December 30, 2012

23andMe Inc.: Patent Law and Lifestyle Genetics

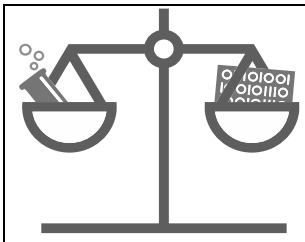
Matthew Rimmer, *Australian National University College of Law*

Title: **23andMe Inc.: Patent Law and Lifestyle Genetics**

Author: **Matthew Rimmer**

EAP Date (approved for print): 20/11/2012

DOI: 10.5778/JLIS.2012.22.Rimmer.1



Journal of Law, Information & Science

Note to users: Articles in the 'Epubs ahead of print' (EAP) section are peer reviewed accepted articles to be published in this journal. Please be aware that although EAPs do not have all bibliographic details available yet, they can be cited using the year of online publication and the Digital Object Identifier (DOI) as follows: Author(s), 'Article Title', Journal (Year), DOI, EAP (pg #).

The EAP page number will be retained in the bottom margin of the printed version of this article when it is collated in a print issue. Collated print versions of the article will contain an additional volumetric page number. Both page citations will be relevant, but any EAP reference must continue to be preceded by the letters EAP.

ISSN-0729-1485

23andMe Inc.: Patent Law and Lifestyle Genetics

MATTHEW RIMMER*

1 Introduction

23andMe Inc. is private company founded in 2006 which, in its own words, is "dedicated to helping individuals understand their own genetic information using recent advances in DNA analysis technologies and web-based interactive tools."[1] This venture has been funded by the giants of information technology and biotechnology — Google,[2] Genentech,[3] as well as the investors Johnson & Johnson Development Corporation, MPM Capital, The Roche Venture Fund, and New Enterprise Associates. 23andMe Inc. is part of a new industry focused upon lifestyle genetics, and personalised medicine. Marcus Wohlsen commented that "direct-to-consumer genomics is bringing the age of genetics into homes across the United States and around the world."[4]

---

* Dr Matthew Rimmer (BA/LLB ANU, Phd UNSW) is an Australian Research Council Future Fellow; an Associate Professor at the ANU College of Law; and an Associate Director of ACIPA. This paper is based on presentations given at the Law Faculty, the University of Otago, New Zealand, and at the Centre for International and Public Law, ANU College of Law, Australia in 2009. The author would like to thank Professor Dianne Nicol for her comments on drafts of this article.

1 23andMe Inc., *Genetic Testing for Health, Disease and Ancestry* (2012) <https://www.23andme.com/>.

2 For a history of Google and its conflicts in intellectual property: David Vise, *The Google Story: Inside the Hottest Business, Media and Technology Success of our Time* (Macmillan, 2005); Randall Stross, *Planet Google: How One Company is Transforming Our Lives* (Atlantic Books, 2008); Ken Auletta, *Googled: The End of the World as we Know it* (Virgin Books, 2009); and Siva Vaidhyanathan, *The Googlization of Everything (and Why we Should Worry)* (University of California Press, 2011).

3 For a history of Genentech and its battles in intellectual property, see Sally Smith Hughes, *Genentech: The Beginnings of Biotech* (The University of Chicago Press, 2011); and Matthew Rimmer, "Genentech and the Stolen Gene: Patent Law and Pioneer Inventions" (2002/2003) 5(6) *Bio-Science Law Review* 198. In 2009, the Swiss health-care company Hoffmann-La Roche acquired complete ownership of Genentech.

4 Marcus Wohlsen, *Biopunk: DIY Scientists Hack the Software of Life* (Current, Penguin Group, 2011) 124.

23andMe Inc.'s scientific model involves a fascinating combination of genetics, information technology, and social networking. One of the co-founders, Linda Avey, commented:

> 23andMe was founded on the principle that the combined potential of personal genetic information and web-based interactive tools can empower individuals to access and understand their own genetic information while also holding the potential of accelerating research in the field of genetics.[5]

23andMe Inc. offers a "high-density, custom gene scan" to consumers from an array of countries.[6] The standard price for the service was $US399 — this has been discounted down to $US299 as of 2012.[7] 23andMe Inc. relies upon genotyping, determining which genetic variants an individual possesses, rather than sequencing. 23andMe Inc. provides this account of the process by which 23andMe's contracted laboratory genotypes the DNA of its subscribers and consumers:

> Once our lab receives your sample, DNA is extracted from cheek cells preserved in your saliva. The lab then copies the DNA many times — a process called 'amplification' — growing the tiny amount extracted from your saliva until there is enough to be genotyped.
>
> In order to be genotyped, the amplified DNA is 'cut' into smaller pieces, which are then applied to our DNA chip, a small glass slide with millions of microscopic 'beads' on its surface. Each bead is attached to a 'probe', a bit of DNA that matches one of the approximately one million genetic variants that we test. The cut pieces of your DNA stick to the matching DNA probes. A fluorescent signal on each probe provides information that can tell us which version of that genetic variant your DNA corresponds to.
>
> Although the human genome is estimated to contain about 10-30 million genetic variants, many of them are correlated due to their proximity to each other. Thus, one genetic variant is often representative of many nearby variants, and the approximately

---

5 23andMe Inc., *23andMe Selected as a 2008 Technology Pioneer by the World Economic Forum* (27 November 2007) <https://www.23andme.com/about/press/20071129/>.

6 23andMe Inc., *Customer Care: Do You Take International Orders?* (1 September 2012) <https://customercare.23andme.com/entries/21262316>.

7 23andMe Inc., (1 September 2012) <https://www.23andme.com/>.

> one million variants on our genotyping chip provide very good coverage of common variation across the entire genome.
>
> Our research team has also hand-picked tens of thousands of additional genetic variants linked to various conditions and traits in the scientific literature to analyse on our genotyping chip. As a result we can provide you with personal genetic information available only through 23andMe.[8]

23andMe explain why they do not carry out genetic sequencing: "Unfortunately, sequencing technology has not yet progressed to the point where it is feasible to sequence an entire person's genome quickly and cheaply".[9]

23andMe Inc. was launched to much fanfare. The company received a glowing endorsement from Oprah: "Thanks to these women, genetics testing is now as easy as spitting into a test tube."[10] Billionaires, celebrities, movie moguls, film stars and high society attended a 23andMe Inc. Spit Party in New York in 2008.[11] The 23andMe Inc. was promoted at the World Economic Forum.[12] The company's staff modelled T-shirts bearing the bad Dickensian pun, "Great Expectorations".[13]

23andMe provides consumers with several types of genetic information. First, the company provides clinical reports about health traits: "Because these associations are widely regarded as reliable, we use them to develop quantitative estimates and definitive explanations of what they mean for you."[14] 23andMe Inc. provides genetic analysis of a wide range of diseases

---

8 23andMe Inc., *Customer Care: How does 23andMe Genotype My DNA?* (10 August 2012) <https://customercare.23andme.com/entries/21263328-how-does-23andme-genotype-my-dna>.

9 23andMe Inc., *Customer Care: What is the Difference Between Genotyping and Sequencing?* (1 September 2012) <https://customercare.23andme.com/entries/21262606-what-is-the-difference-between-genotyping-and-sequencing>.

10 Oprah, *Headline Making News: 23andMe Inc.* (14 November 2008) The Oprah Show <http://www.oprah.com/oprahshow/Live-with-Rob-Lowe-Melissa-Etheridge-and-More/7>.

11 Allen Salkin, 'When in Doubt Spit It Out', *The New York Times* (online), 12 September 2008 <http://www.nytimes.com/2008/09/14/fashion/14spit.html >.

12 23andMe Inc., *Spitting Images at the World Economic Forum* (6 February 2008) *The Spittoon*, http://spittoon.23andme.com/news/inside-23andme/spitting-images/>.

13 Kevin Davies, *The $1000 Genome: The Revolution in DNA Sequencing and the New Era of Personalized Medicine* (Free Press, 2010) 33.

14 23andMe Inc., *Health Reports: Complete List* (1 September 2012)

and conditions by ethnicity.[15] As at September 2012, the company provides genetic analysis of genetic variants and carrier status in relation to 48 conditions — including BRCA Cancer Mutations; Cystic Fibrosis; Beta Thalassemia; Sickle Cell Anaemia; and Tay-Sachs Disease.[16] 23andMe Inc. also offers genetic analysis of 20 conditions in respect of genetic variants and drug response — including in relation to alcohol consumption and smoking; antidepressant response; heroin addiction; and response to Hepatitis C treatment.[17] The company also offers reports on genetic variants and disease risk across some 118 areas — covering everything from asthma to uterine fibroids.[18] 23andMe Inc. also offer genetic analysis of some 57 traits — including asparagus metabolite detection; hair curl; male pattern baldness; and tuberculosis susceptibility.[19]

Second, 23andMe Inc. offers genetic information about DNA ancestry and genetic history — as it quips "prehistory personalized".[20] The service is marketed as, "understand the story of your past".[21] 23andMe Inc. encourages its potential customers to learn about their identity and their "ancestral composition": "At the heart of your ancestral journey is YOU. Find out how much African, Asian, and European ancestry you have. Even determine if you have Native American or Ashkenazi ancestors within the past five generations. Your results may surprise you.[22]

23andMe Inc. also tells its customers that it can help locate their deep roots and ancestry.[23] The company urges — "[s]tay at the forefront of innovation and research with our exclusive Ancestry Labs" and "[o]ur Neanderthal Ancestry Lab provides an estimate of your genome-wide percentage of

---

<https://www.23andme.com/health/all/>.

