

# No one 'owns' the genome: The United States Supreme Court rules that human DNA cannot be patented

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Modern biotechnological innovation has been fertile ground for profound and critical debate – and policy consideration – regarding its associated legal, social, ethical and moral issues. Patent laws exist to encourage the progress of science, innovation and discovery, but battle to provide a clear and stable regulatory framework. In a decision that looks set to shape the future, the United States Supreme Court recently ruled that isolated human DNA cannot be patented. It is argued that this decision will have a potentially serious negative impact on future biotechnological innovation and discovery, and that the more expansive European approach to 'gene patenting' is sounder and enables progress.

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A *TIME* magazine cover story, entitled 'The Angelina Effect', published in May 2013, reported that famous and influential actress Angelina Jolie had undergone an elective double mastectomy, in the hope of reducing her genetically high risk of breast cancer. The probability that she would develop breast cancer was estimated at a staggering 87%. The magazine regarded the 'revelation' as 'so arresting' that it called it a 'cultural and medical earthquake'.<sup>[1]</sup> Jolie's announcement was quickly followed by a landmark decision by the United States' Supreme Court in June 2013. It dealt with the patenting of the very genes for which Jolie had been tested, and which ultimately led her to have the preventive procedure. These, by now much publicised, genes, which correlate to the significantly increased risk of hereditary breast and ovarian cancer, are commonly known as the BRCA1 and BRCA2 genes.

The term 'gene patent' is often used but mostly misunderstood. It should first be placed in its proper context, albeit a simplistic context from both legal and scientific perspectives. The term is something of a misnomer: it is important to make it clear that a gene as it exists in nature, such as a naturally occurring gene in the human body, cannot literally be patented.<sup>[2]</sup> Patent laws typically exclude discoveries from patentability.<sup>[3,4]</sup> Hence, the subjects of 'gene patents' are, generally, the modification of a naturally occurring genetic sequence, or the development of a process for diagnosis or treatment based on naturally occurring genetic information – that is, the processes and products created in laboratories through human effort and ingenuity.<sup>[5]</sup>

It is also a misconception that the granting of a 'gene patent' can be equated to 'ownership', in that a 'patented gene' would in all respects be off limits to anyone else to study or use. A patent right is far more restricted: it merely provides a negative right to exclude others from performing certain actions in relation to the product or process, which should in principle be strictly defined in the patent application and the patent itself.<sup>[2]</sup> The South African Patents Act, for example, states in Section 45(1): 'The effect of a patent shall be to grant to the

patentee ... the right to exclude other persons from making, using, exercising, disposing or offering to dispose of, or importing the invention, so that he or she shall have and enjoy the whole profit and advantage accruing by reason of the invention'.<sup>[3]</sup>

## The landmark US Supreme Court Decision

In the much-awaited decision of *Association for Molecular Pathology v. Myriad Genetics Inc.*,<sup>[6]</sup> the United States Supreme Court endeavoured to clarify whether a naturally occurring segment of DNA is eligible for patent, in terms of United States patent law, by virtue of the fact that the segment had been isolated from the rest of the human genome. The respondent was Myriad Genetics, a leading molecular diagnostic company which dedicates itself to the discovery and commercialisation of transformative tests which assess a person's risk of developing a disease, disease progression, and recurrence,<sup>[7]</sup> and had made a valuable medical breakthrough. Myriad discovered the precise location and sequence of the BRCA1 and BRCA2 genes on the human genome. Changes (so-called mutations) in the genetic sequence of these two genes can substantially increase a person's risk of developing breast and ovarian cancer. Armed with the knowledge of where these genes were located, Myriad developed diagnostic tests that can be used to detect mutations in the BRCA1 and BRCA2 genes, and thus assess whether a person faces this increased risk.<sup>[6]</sup> By July 2013, one of Myriad's world leading genetic tests, called BRACAnalysis, had been used by more than 1 million women to assess their risk of hereditary breast and ovarian cancer.<sup>[7]</sup>

After finding the location and sequence of these two genes, Myriad managed to obtain a number of patents which, if valid, would give Myriad not only the exclusive right to isolate a person's BRCA1 and BRCA2 genes, but also the exclusive right to synthetically create BRCA-complementary DNA (so-called cDNA). Myriad held that it was its exclusive right to manipulate BRCA DNA by the use of either of these methods, and that it could exclude others from doing so.

