in a secure room, with limited University card access. They will be transcribed into encrypted Word documents as soon as possible, and confidentially shredded as soon as this is done. Transcripts of the interviews will be stored in encrypted files on University of Bristol PC as outlined above. Once transcription is complete they will be stored on the University Research Data Storage Facility.
7b. What will happen to the data at the end of the research process? If it is to be archived, how will this be done? If it is to be destroyed, when will this happen and how will this be achieved?
Anonymized data will be archived on the University Research Data Facility for ten years, in line with University of Bristol policy. Non-anonymized data will be destroyed by either over-writing or confidential shredding, depending on the format of such data. As an ESRC funded student I am not required to upload my interview data to the UK Data Archive. However, I intend to upload anonymized data to this system. This will be made clear to participants during the confidentiality negotiating stage as it may impact on their decision regarding identifying themselves or direct quotes. It will also be included on the briefing note sent to participants.

Freedom of Information

8. If a Freedom of Information request was made for the research data to be collected during this project, are there any exemptions that you would seek to claim under the Freedom of Information Act which would require or allow the University to withhold some or all of the data from disclosure, either during the research or if archived?
Yes – under s. 22A Freedom of Information Act 2000. As this empirical research forms a substantial portion of my doctoral thesis, and is likely to contribute to future publications this data could be considered "a programme of research where the programme is continuing with a view to publication."

Health & Safety

9. Are there any significant health and safety risks to the researchers, the research participants, or third parties associated with this research? Please comment on your perception of the degree of risk, in context; whether you think special precautions are necessary; and why your approach is proportionate to any risk.
It is not envisaged that there is any significant risk to the researcher in this project, however there is a small risk as the interviews will potentially take place away from the University of Bristol. As such, a risk assessment form has been completed (attached) and reasonable precautions will be taken. These precautions include providing my supervisors with a schedule of when the interviews will be taking place, the location of the interviews and my mobile number. I will keep my mobile phone charged and on me at all times to ensure I am reachable & can call in case of emergencies. Additionally, my partner will be kept informed of where my interviews will be taking place, and when. I would argue that this minor risk is proportionate to the value the data will contribute my research, particularly as it forms a substantial input to the originality of the research.

Other Information

10. Is there anything further that you think the Research Ethics Committee should know about in relation to your proposed research, such as particular risks not identified by this form, costs imposed on research participants, or particular benefits of the research that should be weighed against the risks and/or costs identified, which the form does not cater for?

Feedback

Feedback from participants in the ethical review process is vital to keeping it a participatory and academic (as opposed to an administrative/managerial) process. If you have any further questions about, or criticisms of, the ethics review process which the Research Ethics Committee can take into account when considering future practice, please take the time to let us know.

Section 6: Sign off for Supervisors and Primary Investigators.

Primary Supervisor's Statement (where the application is made by a research student)

I have reviewed this application, and have discussed the research design, and any training needs, with the applicant prior to its submission. I (or the alternative supervisor also named here) will provide continuing ethical oversight for this research which will take a heightened form if the applicant has not undertaken formal ethics training.	
Date of electronic submission of this form by primary supervisor to Law School Research Ethics Committee	

Primary Investigator's Statement (where application is completed by project researcher)

I have reviewed this application, and have discussed the research design, and any training needs, with the applicant prior to its submission.	
Date of electronic submission of this form by Primary Investigator to Law School Research Ethics Committee	

Section 7: Checklist

All relevant questions completed	YES
Copy of risk assessment document	YES
Copy of information documents to be provided to research participants	YES
Copy of written consent sheet to be completed by research participants	YES
Other documents provided (please specify)	
Registration checklist completed and submitted to Research and Enterprise Development	YES

Appendix 2

Interview Schedule

1. **How did you become involved in the challenges to Myriad's BRCA patents?** (Introducing question, aimed to understand how individuals or organisations become involved in gene patent challenges and understand how 'outsider' networks begin to form).
2. **What factors went in to deciding whether to pursue the challenge?**

   (Understanding what drives engagement with opposition proceedings/litigation and whether these are individual, institutional or resource driven)

3. **Were you familiar with the EPO opposition / litigation process?**
    a. If yes – where did you get this knowledge/training from?
    b. If no – did you become aware of it? How? (Potential expanding question to understand how much they knew of patent law and the opposition grounds – exploring whether they were aware of the difficulty in submitting morality arguments. Aimed to understand if knowledge is a barrier to engaging with opposition process).
4. **Did your views or expectations of the opposition process/litigation change during the process?**
    a. If changed – how and in what ways? (One of the feedback points from the Upgrade process was an interesting point about whether gene patent challenges are problematic because individuals perceive the process to be so e.g. because it is obscure, biased or ineffective – this question seeks to understand this point)
5. **Were there any aspects of the EPO opposition/litigation that you found difficult?**
6. **Did you experience any barriers or problems using the opposition procedure at the EPO/pursuing the litigation?**
    a. If yes – what were they? What would you say was the biggest barrier?
    b. If no – aware of any difficulties faced by colleagues / representatives? (When thinking about themes for the interview I considered if it was worth understanding if the barriers faced were individual, institutional, structural, etc – so asking about individual barriers or problems is a broad question with some potential probes to understand this).
7. **Were you involved in any challenges to gene patents other than through the opposition process/litigation? Would you say these were effective?**
    a. For example, writing newspaper opposition pieces, taking part in interviews on TV? (This is to understand if challenging gene patents can be approach on more than just a legal front (i.e. like James Love/MSF & HIV Medication) and whether the interviewees consider this more effective).
8. **What do you think about the EPO opposition process?**
    a. Did you find it effective or problematic? Ask for the reasons why. (A chance to understand any issues that the interviewee would not perceive as a barrier to using the opposition process but merely problematic).
9. **Have you been involved in other patent oppositions?**

Additional interview questions added following reflection on the earlier interviews:

10. **How did you become aware of Myriad's gene patents? #**
11. **Who made the strategic decisions concerning the opposition/litigation?**
    a. To what extent were you involved in making these decisions?