15 23andMe Inc., *Health Reports: By Ethnicity* (1 September 2012) <https://www.23andme.com/health/ethnicity/>.

16 23andMe Inc., *Health Reports: Complete List*, above n 14.

17 Ibid.

18 Ibid.

19 Ibid.

20 23andMe Inc., *Prehistory Personalized* (1 September 2012) <http://www.jvfoa.com/Vick-and-Allied-Families-DNA-Project.php>.

21 23andMe Inc., *Ancestry* (1 September 2012) <https://www.23andme.com/ancestry/>.

22 23andMe Inc., *Ancestry: Recent* (1 September 2012) <https://www.23andme.com/ancestry/recent/>.

23 23andMe Inc. *Ancestry: Your Deep Roots* (1 September 2012) <https://www.23andme.com/ancestry/deep/>.

Neanderthal ancestry".[24] 23andMe Inc. reflects: "There's a story in you. Venture back 10,000 years, and discover your unique history from over 750 maternal lineages and over 500 paternal lineages."[25] The company offers to "trace everyone's maternal ancestry with a small piece of DNA passed down from mother to child."[26] Moreover, it observes: "Males can uncover their paternal ancestry through the Y chromosome that is passed down from father to son."[27] 23andMe Inc. notes: "Find out if you share an ancestor with famous figures such as Marie Antoinette and Thomas Jefferson."[28]

Third, 23andMe Inc. is engaged in genetic research. The company has commented: "23andMe isn't just about you. Our research arm, 23andWe, gives customers the opportunity to leverage their data by contributing it to studies of genetics. With enough data, we believe 23andWe can produce revolutionary findings that will benefit us all."[29]

The company comments that individuals can become involved in "[d]irect research by participating in studies of conditions and traits you care about" and "[j]oin an effort to translate basic research into improved health care for everyone."[30] It calls for support for "23andMe's efforts to discover new genetic associations that could shed more light on your data."[31] Board member, the eminent technology specialist, Esther Dyson, observed: "As hundreds of thousands, and eventually millions, of people take part, the genetic information collected will enable us to know so much more through data mining, combined with analysis of the interactions of genes and other factors."[32] She predicted: "We'll be able to pre-empt many diseases and treat others better."[33] Dyson said: "I hope this technology will change people's behaviour and encourage them to eat better and exercise more, because they'll have a better understanding of the impact of their behaviour on their health."[34] She rejected calls for stronger regulation of such genetic research:

---

24 Ibid.

25 Ibid.

26 Ibid.

27 Ibid.

28 Ibid.

29 23andMe Inc., *Research* (1 September 2012) <https://www.23andme.com/research/>.

30 Ibid.

31 Ibid.

32 Esther Dyson, 'Big Data: The Next Google' (2008) 455 *Nature* 8-9, <http://www.nature.com/news/2008/080903/full/455008a.html>.

33 Ibid.

34 Ibid.

"It's somewhat paternalistic to say people shouldn't get these tests because we don't want people to misunderstand or get upset."[35] 23andMe Inc. has since formed linkages with particular communities — focusing upon Parkinson's Disease,[36] Myeloproliferative Neoplasms (MPN),[37] and sarcoma.[38]

There has been a range of reactions to 23andMe Inc. In 2008, *Time Magazine* breathlessly proclaimed that the retail DNA test was the "Times Invention of the Year".[39] Journalist Anita Hamilton commented:

> Learning and sharing your genetic secrets are at the heart of 23andMe's controversial new service — a $399 saliva test that estimates your predisposition for more than 90 traits and conditions ranging from baldness to blindness. Although 23andMe isn't the only company selling DNA tests to the public, it does the best job of making them accessible and affordable.[40]

In the very same year, the ETC Group awarded 23andMe with a "Captain Cook Award for Biopiracy" for "convincing consumers to pay for genetic testing and hand over DNA samples and personal medical information, which the company plans to sell to medical researchers".[41] The company 23andMe — with its provocative combination of genetic testing and social networking — has clearly been quite polarising from its very inception. Such absolute judgments of the company and its products, I would argue, are premature. There is a need for a cool, balanced assessment of the potential and the limitations of 23andMe.

This article will provide a critical evaluation of the legal issues raised by 23andMe Inc. — particularly in respect of patent law, health law, and bioethics. 23andMe Inc. has been building a portfolio of intellectual property

---

35 Ibid.

36 23andMe Inc., *Parkinson's Disease* (1 September 2012) <https://www.23andme.com/pd/>.

37 23andMe Inc., *23andMe Inc. Myeloproliferative Neoplasms Research Initiative* (1 September 2012) <https://www.23andme.com/mpn/>.

38 23andMe Inc., *23andMe Inc. Sarcoma Community: A Patient-Driven Revolution in Sarcoma Research* (1 September 2012) <https://www.23andme.com/sarcoma/>.

39 Anita Hamilton, "The Retail DNA Test: Best Inventions of 2008", *Time* (online) 29 October 2008 <http://www.time.com/time/specials/packages/article/0,28804,1852747_1854493_1854113,00.html>.

40 Ibid.

41 The ETC Group, *Captain Hook Awards for Biopiracy 2008* (1 September 2012) <http://www.captainhookawards.org/winners/captain_hook_awards_for_biopiracy_2008>.

rights around its products and services — particularly with a view to obtaining patent protection. The company, 23andMe Inc. also relies upon a variety of other forms of intellectual property — such as trade mark protection,[42] copyright protection, and confidential information. The Terms of Service tells its customers:

> You specifically acknowledge and agree that the Service and any necessary software used in connection with the Service ('Software') contain proprietary and confidential information that is protected by applicable intellectual property and other laws. You further acknowledge and agree that information presented to you through the Service or sponsors is protected by copyrights, trademarks, service marks, patents, or other proprietary rights and laws.[43]

The company, 23andMe Inc., raises a host of interesting questions for patent law, practice, and policy in both information technology and biotechnology. Part 2 of this article considers questions of patentable subject matter raised by the case of 23andMe Inc. Part 3 considers the examination of patent applications made by 23andMe Inc. — particularly focusing upon its patent, "Polymorphisms associated with Parkinson's Disease". Part 4 of this article looks at the intersection between patent law, informed consent, and benefit-sharing. It considers whether research participants properly consent to intellectual property rights protection being sought in respect of 23andMe's research. Part 5 discusses matters of patent infringement and available defences and exceptions. The case study of 23andMe Inc. raises larger questions in respect of patent law, policy, and practice for lifestyle genetics and personalised medicine.

---

[42] In addition to patent protection, 23andMe Inc. has obtain a number of trade mark registrations in respect of the words and numbers, 23andMe, and the accompany design. The registrations are focused upon: "providing scientific analysis and informational reports based upon results of laboratory testing in the field of genetics" (United States Trademark Registrations Nos 7734761 and 77160012); "Online social networking services in the field of genetics" (United States Trade Mark Registration No 77343745); "Application service provider (ASP) featuring software for providing access to multiple databases that contain aggregated results of genotyping" (United States Trade Mark Registration No 77228004); "Computer software for recording, analysis, storage, manipulation and organization of genetic and molecular data" (United States Trade Mark Registration No 77228012); and "Providing an online resource center" (United States Trade Mark Registration Nos 77159986 and 77343754).

[43] 23andMe Inc., *Terms of Service: Version 1.1* (1 September 2012) <https://www.23andme.com/about/tos/?version=1.1>.

2 *Patentable Subject Matter*

The co-founder of 23andMe Inc., Anne Wojcicki, has recognised: "The question of whether innovations related to genetics can be patented is in hot debate as evidenced by recent rulings related to *Prometheus* and *Myriad* patents."[44] She wondered: "Patents were created to protect innovation. Is discovering the function of a gene an innovation?"[45]

There have been parallel controversies over the patenting of genes, and the patenting of information technology, particularly in respect of business methods. There has been some discussion of the operation of patent law in respect of areas of convergence — such as bioinformatics.[46] There has been much discussion about patent law and the combination of various emerging technologies in information technology, biotechnology, nanotechnology, and the cognitive sciences.[47] Arguably, 23andMe Inc. raises larger questions about patentable subject matter — particularly where there is a convergence of information technology and biotechnology.

In the 2010 case of *Bilski v Kappos* ("*Bilski*"), the Supreme Court of the United States reviewed the decision of the Court of Appeals for the Federal Circuit on the eligibility of business methods for patent protection.[48] Writing the lead opinion, Kennedy J held that: "The Court of Appeals incorrectly concluded that this Court has endorsed the machine-or-transformation test as the exclusive test."[49] His Honour elaborated that this was but one of a number of tests:

---

44 Anne Wojcicki, *Announcing 23andMe's First Patent* (28 May 2012) *The Spittoon* <http://spittoon.23andme.com/news/announcing-23andmes-first-patent/>.

45 Ibid.

46 Matthew Rimmer, "Beyond Blue Gene: Intellectual Property and Bioinformatics" (2003) 34(1) *International Review of Industrial Property and Copyright Law* 31; Matthew Rimmer, "Japonica Rice: Intellectual Property, Scientific Publishing, and Data-Sharing" (2005) 23(3) *Prometheus* 325; Ian Cockburn, "State Street Meets the Human Genome Project: Intellectual Property and Bioinformatics" in Robert Hahn (ed), *Intellectual Property Rights in Frontier Industries: Software and Biotechnology* (AEI-Brookings Joint Center for Regulatory Studies, 2005); and Donna Gitter, (2007), "Resolving the Open Source Paradox in Biotechnology: A Proposal for a Revised Open Source Policy for Publicly Funded Genomic Databases" (2007) 43(4) *Houston Law Review* 1476.