After Myriad made its breakthrough discovery of the two BRCA genes, other entities also provided similar genetic testing services. One person who regularly used genetic testing for his patients was the petitioner in the Supreme Court case at hand, Dr Harry Ostrer. He routinely sent samples of BRCA1 and BRCA2 DNA for testing to the Genetic Diagnostic Laboratory of the University of Pennsylvania. Myriad became aware of this practice and notified both the laboratory and Dr Ostrer that they were infringing Myriad's patents. The laboratory gave in to Myriad's demands and ceased doing genetic testing associated with Myriad's patents. Myriad also filed patent infringement actions against many other entities that provided BRCA testing services, in this way entrenching itself as the only entity in the United States providing BRCA testing services.<sup>[6]</sup>

Some years after Myriad first accused him of infringing its BRCA genetic testing patents, Dr Ostrer along with a divergent group which included cancer patients, medical doctors, academics and a number of advocacy groups, collectively filed a lawsuit to challenge the validity of a number of Myriad's patents associated with its discovery of the location of the BRCA1 and BRCA2 genes. The District Court granted summary judgment to the petitioners, based on its conclusion that Myriad's patent claims, including the claims relating to the synthetically created cDNA, were invalid, as they covered products of nature.<sup>[8]</sup> On appeal, the Federal Circuit Court reversed the decision of the District Court and held that both isolated DNA and synthetically created cDNA were eligible for patent.<sup>[9]</sup>

It was clear that the Supreme Court had the unenviable task of providing clarity and certainty on some hugely important and fundamental human DNA patenting issues, which provoked strong and obviously divergent views. The Court's decision centres on what it describes as a 'long held' and 'important implicit exception', citing its 2012 decision in *Mayo Collaborative Services v. Prometheus Laboratories Inc.*<sup>[10]</sup> to Section 101 of the United States' Patent Act. Section 101 states that 'whoever invents or discovers any new and useful ... composition of matter, or any new and useful improvement thereof, may obtain a patent therefore.'<sup>[11]</sup> The relevant 'important implicit exception' to Section 101 states that, the 'laws of nature, natural phenomena, and abstract ideas are not patentable.'<sup>[6]</sup> According to the Supreme Court, the 'laws of nature, natural phenomena, and abstract ideas' are 'the basic tools of scientific and technological work', and are not eligible for patent protection. Without this exception, the Court argues, there is the risk that 'future innovation premised upon' these basic tools would be inhibited – and such innovation is the reason patents exist. Reiterating statements made in the Mayo decision, the Court explains that 'patent protection strikes a delicate balance between creating "incentives that lead to creation, invention and discovery" and "impeding the flow of information that might permit, indeed, spur, innovation."<sup>[6]</sup>

In contextualising Myriad's discovery, the Court states that it is beyond contention that: (i) the genetic information contained in the BRCA1 and BRCA2 genes was not created by Myriad, nor altered by Myriad in any way; (ii) the location and order of the BRCA1 and BRCA2 genes were present in nature before Myriad discovered the genes; and (iii) Myriad did not create or in any way alter the DNA's genetic structure. What Myriad did do was to pinpoint the exact location of the BRCA1 and BRCA2 genes.

Therefore, the question is whether the fact that Myriad located these genes would entitle the company to claim patent rights on them.

Writing for a unanimous court, Justice Clarence Thomas answered: 'Myriad did not create anything. To be sure, it found an important and useful gene, but separating that gene from its surrounding genetic material is not an act of invention. Groundbreaking, innovative, or even brilliant discovery does not by itself satisfy the Section 101 inquiry.' According to the Court, Myriad's patent claim 'fell squarely within the law of nature exception. ... Myriad found the location of the BRCA1 and the BRCA2 genes, but the discovery, by itself, does not render the BRCA genes "new... composition[s] of matter," ... that are patent eligible.'<sup>[6]</sup>

Importantly, though, the Court also distinguished between the patentability of a naturally occurring isolated DNA sequence and that of synthetically created cDNA. Justice Thomas, affirming in part the Federal Circuit judgment, wrote: 'The lab technician unquestionably creates something new when cDNA is made. cDNA retains the naturally occurring exons of DNA, but is distinct from the DNA from which it is derived. As a result, cDNA is not a "product of nature" and is patent eligible under Section 101 ... '<sup>[6]</sup>

The judgment concluded by clearly indicating that its decision does not implicate: (i) any method patents; (ii) any patents regarding new applications of knowledge about the BRCA1 and BRCA2 genes; or (iii) the patentability of DNA that was scientifically altered through changing the order of naturally occurring nucleotides. Rather, its decision 'merely hold[s] that genes and the information they encode are not patent eligible under Section 101 simply because they have been isolated from the surrounding genetic material.'<sup>[6]</sup>