Appendix 3

Briefing Note Sent to Participants

Briefing Note

Research Project Title: Public Interest Challenges to Gene Patents: An analysis of the legal obstacles faced by NGOs and Public Interest Groups

Researcher: Louise Hatherall, PhD Candidate, University of Bristol

Researcher Contact Information: louise.hatherall@bristol.ac.uk

Background To The Study

The proposed research relates to my PhD thesis concerning the engagement of NGOs and public interest groups with the patent system. This research is concerned with understanding the legal obstacles encountered by public interest groups when challenging gene patents. It is specifically interested in genetic patents, as these raise broad and wide- ranging public interest issues such as access for patients to diagnostic tests and treatments. A review of the field reveals that legal challenges by NGOs are pertinent to the regulation and protection of gene patents but, NGOs face multiple legal obstacles, for instance they need to show that they have standing to sue. The challenges faced by NGOs are understudied, both from a doctrinal and socio-legal perspectives. This research seeks to examine these obstacles from a theoretical, doctrinal and empirical angle.

The aim of the empirical arm of this research is to explore the legal challenges faced by public interest groups through interviews with individuals who have been involved in these challenges. This will be done through interviews which focus on the legal obstacles faced when attempting to challenge gene patents.

Participation In This Research

Agreeing to participate in this research will involve being interviewed for around an hour. Ideally, I will travel to meet and interview you at a convenient location. However, if this is not possible other arrangements (such as Skype) can be made.

Participation in this research is entirely voluntary, and consent can be withdrawn at any time during the interview, and for up to six months after the interview date. This time restriction is a practical restriction as there will become a point at which removal of your interview data from the research will no longer be possible (e.g. due to submission of my doctoral thesis).

Storage of Data

Any data collected will be anonymized following the interview, unless agreed otherwise. This will be agreed with you prior to the start of the interview.

During the research project all data (both digital and hard copy) will be securely stored in the following ways:

During interviews and before transcription digital recordings will be held on an encrypted recording device before being transferred as an encrypted file onto a University of Bristol Computer.

Hard copies of my interview notes, or hand-written transcripts of interviewees who do not wish to be recorded, will be kept in a locked filing cabinet at the University of Bristol. This cabinet is in a secure room, with limited University card access. They will be transcribed into encrypted Word documents as soon as possible, and confidentially shredded as soon as this is done.

Transcripts of the interviews will be stored in encrypted files on University of Bristol PC as outlined above. Once transcription is complete they will be stored on the University Research

Data Storage Facility (RDSF). More information about the RDSF can be found here: https://www.acrc.bris.ac.uk/acrc/RDSF-faqs.html#What

Anonymized data will be kept for ten years, in line with University of Bristol Policy. Any data that is not anonymized (due to agreement with the participant) will be destroyed on completion of the project. Any data on paper will be shredded and disposed of confidentially once anonymized and encrypted. Any digital data will be overwritten, again, once anonymized and encrypted. The current date for completion of the project is March 2020.

Use Of Data By Other Researchers

As this project is funded by the ESRC any interview data that is anonymised will be uploaded onto the UK Data Archive. This service curates data from a wide range of sources for re-use by other social science researchers. As such, your data may be used by researcher's other than myself and may appear in other publications. However, confidentiality and anonymity will be preserved. Data that is not anonymised will not be uploaded onto the UK Data Archive service. More information about the archive can be found here: http://www.data-archive.ac.uk/about.

Appendix 4

Interview Participant Consent Form

Interview Consent Form

Research Project Title: Public Interest Challenges to Gene Patents: An analysis of the obstacles faced by NGOs and Public Interest Groups

Researcher: Louise Hatherall, University of Bristol

Researcher Contact Information: louise.hatherall@bristol.ac.uk

By signing below I confirm that:

- I understand that this interview is for research concerning public interest challenges to genetic patents and I have had the opportunity to ask questions about it.
- I understand that I am free to withdraw from the interview at any time.
- I understand that I am free to withdraw my consent to the interview data being used for up to six months following the interview date.
- I understand that provision of this data is strictly for research purposes and may result in journal articles and/or other publications.
- I understand that all data will be rendered anonymous and identities of all participants kept strictly confidential irrespective of publication. The only exception to this is where it is requested in advance by the participant, and agreed between both the interviewer and interviewee.
- I understand that this data will be copied, stored, and may be reused by other researchers.
- **I consent to take part in this research.**

……	……	……
Name of participant	**Signature**	**Date**
…Louise Hatherall		
Name of researcher	**Signature**	**Date**

By signing the below I confirm that I give my consent for the interview to be digitally recorded:

……	……....	……
Name of participant	**Signature**	**Date**
…Louise Hatherall		
Name of researcher	**Signature**	**Date**

Bibliography

Books

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