47 See the various contributions to the collection, Matthew Rimmer and Alison McLennan (eds), *Intellectual Property and Emerging Technologies: The New Biology*, (Edward Elgar, 2012).

48 *Bilski v Kappos* 130 S Ct 3218 (2010).

49 Ibid 3226.

> This Court's precedents establish that the machine-or-transformation test is a useful and important clue, an investigative tool, for determining whether some claimed inventions are processes under §101. The machine-or-transformation test is not the sole test for deciding whether an invention is a patent-eligible 'process'.[50]

Kennedy J commented: "The machine-or-transformation test may well provide a sufficient basis for evaluating processes similar to those in the Industrial Age — for example, inventions grounded in a physical or other tangible form".[51] However, his Honour recognised that "there are reasons to doubt whether the test should be the sole criterion for determining the patentability of inventions in the Information Age".[52] The judge reflected:

> As numerous *amicus* briefs argue, the machine-or-transformation test would create uncertainty as to the patentability of software, advanced diagnostic medicine techniques, and inventions based on linear programming, data compression, and the manipulation of digital signals.[53]

His Honour suggested that there was scope for further refinement:

> In the course of applying the machine-or-transformation test to emerging technologies, courts may pose questions of such intricacy and refinement that they risk obscuring the larger object of securing patents for valuable inventions without transgressing the public domain.[54]

There has been discussion about the implications of *Bilski* for the disciplines of medicine, biotechnology, and pharmacology.[55]

---

50 Ibid 3227.

51 Ibid.

52 Ibid.

53 Ibid.

54 Ibid.

55 See Yann Joly and Francis Hemmings, "*Bilski* v. *Kappos* and Biotechnology Patents: Back to the Future?" in Matthew Rimmer and Alison McLennan (eds), *Intellectual Property and Emerging Technologies: The New Biology* (Edward Elgar, 2012) 63-83; and Joshua Sarnoff, "The Current State of Patent Eligibility of Medical and Biotechnological Inventions in the United States" in Matthew Rimmer and Alison McLennan (eds), *Intellectual Property and Emerging Technologies: The New Biology* (Edward Elgar, 2012) 84-116.

In the 2012 case of *Mayo Collaborative Services v Prometheus Laboratories Inc.* ("*Prometheus*"), the Supreme Court of the United States rejected a patent application in respect of medical information on the grounds that it claimed the underlying laws of nature.[56] This decision marked an important shift from an earlier consideration of the matter.[57] Writing for the Supreme Court of the United States, Breyer J re-articulates the law with respect to patentable subject matter:

> If a law of nature is not patentable, then neither is a process reciting a law of nature, unless that process has additional features that provide practical assurance that the process is more than a drafting effort designed to monopolize the law of nature itself. A patent, for example, could not simply recite a law of nature and then add the instruction 'apply the law.' Einstein, we assume, could not have patented his famous law by claiming a process consisting of simply telling linear accelerator operators to refer to the law to determine how much energy an amount of mass has produced (or vice versa). Nor could Archimedes have secured a patent for his famous principle of flotation by claiming a process consisting of simply telling boat builders to refer to that principle in order to determine whether an object will float.[58]

Focusing on "laws of nature", Breyer J comments: "The Court has repeatedly emphasized … a concern that patent law not inhibit further discovery by improperly tying up the future use of laws of nature."[59] His Honour noted: "These statements reflect the fact that, even though rewarding with patents those who discover new laws of nature and the like might well encourage their discovery, those laws and principles, considered generally, are 'the basic tools of scientific and technological work.'"[60] Breyer J was concerned about the danger "that the grant of patents that tie up their use will inhibit future innovation" — particularly where "patented process amounts to no more than an instruction to 'apply the natural law'".[61] In his reasoning, Breyer J

---

56 *Mayo Collaborative Services v Prometheus Laboratories Inc.*, 132 S Ct 1289 (2012).

57 In *Laboratory Corp of America Holdings v Metabolite Laboratories Inc.*, 126 S Ct 2921, the majority of five judges of the Supreme Court of the United States ruled that the writ of certiorari had been improvidently granted, and dismissed the action. Breyer J wrote a dissenting judgment, with the support of Stevens J and Souter J See Matthew Rimmer, *Intellectual Property and Biotechnology: Biological Inventions* (Edward Elgar, 2008) 110-37.

58 *Prometheus*, 132 S Ct 1289, 1297 (2012).

59 Ibid 1301.

60 Ibid.

61 Ibid.

was, in particular, influenced by the work of Professor Mark Lemley and Professor Rebecca Eisenberg.[62]

Summing up, Breyer J considered the competing policy arguments by the parties and the amici curiae in the case. His Honour counterpointed the views. On one side, "Prometheus, supported by several *amici,* argues that a principle of law denying patent coverage here will interfere significantly with the ability of medical researchers to make valuable discoveries, particularly in the area of diagnostic research."[63] On the other side,

> the American Medical Association, the American College of Medical Genetics, the American Hospital Association, the American Society of Human Genetics, the Association of American Medical Colleges, the Association for Molecular Pathology, and other medical organizations tell us that if 'claims to exclusive rights over the body's natural responses to illness and medical treatment are permitted to stand, the result will be a vast thicket of exclusive rights over the use of critical scientific data that must remain widely available if physicians are to provide sound medical care'.[64]

Breyer J reflected upon this difference of opinion:

> Patent protection is, after all, a two-edged sword. 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, by, for example, raising the price of using the patented ideas once created, requiring potential users to conduct costly and time-consuming searches of existing patents and pending patent applications, and requiring the negotiation of complex licensing arrangements. At the same time, patent law's general rules must govern inventive activity in many different fields of human endeavor, with the result that the practical effects

---

62 Mark Lemley, Michael Risch, Ted Sichelman, and R Polk Wagner, "Life After Bilski" (2011) 63 *Stanford Law Review* 1315; and Rebecca Eisenberg, "Wisdom of the Ages or Dead–Hand Control? Patentable Subject Matter for Diagnostic Methods After In re Bilski" (2012) 3 *Case Western Reserve Journal of Law, Technology & the Internet* 1.

63 *Prometheus*, 132 S Ct 1289, 1304 (2012).

64 Ibid 1304-1305.

> of rules that reflect a general effort to balance these considerations may differ from one field to another.[65]

Accordingly, Breyer J observed: "In consequence, we must hesitate before departing from established general legal rules lest a new protective rule that seems to suit the needs of one field produce unforeseen results in another."[66] He concluded "that the patent claims at issue here effectively claim the underlying laws of nature themselves … [and] the claims are consequently invalid".[67]

The decision marked a shift away from an expansionist approach to patentable subject matter. The ruling has been the cause of some anxiety for those in the fields of medicine and biotechnology.[68]

There has been longstanding controversy over Myriad Genetics and its patents in respect of genetic testing for breast cancer and ovarian cancer.[69] There has been significant litigation in the United States over the validity of the patents — in the District Court of the United States[70] and the Court of Appeals for the Federal Circuit.[71] The Supreme Court of the United States remanded the case to the United States Court of Appeals for the Federal Circuit for further consideration in light of the ruling in the *Prometheus* case.[72]

---

65 Ibid 1305.

66 Ibid.

67 Ibid.

68 Jeffrey Fox, "Industry reels as Prometheus falls and Myriad faces further reviews" (2012) 30 *Nature Biotechnology* 373; and Gauri Dhavan, Irene Hudson, and J Peter Fasse, "Patent Eligibility of Method Claims: What is the Impact of the Supreme Court's Prometheus Decision?" (2012) 8(3) *Industrial Biotechnology* 107.

69 See, for instance, Matthew Rimmer, "Myriad Genetics: Patent Law and Genetic Testing" (2003) 25(1) *European Intellectual Property Review* 20; Jonathan Stroud, "A Thousand Tiny Pieces: The Federal Circuit's Fractured Myriad Ruling, Lessons to be Learned, and the Way Forward" (2012) 2(2) *IP Theory* 71; and Isabelle Huys, Gert Matthijs and Geertrui Van Overwalle, "The Fate and Future of Patents on Human Genes and Genetic Diagnostic Methods' (2012) 13 *Nature Reviews Genetics* 441.

70 *Association for Molecular Pathology v United States Patent and Trademark Office and Myriad Genetics Inc.*, 702 F Supp 2d 181 (SD NY, 2010).

71 *Association for Molecular Pathology v United States Patent and Trademark Office and Myriad Genetics Inc.*, 653 F 3d 1329 (CA Fed (NY) 2011).

72 *Association for Molecular Pathology v United States Patent and Trademark Office and Myriad Genetics Inc.*, 132 S Ct 1794 (2012).