## The position in other jurisdictions

Apart from the US, Europe and Japan are the most notable jurisdictions in biotechnological innovation. Their position regarding the patentability of isolated DNA has been summarised by Professor Joseph Straus, a biotechnological patent law scholar, Director Emeritus of the renowned Max Planck Institute for Intellectual Property, Competition and Tax Law, and current incumbent of the National Intellectual Property Management Office (NIPMO) Chair of Intellectual Property Law and Innovation. In *Association for Molecular Pathology et al. v. United States Patent and Trademark Office*, et al.,<sup>[8]</sup> (the court of first instance in the Supreme Court's Myriad decision), Straus was asked to submit a declaration<sup>[12]</sup> informing the District Court about the position regarding the patentability of isolated DNA in Europe. He described the 'common ground' that regarding the patenting of isolated DNA has been reached by the European Patents Office, the US Patent and Trademark Office, and the Japanese Patent Office: the inventor who first identifies a gene and its useful function (thus, a gene 'available for use in diagnosis or therapy') can expect that patent offices around the world will accept that a patent can be granted for such an invention.

With reference to the European Parliament and the Council's directive on the legal protections of biotechnological inventions<sup>[13]</sup> in Europe, Professor Straus explains that, assuming that a DNA sequence is novel (i.e. was not previously publicly known or used), and the other criteria for patentability (utility, non-obviousness, and sufficient disclosure) are met, the isolated substance of the DNA itself is patentable. He informed the Court: 'Specifically, the approach adopted by the EU Directive is that a nucleic acid corresponding to a complete or part of a gene, even if its structure is identical to that of a natural element, may constitute a patentable invention, if isolated from the human body or otherwise technically produced....

Indeed, the natural pre-existence of biological material alone does not constitute a patentability obstacle.' Expressing his opinion on Myriad's patents under European patent law, Professor Straus concluded: 'Under the EU Directive, the Implementing Regulations of the European Patent Convention ("EPC") and case law interpretation of it, "isolated and purified" DNA molecules are patent-eligible subject matter. Thus, Myriad's isolated DNA claims are patent-eligible.'<sup>[12]</sup>

The position in Australia seems to be comparable to the European approach. Earlier this year in *Cancer Voices Australia v. Myriad Genetics Inc.*,<sup>[14]</sup> the Australian Federal Court tracked the more expansive European approach and ruled that the process of isolating or extracting DNA often requires extensive skill and investment, and accordingly the granting of a patent as a reward for the research and intellectual effort expended is justified. The Court found it 'an unhelpful approach' to ask whether a composition of matter is a 'product of nature.' It added that DNA as it exists inside cells of the human body is not patentable. However, isolated DNA is patentable as long as it still meets the patentability criteria of novelty, usefulness, and an inventive step.<sup>[15]</sup>

## Conclusion

The decision of the US Supreme Court will undoubtedly have a significant impact on biotechnological innovation. It will be viewed by many as a major victory, especially by those concerned more with the moral and ethical dilemmas and implications of human gene patenting.<sup>[16,17]</sup> On a more practical level, many will rejoice in the perceived greater freedom to research, test, diagnose, and develop without impediment. The reality, however, is that this decision will also have substantial negative ramifications for past and future human genetic discovery and innovation. This decision signals the green light for opportunistic and unwarranted attacks on numerous already existing gene patents deservedly granted for substantial investment in time, intellectual effort, and financial resources. Furthermore, it could potentially deter those who must decide whether to expend substantial investments on future innovation and discovery, for which the critical incentive has essentially now been removed.

The Supreme Court's 'sledgehammer' approach in finding Myriad's patents ineligible will be broadly applied to gene patents generally, as well as to DNA of plant, animal or microbial origin. This will surely have profound implications for future developments and innovation that will reach much further than the limited context of Myriad's BRCA gene patents.<sup>[2]</sup> It is suggested that the broader, more measured European approach to genetic patenting, which is not focused

on a strict patent eligibility doctrine but which also includes the use of other patentability criteria (such as non-obviousness, utility, and sufficient disclosure) is sounder. This would still allow for the patenting of truly deserved discoveries and inventions, while keeping in check problematic and inappropriate gene patents that are not worthy of patent protection.<sup>[2,18]</sup>

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