In the ruling in *Association for Molecular Pathology v United States Patent and Trademark Office and Myriad Genetics Inc* ("*Myriad*"), the United States Court of Appeals for the Federal Circuit reconsidered its ruling in light of the new *Prometheus* precedent.[73] The three judges became even more entrenched in their respective positions. For the majority, Lourie J summarised the new decision:

> On the threshold issue of jurisdiction, we affirm the district court's decision to exercise declaratory judgment jurisdiction because we conclude that at least one plaintiff, Dr. Harry Ostrer, has standing to challenge the validity of Myriad's patents. On the merits, we reverse the district court's decision that Myriad's composition claims to 'isolated' DNA molecules cover patent -ineligible products of nature under § 101 because each of the claimed molecules represents a nonnaturally occurring composition of matter. We also reverse the district court's decision that Myriad's method claim to screening potential cancer therapeutics via changes in cell growth rates of transformed cells is directed to a patent-ineligible scientific principle. We affirm the court's decision, however, that Myriad's method claims directed to 'comparing' or 'analyzing' DNA sequences are patent ineligible; such claims include no transformative steps and cover only patent-ineligible abstract, mental steps.[74]

Considering the composition claims, Lourie J noted: "The remand of this case for reconsideration in light of *Mayo* might suggest, as Plaintiffs and certain amici state, that the composition claims are mere reflections of a law of nature'.[75] Lourie responded: "Respectfully, they are not, any more than any product of man reflects and is consistent with a law of nature."[76] Lourie J concluded that, while "Everything and everyone comes from nature … the compositions here are not natural products."[77] Lourie J held that the inventions "are the products of man, albeit following, as all materials do, laws of nature."[78]

Concurring, in part, Moore J again reiterated concerns about unsettling established business expectations: "The settled expectations of the

---

73 *Myriad*, F 3d, 2012 WL 3518509.

74 Ibid *1.

75 Ibid *21.

76 Ibid.

77 Ibid.

78 Ibid.

biotechnology industry — not to mention the thousands of issued patents — cannot be taken lightly and deserve deference".[79] The judge observed: "I believe leaving intact the settled expectations of property owners is particularly important in light of the large number of property rights involved, both to isolated DNA and to purified natural products generally."[80] Moore J insisted: "Given the complicated technology and conflicting incentives at issue here, any change must come from Congress."[81]

Bryson J dissented from "the court's holding that Myriad's BRCA gene claims and its claims to gene fragments are patent-eligible."[82] The judge held:

> Although my colleagues believe our analysis of the legal question in this case should be influenced by purported expectations of the inventing community based on the PTO's past practice of issuing patents on human genes, that is in effect to give the PTO lawmaking authority that Congress has not accorded it. There is no collective right of adverse possession to intellectual property and we should not create one. Our role is to interpret the law that Congress has written in accordance with the governing precedents.[83]

Citing the *Prometheus* case as instructive, the judge noted:

> Just as a patent involving a law of nature must have an 'inventive concept' that does 'significantly more than simply describe ... natural relations,' *Mayo*, a patent involving a product of nature should have an inventive concept that involves more than merely incidental changes to the naturally occurring product.[84]

On the 30th November 2012, the Supreme Court of the United States announced that it would hear an appeal in respect of the *Myriad* case on the question, 'Are human genes patentable?' That dispute may well have a significant bearing on patents in the field of biotechnology – including those held by 23andMe Inc.

---

79 Ibid *34.

80 Ibid.

81 Ibid *36.

82 Ibid *38.

83 Ibid *47.

84 Ibid *44.

Jon Corley and Dan Vorhaus see the conflict in the *Myriad* litigation as representing a "continuing struggle to balance the benefits and costs of personalized medicine".[85] The pair commented that:

> the future of personalized medicine hinges upon the ability to strike the appropriate balance between the desire of patients, providers and payers for broad and affordable access to personalized medicine products against the demands of the corporations, investors and shareholders who require a return on the capital that must be invested to produce those very same personalized medicine products.[86]

In their view, patents are only one of the factors involved in overhauling "reimbursement regimes and regulatory structures to accommodate personalized medicine."[87]

3 Patent Landscapes

The company 23andMe Inc have filed a number of patent applications thus far in the fields of information technology and biotechnology. Such applications are best represented in tabular form (see Table 1). At the outset, it is worth observing that 23andMe Inc has a modest collection of patent applications. The company is not a well-established information technology or biotechnology or pharmaceutical drug company, with a dragon's hoard of patents in its portfolio. 23andMe Inc. is still a minnow in the marketplace. Nonetheless, the company's patent collection is worth exploring — especially given its subject matter. The company's practices raise matters about the operation of patent thresholds — such as novelty, inventive step, and utility.

---

[85] John Corley and Dan Vorhaus, "Applying Mayo to Myriad: Latest Decision Brings No New News", *Genomics Law Report* (online) 17 August 2012, <http://www.genomicslawreport.com/index.php/2012/08/17/applying-mayo-to-myriad-latest-decision-brings-no-new-news/>.

[86] Ibid.

[87] Ibid.

Table 1: 23andMe Inc.'s Patent Applications under the Patent Co-operation Treaty

Name	Pub. Date	WIPO No.	Application No.	Inventor
1. Genetic Comparisons Between Grandparents and Grandchildren	23/4/2009	WO/2009/051749	PCT/US2008/011806	Linda Avey
2. Genome Sharing	23/4/2009	WO/2009/051768	PCT/US2008/011837	Brian Lee Hawthorne
3. Family Inheritance	23/4/2009	WO/2009/051766	PCT/US2008/011833	Linda Avey
4. Processing Data from Genotyping Chips	4/3/2010	WO/2010/024894	PCT/US2009/004857	Alexander Wong
5. Gamete Donor Selection Based on Genetic Calculations	10/6/2010	WO/2010/065139	PCT/US2009/006398	Anne Wojcicki
6. Finding Relatives in a Database	8/7/2010	WO/2010/077336	PCT/US2009/006706	Lawrence Hon
7. Polymorphisms Associated with Parkinson's Disease	3/6/2011	WO/2011/065982	PCT/US2010/003071	Nicholas Eriksson
8. Finding Relatives in a Database	5/10/2011	EP 2370929	09836517	Lawrence Hon

Information accessed 1 September 2012.

As part of its research, 23andMe Inc formed a network involving the Parkinson's disease patient community — with the Michael J Fox Foundation, the National Parkinson Foundation, and the Parkinson's Institute and Clinical Centre.[88] Noting that "recent discoveries suggest that genetics plays a greater role in Parkinson's disease than was previously thought", 23andMe Inc asked: "help us understand how both genes and environment affect risk for Parkinson's Disease by joining over 5,000 people that are already part of this

[88] 23andMe Inc., *Parkinson's Disease*, above n 36.

movement."[89] 23andMe Inc has enlisted Muhammad Ali in its campaign in this particular field — with the "Give Us Your Hand" video campaign on sites such as YouTube.[90] Google's Sergey Brin — husband of 23andMe's co-founder Anne Wojcicki — has also discussed his family interest in the relationship between genetics and Parkinson's disease.[91]

On the 28 May 2012, Anne Wojcicki triumphantly announced 23andMe's first granted patent.[92] She emphasised: "23andMe has a substantial research arm with more than 20 scientists dedicated to making meaningful discoveries that will improve the lives of all of us."[93] Wojcicki explained:

> Our patent, 'Polymorphisms Associated With Parkinson's Disease' is expected to issue on Tuesday, May 29, 2012. This relates to our discovery of a variant in the SGK1 gene that may be protective against Parkinson's disease in individuals who carry the rare risk-associated LRRK2 G2019S mutation. Our patent is an important step in ensuring that we've done all we can towards successful translation of this discovery. If the follow up work we are now doing with the Scripps Research Institute and the Michael J Fox Foundation looks promising and moves towards drug development, the patent will be important for a biotech or pharmaceutical company to pursue drug development.[94]

Wojcicki emphasised that 23andMe Inc would not use the patent rights to interfere with access to genetic information by researchers or individuals: "We believe patents should not be used to obstruct research or prevent individuals from knowing what's in their genome".[95] She commented: "We believe that everyone has a right to know their genomes — their sequence of As, Ts, Cs, and Gs — and should be able to access them should they want to".[96] Wojcicki certainly recognised that there had been significant controversies over the expansion of patent law into the fields of information

---

89 Ibid.

90 23andMe Inc., *Give us Your Hand* (25 April 2012) <https://www.youtube.com/watch?feature=player_embedded&v=9B9cgyEeULU>.

91 Sergey Brin, "LRRK2", on Too, *Blogspot* (18 September 2008) <http://too.blogspot.com.au/2008/09/lrrk2.html>.

92 Anne Wojcicki, *Announcing 23andMe's First Patent*, above n 44.

93 Ibid.

94 Ibid.

95 Ibid.

96 Ibid.

technology and biotechnology: "We recognize that patents are complicated and can be controversial."[97] The decision to apply for patents was a mature, calculated decision — not the result of accident or naivety. Wojcicki emphasised: "We will continue to pursue patents that we believe will eventually benefit us all".[98] She commented that the company wished to translate its research into medical outcomes: "We want those discoveries to move from the realm of academic publishing to the world of impacting lives by preventing, treating or curing disease."[99]

In response to this announcement, there was much disquiet and distemper amongst the consumers of 23andMe Inc. The first commentator, Arturo, was disappointed and threatened to leave the service: "It is not clear to me how patents on a discovery can benefit the movement of discoveries from the realm of academic publishing to the real world of medical practice."[100] Dave Mackey asked: "Will these patents be used offensively or defensively? Will the prices of treatment increase because a single pharmaceutical company is eventually granted rights to create treatments based on this discovery? If so — then I'm not a fan."[101]

A number of commentators also denied having provided specific consent for the patenting of the research they participated in. Holly Dunsworth was shocked: "I had assumed that 23andMe was against patenting genes and felt in total cahoots all along with you guys". [102]

Stuart Hogarth wrote in a detailed response to the statement, highlighting that the statement did not necessarily match the breadth of the patent application:

---

97 Ibid.

98 Ibid.

99 Ibid.

100 Arturo, "Comment on the Announcement of 23andMe's First Patent" on Anne Wojcicki, *Announcing 23andMe's First Patent* (28 May 2012) <http://spittoon.23andme.com/news/announcing-23andmes-first-patent/#comment-84463>.

101 Dave Mackey, "Comment on the Announcement of 23andMe's First Patent" on Anne Wojcicki, *Announcing 23andMe's First Patent* (29 May 2012) <http://spittoon.23andme.com/news/announcing-23andmes-first-patent/#comment-84649>.

102 Holly Dunsworth, "Comment on the Announcement of 23andMe's First Patent" on Anne Wojcicki, *Announcing 23andMe's First Patent* (30 May 2012) <http://spittoon.23andme.com/news/announcing-23andmes-first-patent/#comment-84785>.

(1) If your intent was only to support therapeutic R&D then why does the patent cover diagnostic applications?

(2) Will you try to prevent other companies selling Parkinson's Disease tests for these polymorphisms, or, will you seek license fees from other companies selling Parkinson's Disease tests for these polymorphisms?

(3) Given your company's avowed mission to 'democratise genomics', what were the participants in the Parkinson's Disease study told about the intended commercial exploitation of discoveries arising from the study, and did you ask them what their preferences were?

(4) Given the controversy surrounding gene patenting why have you not invited discussion and debate on this issue? [103]

He observed: "If, as you frequently avow, 23andMe wants to 'democratise genomics', then this is the kind of issue on which you should be seeking feedback from your customers and the broader polity."[104] This is a pertinent point. There is dissonance between 23andMe Inc's unilateral decision to patent the research, and the rhetoric about community consultation, public participation, and democratic deliberation.

As an addendum, Anne Wojcicki made a number of responses to the discussion around the patent announcement.[105] First, she insisted: "23andMe will not prevent others from accessing their genetic data or its interpretation specific to our patents".[106] Second, Anne Wojcicki stressed that "23andMe is a business with a mission to improve lives" and that it aimed"for these discoveries to benefit everyone".[107] She commented: "We sell a service to our customers and we conduct research, on our own and with partners, that we believe will lead to better treatments, diagnostics, and prevention of disease."[108] Third, Anne Wojcicki made a commercial justification seeking patents in respect of the research. She argued: "Patents give organizations

---

[103] Stuart Hogarth, "Comment on Announcement of 23andMe's First Patent" on Anne Wojcicki, *Announcing 23andMe's First Patent* (30 May 2012) <http://spittoon.23andme.com/news/announcing-23andmes-first-patent/#comment-84732>.

[104] Ibid.

[105] Anne Wojcicki, *Announcing 23andMe's First Patent*, above n 44.

[106] Ibid.

[107] Ibid.

[108] Ibid.

researching and developing new drugs confidence that their significant investments will be commercially viable".[109] Wojcicki commented: "Often the only way a company will even think about pursuing a drug lead is if they have assurance that they can recoup their investment."[110] Such a statement is striking — given that it assumes that 23andMe Inc is intent upon doing research leading to work on pharmaceutical drugs. Finally, Wojcicki commented: "Many of you, especially in the Parkinson's community, saw this as a major milestone and the first step in potentially having a meaningful impact on the lives of Parkinson's patients."[111]

In response, there was an interesting commentary by the champion of open access, John Wilbanks — a past director Science Commons, and now a Senior Fellow at the Ewing Marion Kauffman Foundation and director of the Consent to Research Project.[112] He responded, with the question: "Why on earth did you expect anything else?"[113] Wilbanks commented further:

> Genotyping is a commodity service. That's not 23andme's business. Their business is selling the anonymized data to those who wish to use it for research purposes and in doing their own research on the data … Companies exist not just to provide you with neat services, but to make money. And patenting genes is part of how companies in the drug and health space make money.[114]

Wilbanks questioned the closed nature of the company: "23andMe wants to be at the center — the czar — of a closed personalized medicine revolution".[115] He noted that 23andMe "want to build a walled garden so big that no one person notices the walls — unless that person wants to do something without getting permission from 23andme, like new research, or starting a company."[116] Wilbanks also argued that the case showed the need

---

109 Ibid.

110 Ibid.

111 Ibid.

112 John Wilbanks, "23andMe: It's in Their Nature" on *Del-Fi* (31 May 2012) <http://del-fi.org/post/24133199134/23andme-its-in-their-nature>. See also Helen Walters, "Unreasonable People Unite: John Wilbanks at TEDGlobal2012" on *TED Blog* (29 June 2012) <http://blog.ted.com/2012/06/29/unreasonable-people-unite-john-wilbanks-at-tedglobal-2012/>.

113 Ibid.

114 Ibid.

115 Ibid.

116 Ibid.

for open systems. He encouraged a different model of genetics research based upon Consent to Research.[117]

In the *Genomics Law Report*, Dan Vorhaus commented[118] on the furore surrounding the announcement: "Taking a step back, it is hardly surprising that 23andMe appears to be unsure, at this point in time, as to how exactly it intends to use its newly issued patent."[119] Vorhaus also granted: "It is also not surprising that the company is proud of earning its first patent, which represents an important and validating milestone for a young company."[120] Vorhaus commented that 23andMe Inc's patent application was "a relatively pedestrian diagnostic method patent that, if it ever becomes valuable enough to be challenged, might not survive the challenge".[121] He noted, though, the "company's most valuable asset" was "an engaged, enthusiastic and growing community of customers-qua-research-participants who, provided 23andMe can keep from alienating too many of them, represent something much more unique, and inventive, than US Patent number 8,187,811".[122]

In response, Darren Smyth noted that "the comment in the *Genomics Law Report* sought to draw comfort from the fact that the patent had been narrowed during prosecution from what had originally been applied for."[123] He observed: "This was taken as evidence that the examination system was working, and that the *Myriad* decision of the Court of Appeals for the Federal Circuit and the *Prometheus* decision of the Supreme Court had been applied."[124] Smyth argued: "Review of the actual prosecution history shows that the narrowing of the claims was for reasons of restriction practice (a formal procedure designed to limit a patent to a single invention) and nothing to do with substantive patentability".[125] He comments that the "claims in US

---

[117] Consent to Research (1 September 2012) <http://weconsent.us/>.

[118] Dan Vorhaus, "Patenting and Personal Genomics: 23andMe Receives its First Patent, and Plenty of Questions", *Genomics Law Report* (online) 1 June 2012, <http://www.genomicslawreport.com/index.php/2012/06/01/patenting-and-personal-genomics-23andme-receives-its-first-patent-and-plenty-of-questions/>.

[119] Ibid.

[120] Ibid.

[121] Ibid.

[122] Ibid.

[123] Darren Smyth, "Does Patenting Alienate Customers? 23andMe gets first US patent" on *IPKat*, (11 June 2012) <http://ipkitten.blogspot.com.au/2012/06/does-patenting-alienate-customers.html>.

[124] Ibid.

[125] Ibid.

8187811 in fact seem precisely the type that might be in trouble following the extraordinary Supreme Court decision in *Prometheus*".[126]

It should be noted that it remains uncertain how 23andMe Inc plans to exploit its new patent in respect of "Polymorphisms Associated With Parkinson's Disease". The management of the patent and licensing will have an important impact upon both community and industry perceptions of the company. 23andMe Inc's patent may well be opposed — if the company ever engages in strict exclusive licensing or aggressive litigation. At this stage, though, the patent strategy of 23andMe Inc remains inchoate.

Otherwise, 23andMe Inc has struggled thus far with its patent applications. An examination of the reports of the international searching authorities under the *Patent Cooperation Treaty* reveals that Patent Offices have queried whether the claims of the other patent applications are obvious.[127] In light of the decision of the Supreme Court of the United States in *KSR v Teleflex*,[128] and its application in *In Re Kubin*,[129] 23andMe Inc would appear to be finding it hard to demonstrate that its patent applications represent novel, inventive, and useful inventions. Despite all the media attention lavished on 23andMe Inc for being a pioneer of genetic testing, the company has found it difficult thus far to convince patent offices that its research is inventive, compared to the prior art of existing patents and scientific publications.

4 Patent Law, Informed Consent and Benefit-Sharing

In a chapter in *Lessons from the Identity Trail*, Marsha Hanen reflects that

> the increased use of genetic information in medical contexts raises questions about who decides on the collection of genetic material and applications of genetic technology and what safeguards need to be in place to guard against errors of fact or interpretation and poor decisions that could be harmful to individuals or groups.[130]

---

126 Ibid.

127 A search of Patentscope reveals the reports of International Searching Authorities in respect of 23andMe's patent applications: World Intellectual Property Organisation, *Patentscope* (1 September 2012) <http://patentscope.wipo.int>.

128 *KSR v Teleflex* 550 US 398 (2007).

129 *In Re Kubin* 561 F 3d 1351 (2009).

130 Marsha Hanen, "Genetic Technologies and Medicine: Privacy, Identity, and Informed Consent" in Ian Kerr, Valerie Steeves and Carole Lucock (eds), *Lessons from the Identity Trail: Anonymity, Privacy and Identity in a Networked Society* (Oxford University Press, 2008) 173, 189.

She comments that "informed consent plays a major role, because it represents people's ability to make autonomous decisions about their lives".[131] She reflects that

> such decisions may be different for different people, so it is important that the framework within which decisions are made allows for such variations, and recognizes that the groups to which people belong, whether through their choice or not, play a significant role in how their medical care will develop.[132]

There has long been a concern about the inter-relationship between patent law, informed consent, and benefit-sharing in a number of contexts: access to genetic resources;[133] plant genetic resources;[134] biomedical research;[135] and scientific research involving Indigenous communities.[136] There have been a number of legal conflicts in this area.

In the matter of *Moore v the Regents of the University of California*, John Moore objected to a patent being grant in respect of a cell line, without his consent.[137] After much litigation, the Supreme Court of Californian considered the matter. For the majority, Panelli J held that Moore only had a right to be informed about the intent to develop a cell line and the potential commercial interests of the clinician researchers. Mosk J dissented and denied the majority's view that the patent cut off all Moore's rights to share in the proceeds of the exploitation of the cell line derived from his own body tissue.

---

131 Ibid 190.

132 Ibid.

133 Daniel Robinson, *Confronting Biopiracy: Challenges, Cases and International Debates* (Earthscan, 2010); and Charles Lawson, *Regulating Genetic Resources: Access and Benefit-Sharing in International Law* (Edward Elgar, 2012).

134 Geoffrey Tansey and Tasmin Rajotte, *The Future Control of Food: A Guide to International Negotiations and Rules on Intellectual Property, Biodiversity and Food Security* (Earthscan, 2008).

135 Richard Gold and Bartha Knoppers (eds), *Biotechnology IP and Ethics*, (LexisNexis Canada, 2009).

136 Rachel Wynberg, Roger Chennells and Doris Schroeder (eds), *Indigenous Peoples, Consent and Benefit Sharing: Lessons from the San-Hoodia Case* (Springer, 2009).

137 *Moore v Regents of University of California*, 249 Cal Rptr 494 (Cal App 2 Dist Jul 21, 1988) (NO B021195); *Moore v Regents of University of California*, 252 Cal Rptr 816 (Cal Nov 10, 1988) (NO S006987); *Moore v Regents of University of California*, 271 Cal Rptr 146 (Cal Jul 09, 1990) (NO S006987), rehearing denied (Aug 30, 1990); and *Moore v Regents of University of California* 499 US 936 (US Cal Mar 25, 1991) (NO 90-1037).

The case of *Greenberg v Miami Children's Hospital* featured much debate as to whether the granting of patent rights in respect of genetic research should be conditional upon the informed consent of patients.[138] In 1997, Reuben Matalon and his employer, the Miami Children's Hospital, obtained a patent on the gene related to the Canavan disease, and an accompanying genetic test. The law offices of Chicago-Kent College of Law filed a law suit against the Miami Children's Hospital on behalf of participants in respect of the research including three families, the National Tay Sachs and Allied Diseases Association, and Dor Yeshorim. The law offices filed a six-count complaint against the hospital and Matalan, asserting the following causes of action: lack of informed consent; breach of fiduciary duty; unjust enrichment; fraudulent concealment; conversion; and misappropriation of trade secrets. They sought an injunction restraining the defendants from enforcing their patent rights, damages in respect of the patent royalties, and the recovery of financial contributions made to benefit the research. The judge held only the unjust enrichment claim could proceed. In the end, the parties finally reached a settlement in the case in 2003 allowing for the free use of the Canavan gene in research to cure Canavan disease.

In 2004, members of the Havasupai tribe filed two lawsuits against Arizona State University, the Arizona State University Institutional Review Board, the Arizona Board of Regents, and three researchers.[139] The group alleged that researchers collected 400 blood samples, and undertook additional unauthorised research on those samples regarding schizophrenia, inbreeding and population migration. In 2010, there was a settlement of the dispute.[140] As part of this settlement, the university's Board of Regents agreed to pay $US700 000 to 41 of the tribe's members, return the blood samples and provide other forms of assistance to the Havasupai Tribe.

In 2009, five parents filed a federal lawsuit in San Antonio US District Court against the Texas Department of State Health Services, claiming they had unlawfully collected blood samples from their children at time of birth and

---

[138] *Greenberg v Miami Children's Hospital* 264 F Supp 2d 1064 (2003); and Matthew Rimmer, "Miami Heat: Patent Law, Informed Consent, and Benefit-Sharing" (2006) 3 *Journal of International Biotechnology Law*, 177.

[139] *Tilousi v Arizona State University*, Case No CV2004-0115 (Ariz Sup Ct, 2004); *Havasupai Tribe v Arizona State University*, Case No CV2004-0146 (Ariz Sup Ct, 2004); and Matthew Rimmer, "The Genographic Project: Traditional Knowledge and Population Genetics" (2007) 11(2) *Australian Indigenous Law Review*, 33.

[140] Amy Harmon, "Indian Tribe Wins Fight to Limit Research of its DNA", *New York Times* (online) 21 April 2010, <http://www.nytimes.com/2010/04/22/us/22dna.html?_r=1&hp=&pagewanted=all>.

stored those samples indefinitely for undisclosed research purposes, without plaintiffs' knowledge or consent.[141] In 2010, there was a settlement of this case.[142] The Texas authorities observed: "As a result of this settlement, DSHS will destroy all bloodspot cards received by the department before May 27, 2009".[143] They promised: "We will continue to be very sensitive to the privacy concerns of parents and the confidentiality of all medical information."[144]

In this context, it is worth considering how 23andMe Inc have addressed the issue of the relationship between patent law, informed consent, and benefit-sharing.

23andMe Inc's consent document has gone through a number of revisions and iterations. The new consent document developed by 23andMe Inc takes the form of a research participation agreement.[145] In bold lettering, the consent document stresses:

> By participating in this study, you are agreeing to allow us to use your genetic data, survey responses and any other non-identifying data for research on genetic markers associated with traits, disease and other physical conditions. We will remove the Registration Information (information you provided about yourself when registering for and/or purchasing our Services, such as name, email, address, user ID and password, and payment information) that can identify you prior to using the data for research, in order to help protect your privacy as much as possible.[146]

The document notes: "The research consists of using your genetic data and/or survey responses and other non-identifying personal information to discover genetic and non-genetic markers related to traits, diseases, and other physical conditions".[147] It emphasises the need for full and proper informed consent: "In order for this research to receive approval by an external ethical

---

141 *Beleno v Texas Department of Health Services*, 5:2009cv00188 (Texas Western District Court, 2009).

142 Jay Root, "Texas officials agree to destroy babies" Blood samples after settling lawsuit', *The Dallas Morning News* (online) 14 February 2010, <http://www.texascivilrightsproject.org/?p=1822>.

143 Ibid.

144 Ibid.

145 23andMe Inc., *Consent Document* (1 September 2012) <https://www.23andme.com/about/consent/>.

146 Ibid.

147 Ibid.

review board, people must give informed consent before joining."[148] The document stresses: "*Your data will be used to discover links between genetic and non-genetic markers and a variety of traits, diseases, and other physical conditions.*"[149] However, the study notes: "This study will not cover potentially sensitive topics such as sexual orientation, illicit drug use or other illegal behavior, or HIV/AIDS status."[150] The document emphasises: "If 23andMe conducts future studies on these topics, 23andMe will seek specific ethical approval for the projects and you will be asked to provide separate informed consent for use of your information in research on those topics."[151]

In her statement about 23andMe Inc's first patent, Wojcicki emphasised: "We will continue to pursue patents that we believe will eventually benefit us all".[152] However, a close examination of the terms of service reveals that customers will only receive an indirect benefit from participation in research.

Strikingly, 23andMe Inc disavow any obligation to engage in benefit-sharing with research participants:

> One of 23andMe's missions is to make meaningful scientific contributions by enabling its customers to participate directly in genetic research. If 23andMe publishes study results in peer-reviewed journals, there may be an indirect benefit to you as scientific knowledge increases and/or new drugs or tests are developed. However, you will not receive any direct compensation or other benefits from 23andMe or researchers for participating in research. If 23andMe develops intellectual property and/or commercializes products or services, directly or indirectly, based on the results of this study, you will not receive any compensation.[153]

This stance is controversial — given a number of cases in the United States in which research participants have demanded meaningful benefit-sharing in respect of genetic research.

In the *Nature News Blog*, Monya Baker commented that there was consumer and customer distress about the announcement:

---

148 Ibid.

149 Ibid.

150 Ibid.

151 Ibid.

152 Anne Wojcicki, *Announcing 23andMe's First Patent*, above n 44.

153 23andMe Inc., *Consent Document*, above n 145.

> The post generated about a score of comments in the first two days, mainly from individuals asking how 23andMe intended to enforce its patent. One post also asks whether participants in the study were told of potential commercial impact, why 23andMe did not solicit feedback from customers, and why 23andMe claimed diagnostic use if its intention was drug development.[154]

This raises the question of whether there was proper, full, and informed consent regarding the research participants consenting to a patent application.

It was striking that a number of research participants objected to 23andMe Inc claiming a patent in respect of its research on Parkinson's disease. Holly Dunsworth noted: "When we agreed to the terms of service and then when some of us consented to participate in research, were we consenting to that research being used to patent genes? What's the language that covers that use of our data? I can't find it."[155] She observed: "If I'd known you might go that route with my data, I'm not sure I would have answered any surveys."[156]

Such reactions should not come as a surprise to 23andMe Inc. In an insightful analysis, Dr Megan Allyse, a Post Doctoral Fellow at the Stanford Center for Biomedical Ethics, at Stanford University, commented: "There is a considerable history in the USA of protest when a person's genetic information is used to enrich or benefit someone else without their knowledge."[157] She observes:

> Many people genuinely want to contribute to the progress of medical research but the process of biomedical research is heavily predicated on trust. Trust that scientists and doctors are concerned with the public interest and that they are capable of dealing fairly with research participants who entrust to them their genetic information. Belated discoveries that expectations and reality do not mesh engender outrage, feelings of betrayal, and the possibility

---

[154] Monya Baker, "Personal-Genetics Company Patent Raises Hackles" on *Nature News Blog* (13 May 2012) <http://blogs.nature.com/news/2012/05/personal-genetics-company-patent-raises-hackles.html>.

[155] Holly Dunsworth, "Comment on the Announcement of 23andMe's First Patent" on Anne Wojcicki, *Announcing 23andMe's First Patent* (30 May 2012) <http://spittoon.23andme.com/news/announcing-23andmes-first-patent/#comment-84785>.

[156] Ibid.

[157] Megan Allyse, "23 and You? Genome research, Direct-to-consumer Genetics and Informed Consent" *BioNews* (online) 9 July 2012, <http://www.bionews.org.uk/page_156806.asp>.

> that participants will begin to avoid involvement in future research.[158]

Allyse comments that the online consent form provides inadequate disclosure, because it "does not mention the word 'patent', nor state how it intends to defend its intellectual property rights against researchers or pharmaceutical companies".[159] She comments:

> As customer reaction to its patent announcement seems to indicate, more attention needs to be devoted to ensuring that customers of commercial genetics companies (of any kind) are fully aware if the company intends to retain and conduct research on customer samples and potentially profit from the results.[160]

Allyse concludes:

> There are practical issues to consider as well — biomedical companies who fail to ensure honest and open communication with their customers about their true intentions in using genetic information, may find it increasingly difficult to build up the kind of large biobanks they need to do genuinely useful research.[161]

The ETC Group has been a harsh critic of 23andMe Inc, giving the company a "Captain Cook Award for Biopiracy" for "convincing consumers to pay for genetic testing and hand over DNA samples and personal medical information, which the company plans to sell to medical researchers".[162] In its view, the lack of adequate protection in respect of informed consent and benefit-sharing is tantamount to 'biopiracy'. Such an accusation of biopiracy does seem somewhat extreme, in my view, given the evidence. As discussed, 23andMe Inc is still a youthful company — it is hard to judge its conduct, particularly as regards to patent exploitation at this stage.

Nonetheless, the model of informed consent and benefit-sharing employed by 23andMe Inc falls short of international best practice.

The *UNESCO Universal Declaration on Bioethics and Human Rights* 2005, places particular emphasis upon informed consent and benefit sharing in the context

---

158 Ibid.

159 Ibid.

160 Ibid.

161 Ibid.

162 The ETC Group, *Captain Hook Awards for Biopiracy* 2008, above n 41.

of biomedical research.[163] Article 6(1) provides that "Any preventive, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free and informed consent of the person concerned, based on adequate information."[164] Moreover, it notes: "The consent should, where appropriate, be express and may be withdrawn by the person concerned at any time and for any reason without disadvantage or prejudice."[165] Similarly, Article 6(2) emphasises: "Scientific research should only be carried out with the prior, free, express and informed consent of the person concerned."[166] Article 6(3) observes: "In appropriate cases of research carried out on a group of persons or a community, additional agreement of the legal representatives of the group or community concerned may be sought."[167]

Article 8 stresses the need to pay due regard to vulnerable individuals and communities, emphasising: "In applying and advancing scientific knowledge, medical practice and associated technologies, human vulnerability should be taken into account."[168] Moreover, "[i]ndividuals and groups of special vulnerability should be protected and the personal integrity of such individuals respected."[169]

Article 15(1) provides that "benefits resulting from any scientific research and its applications should be shared with society as a whole and within the international community, in particular with developing countries."[170] The *Declaration* observes that benefits may include special assistance to research participants; access to quality health care; provision of new diagnostic and therapeutic modalities or products stemming from research; support for health services; access to scientific and technological knowledge; and capacity-building facilities for research purposes. However, the *Declaration* also warns that "benefits should not constitute improper inducements to participate in research."[171]

---

[163] *UNESCO Universal Declaration on Bioethics and Human Rights* 2005, (Paris: UNESCO) signed 19 October 2005, <http://portal.unesco.org/en/ev.php-URL_ID=31058&URL_DO=DO_TOPIC&URL_SECTION=201.html>.

[164] Ibid.

[165] Ibid art 6.

[166] Ibid.

[167] Ibid.

[168] Ibid art 8.

[169] Ibid.

[170] Ibid art 15.

[171] Ibid.

5 Patent Infringement

Julia Carbone and her colleagues observe that "biotech patents continue to generate controversy — particularly human gene patents used in diagnostic testing".[172]

A number of commentators have highlighted issues surrounding patent thickets in the field of genetics.[173] Michael Heller and Rebecca Eisenberg have written about the problem of the "tragedy of the anticommons", in which a proliferation of patent rights creates difficulties in accessing inventions in the field of genetics.[174]

Robert Cook-Deegan has painted a grim picture of patents and genetic testing. He observes that there is great uncertainty about the existence and extent of patent rights in the field:

> Promising new methods for full-genome analysis might or might not face patent infringement liability. Some assert that patent rights have hindered research, although evidence of such harm is not compelling, but the evidence that patent rights have fostered diagnostic innovation is even weaker. Many laboratories have gotten genetic tests to market without patent rights. Those with exclusive rights have rarely, if ever, been first to market. Companies that became sole U.S. providers did so by clearing the market of competitors. This is not unique to gene patents, but it creates intense controversy. Patent rights could, however, prove crucial to product development if payers demand evidence of clinical utility or if the U.S. Food and Drug Administration begins to regulate genetic tests, because developing such tests would suddenly become more costly and time-consuming, and a patent incentive could help induce private investment.[175]

---

[172] Julia Carbone et al, "DNA Patents and Diagnostics: Not a Pretty Picture" (2010) 28 *Nature Biotechnology* 784.

[173] Arti Rai (ed), *Intellectual Property Law and Biotechnology*, (Edward Elgar, 2011).

[174] Michael Heller, "The Tragedy of the Anticommons: Property in the Transition from Marx to Markets" (1998) 111(3) *Harvard Law Review* 621; Michael Heller, and Rebecca Eisenberg, "Can Patents Deter Innovation? The Anticommons in Biomedical Research" (1998) 280 *Science* 698; Michael Heller, *The Gridlock Economy: How Too Much Ownership Wrecks Markets, Stops Innovation and Costs Lives* (Basic Books, 2008); and Michael Heller (ed), *Commons and Anticommons* (vols I and II, Edward Elgar, 2010).

[175] Robert Cook-Deegan, "Gene Patents: The Shadow of Uncertainty" (2011) 331(6019) *Science* 873-4.

He concludes: "Reducing the uncertainty surrounding diagnostic uses of gene patents is important."[176]

So, as well as being a patent applicant, 23andMe Inc also faces the prospect of being a defendant to possible actions in respect of patent infringement.

There has been some speculation as to whether the genotyping of BRCA1 and BRCA2 may infringe patents held by the Utah biotechnology company, Myriad Genetics.

23andMe Inc comment that Breast and Ovarian Cancer is one of the diseases that the company analyses.[177] The company notes:

> Hundreds of mutations have been reported in the BRCA1 and BRCA2 genes. 23andMe provides data for only three specific cancer-associated mutations that are found mainly in people with Ashkenazi Jewish ancestry — 185delAG (DD or DI at i4000377) in BRCA1, 5382insC in BRCA1 (II or DI at i4000378), and 6174delT in BRCA2 (DD or DI at i4000379). Unlike most of the genetic variants we report, these mutations are not due to one-letter changes in the DNA sequence, but the addition or deletion of one or more letters. Together these mutations account for 80-90% of all hereditary breast and ovarian cancer cases in this ethnic group.[178]

The *Pharmacogenomics Reporter* commented: "23andMe's new offering also raises questions about patent rights".[179] It noted: "23andMe did not respond to questions about the status of the patents covering the BRCA SNPs it uses".[180] The magazine noted: "Myriad is widely reputed throughout the genetic testing industry for aggressively defending its BRCA patents and charging high licensing fees to laboratories that want to offer such testing".[181]

Steven Murphy, founder of Helix Health, commented: "The real question lies not in the sequence itself, it lies in the chemical reactions required to create a new molecule which then is converted to something which can be

---

176 Ibid.

177 23andMe Inc., *BRCA Cancer Mutations* (Selected) (1 September 2012) <https://www.23andme.com/health/BRCA-Cancer/>.

178 Ibid.

179 Tuma Ray, "23andMe Adds BRCA Breast/Ovarian Cancer Testing to Service", *The Pharmacogenomics Reporter* (online) 18 February 2009, [article no longer available on the internet; on file with author].

180 Ibid.

181 Ibid.

interpreted."[182] He noted that Myriad Genetics "created all sorts of patents around the sequences including how to extract the sequence and obtain the information".[183] This could be particularly problematic for the Laboratory Corporation of America, which performs the genotyping for 23andMe's service. 'So whether or not there is a sequence violation, LabCorp could face an extraction violation'.[184]

The Australian company Genetic Technologies Limited has demanded licence fees and brought patent infringement actions in respect of a wide range of forms of genetic testing.[185] 23andMe Inc could be a potential target for litigation, given its activities.

In the United States, 23andMe Inc has little protection in terms of patent defences and exceptions. The defence of experimental use has been interpreted very narrowly by the United States courts in a number of matters.[186] In the case of *Third Wave Technologies v Stratagene Corporation*, the owner of patents related to cleavage of nucleic acids sued competitor for patent infringement.[187] The judge considered the scope of the defence of experimental use in the United States:

> Although defendant's testing of its products might seem to fall under the experimental use exception, the Court of Appeals for the Federal Circuit has held that the scope of the exception is markedly narrow and that a defendant bears the burden of proving its applicability. To qualify for the exception, a defendant's actions must be performed 'for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry.' Actions do not qualify for the experimental use defense when undertaken in the 'guise of scientific inquiry' if there are 'definite, cognizable, and not insubstantial commercial purposes' motivating them. None of defendant's evidence shows that its actions fall into the realm of idle curiosity. To the contrary, defendant's assertion that it intends to obtain FDA approval in order to market its diagnostic assays

182 Ibid.

183 Ibid.

184 Ibid.

185 Matthew Rimmer, "The Alchemy of Junk: Patent Law and Non-Coding DNA" (2006) 3(2) *The University of Ottawa Law and Technology Journal* 539.

186 *Madey v Duke University* 307 F 3d 1351 (2002).

187 *Third Wave Technologies v Stratagene Corporation* 381 F Supp 2d 891 (2005).

> belies any notion that its actions were without commercial motivation.[188]

The Supreme Court of the United States, though, has taken a broader view of the defence of safe harbour in relation to regulatory activities for pharmaceutical drugs.[189] Other jurisdictions have sought to engage in patent law reform in respect of patent exceptions. Notably, the Australian Government established a statutory defence of experimental use under the *Intellectual Property Laws Amendment (Raising the Bar) Act 2012* (Cth).

W Nicholson Price has argued in the *Cardozo Law Review* that "policy options to shield diagnostic testing from infringement lawsuits are likely to smooth the way for personalized medicine". [190] He suggests that such policy options,

> include a research exemption for diagnostic testing (which would allow the improvement of tests, but not solve the issue of Whole-Genome Sequencing), a generalized exemption from infringement for all diagnostic use (which would upset companies like Myriad but open wide the path for personalized medicine), and mandatory gene-patent clearinghouses, which could eliminate the problem of holdouts and provide for at least some revenue sharing.[191]

Some commentators have explored the use of collaborative licensing models to deal with gene patents. In a collection, Geertrui Van Overwalle explores patent pools, clearinghouses, open source models and liability regimes.[192] She observes in the conclusion to the collection:

> Expediting access and use of genetic inventions may well be best served by the design of (1) contractual, collaborative models (2) which are based on pre-existence of IP rights, (3) which are economically viable and commercially sustainable without overriding social motives, (4) thus restoring trust in the patent system and offering an alternative for ignoring the patent norm.[193]

---

188 Ibid.

189 *Merck KGaA v Integra Lifesciences I, Ltd* 545 US 193 (2005).

190 W Nicholson Price II, "Unblocked Future: Why Gene Patents Won't Hinder Whole Genome Sequencing and Personalized Medicine" (2012) 33 *Cardozo Law Review* 1601.

191 Ibid 1630.

192 Geertrui Van Overwalle (ed), *Gene Patents and Collaborative Licensing Models: Patent Pools, Clearinghouses, Open Source Models and Liability Regimes* (Cambridge University Press, 2009).

193 Ibid 384.

Geertrui Van Overwalle considers what might be ideal in terms of collaborative arrangements:

> The optimal patent pool model in diagnostic genetics may well be a patent platform where individual patent pools are narrowly defined around single genes comprising vertically oriented patents, thereby providing access to horizontally oriented thickets … The optimal clearinghouse might well be a fully fledged patent royalty collection clearinghouse … As to open source models, translating open source from software to genetics and introducing copyleft-style open source licences in relation to diagnostic tests based on gene patents seems also feasible, but might not be unproblematic.[194]

In the context of 23andMe Inc, there would be countervailing considerations — it may require access to others' genetic testing patents, but at the same time, it would be seeking revenue in respect of its own emerging patent portfolio. Given its professed collaborative ethos, 23andMe Inc would benefit from collaborative arrangements.

It has been difficult to invoke compulsory licensing and crown use provisions in battles over patents and genetic testing, thus far. A number of commentators have advocated law reform to allow for the flexible use of compulsory licensing in respect of gene patents. Co-discoverer of the double helix structure of DNA and Nobel Laureate, James D Watson, has contended that compulsory licensing for gene patents is a good fallback option:

> Compulsory licensing ensures that scientists and researchers will have reasonable access to human genes and genetic information. Compulsory licensing will attenuate the negative consequences of the genetic monopolies created by patents. Implementing a compulsory license protocol will also reduce the risk that a patient is denied access to life-saving medicines and technologies using human genes and the information encoded in the genes.[195]

Bruce Arnold also maintains that compulsory licensing would be a useful mechanism to facilitate access to gene patents: "In an era where the patent-

---

[194] Ibid 454.

[195] James D Watson, "Brief for Amicus Curiae James D. Watson in Support of Neither Party" in *Association for Molecular Pathology v United States Patent and Trademark Office and Myriad Genetics Inc.* (12 June 2012) <http://keionline.org/sites/default/files/Amicus_james_d__watson_AMPvUSPTO_remand.pdf>.

protected life sciences are increasingly important, that would be a positive outcome."[196]

6 Conclusion

This article has considered the policy challenges posed by 23andMe Inc to patent law, bioethics and human rights. After many years of stalled attempts and efforts, the United States Congress passed *The America Invents Act 2011* (US).[197] President Barack Obama enthused:

> I am pleased to sign the *America Invents Act*. This much-needed reform will speed up the patent process so that innovators and entrepreneurs can turn a new invention into a business as quickly as possible. I'm also announcing even more steps today that will help bring these inventions to market faster and create jobs. Here in America, our creativity has always set us apart, and in order to continue to grow our economy, we need to encourage that spirit wherever we find it.[198]

However, the specific debates over medical patents, gene patents, and information technology patents remain as polarised as ever in the legislative arena. Industry associations have pushed for strong intellectual property rights in respect of inventions in the fields of medicine, biotechnology, and information technology. Against the advocacy for such a militant form of intellectual property maximalism, various opponents have called for prohibitions in particular controversial subject matter fields — such as methods of human treatment, gene patents, software patents, and business method patents. In the face of such a divisive debate, there has been a call for nuanced patent law reform.[199]

---

[196] Bruce Arnold, "Is it Time to Unlock Biotech Patents?" *The Conversation* (online) 10 July 2012 <http://theconversation.edu.au/is-it-time-to-unlock-biotech-patents-8034>.

[197] *Leahy-Smith America Invents Act*, Pub L No 112-29, 125 Stat 284, 325 (2011).

[198] The White House, "President Obama Signs America Invents Act, Overhauling the Patent System to Stimulate Economic Growth, and Announces New Steps to Help Entrepreneurs Create Jobs" (Press Release, 16 September 2011) <http://www.whitehouse.gov/the-press-office/2011/09/16/president-obama-signs-america-invents-act-overhauling-patent-system-stim>.

[199] Isabelle Huys, Gert Matthijs and Geertrui Van Overwalle, "The Fate and Future of Patents on Human Genes and Genetic Diagnostic Methods" (2012) 13 *Nature Reviews Genetics* 441.

The case study of 23andMe Inc has raised important issues for patent law, policy, and practice in respect of lifestyle genetics and personalised medicine. Particularly important are matters of patentable subject matter; the threshold standards for patent examination; the requirement of informed consent and benefit-sharing; and questions of patent infringement and exceptions. In his fascinating 2012 book, *Identity and Invention*, Shubha Ghosh explores the culture and ethics of patent law and personalised medicine.[200] He comments upon the challenges posed by the new scientific fields:

> Whatever one's perspective on patenting, personalized medicine, or innovation, one has to recognize that we are at a watershed in how medical treatment and diagnosis will be delivered and structured. Medical practitioners will be able to agglomerate information about a person's genetic and biomedical history in order to tailor diagnoses and therapies that can cure or at least curb diseases. Medical information is as much a part of the information age as the Internet, software, and social networking …
>
> As the many patents and inventions discussed show, trends in innovation in the area of personalized medicine will increase. These inventions will allow for more sophisticated identification of disease and tailoring of treatment as well as methods for managing and obfuscating this information. The patent system plays a role in these paths of innovation. Reform of patent law, and intellectual property more generally, is no longer a specialized interest. Intellectual property affects what products and services we have access to and on what terms. In no area is this point more salient than in the area of patents that affect heath care.[201]

The Supreme Court of the United States hearing on *Myriad* will provide an important guide to the future treatment of patent law, genetic testing, and personalised medicine.[202] The case study of 23andMe Inc highlights the need for an integrated approach to lifestyle regulations and personalised medicine — which takes into account patent law, bioethics and human rights, and

---

200 Shubha Ghosh, *Identity and Invention: The Culture and Ethics of Personalized Medicine Patenting* (Cambridge University Press, 2012).

201 Ibid 279-280.

202 *Association for Molecular Pathology v Myriad Genetics*, No. 12-398 (2012) <http://www.scotusblog.com/case-files/cases/association-for-molecular-pathology-v-myriad-genetics-inc/>.

health regulation. There is a need for further research into the regulation of direct-to-consumer marketing of genetic testing.[203]

[203] Presidential Commission for the Study of Bioethical Issues, *Privacy and Progress in Whole Genome Sequencing*, (The White House, 2012) <http://www.bioethics.gov/cms/node/764>.