

US Perspectives

US Supreme Court May Invalidate Gene Patents, But Create Little Change *

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By [Steven Seidenberg](#) for Intellectual Property Watch

OPrior to 15 April, most experts had expected the United States Supreme Court to rule in *Association for Molecular Pathology v. Myriad Genetics* that genes cannot be patented. The oral argument on that date strengthened this consensus opinion, but also suggested that the court would issue a narrow decision which would allow many types of gene-related patents. Should this happen, the US would move significantly closer to other countries' rules for gene patents, but the US would continue to have problems limiting patent rights in order to protect the public interest.

The *Myriad* case began in 2009. A collection of patients, researchers, genetic counselors, medical associations, and breast cancer and women's health groups sued for the right to use two naturally occurring human genes, BRCA1 and BRCA2, in cancer screenings and medical research.

They went to court because Myriad owns a variety of patents relating to the BRCA1/2 genes, including patents on the isolated form of the BRCA1/2 genes and cDNA versions of the genes (which are not found in nature and are synthesized using messenger RNA). Myriad claims that these patents give it the exclusive right to use the genes in medical tests, and the company has earned a tidy profit by performing such tests.

The company has used its patents to stifle competition, preventing others from offering cheaper or more accurate cancer screenings. As a result, patients have been unable to get second tests to confirm or deny the results from Myriad. Myriad also has allegedly used its patents to stop scientists from doing research involving the BRCA1/2 genes, thus preventing investigations into improved cancer screenings.

The lawsuit challenges the validity of Myriad's gene patents. And now the US Supreme Court is to decide if human genes are patent-eligible subject matter or if they are unpatentable products of nature.

At [oral argument](#) [pdf], the justices appeared skeptical of Myriad's contention that snipping some DNA from a naturally occurring chromosome made the isolated DNA sequences no longer products of nature. "The Supreme Court seemed to say that merely isolating DNA from a chromosome didn't sufficiently distinguish that DNA from its naturally occurring form. Chief Justice Roberts said that is not enough of an invention," noted Courtenay Brinckerhoff, a partner at Foley & Lardner.

If isolating a naturally occurring substance suffices to render it patent eligible, all sorts of items could suddenly become patentable, the justices fretted. "Where would we draw the line, the justices asked repeatedly. Are isolated chromosomes patentable? How about an isolated kidney [that has been

removed from a human body]? The justices couldn't find a logical way to draw the line that would permit the patenting of naturally occurring DNA sequences but not these other things, which the justices felt confident shouldn't be patent eligible," Brinckerhoff said.

The justices were far more receptive to Myriad's assertion that cDNA was patent eligible. Justice Sonia Sotomayor, for instance, said that cDNA "is artificially created in the laboratory, so it's not found in nature. It's not taking a gene and snipping something that's in nature."

The justices also seemed to welcome gene-related patents. They repeatedly stated that although products of nature are unpatentable, it is possible to patent new methods of obtaining or manipulating natural products (e.g., genes). Similarly, one can patent new uses for natural products (e.g., genes). Unless such method or use patents were allowed, companies might not invest in gene-related research, the justices feared.

The justices thus seemed to favour the position advanced by the US Department of Justice, which argued that isolated genes are not patent eligible but gene-related inventions are. "At the end of oral argument, the justices repeatedly asked, 'if we adopt the government's position, would that be good enough for you?' That seems to indicate that a number of justices thought this position was a plausible middle ground," said Prof. Arti Rai of Duke Law School.

All or Nothing

Should the court adopt the Justice Department's view, the decision in *Myriad* would make the US the only major country to outlaw gene patents. Yet that would not cause US patent law to diverge from international standards. Quite the reverse. It would increase patent harmonisation.

"Other countries don't have sweeping gene patents [like the US currently has]. Other countries allow gene patents, but put restrictions on them, so they are similar to the types of patents that would be granted under the Justice Department's position," Rai explained.

Other countries, moreover, restrict patent rights in ways that the US does not. "Virtually every other country has a research defence. Only in the US are researchers subject to patent infringement claims," said Prof. Rochelle Dreyfuss of New York University Law School.

The EU also recognizes that patent rights are limited by the antitrust law's "essential facilities doctrine." Under that doctrine, "a patentee can't refuse to license its patent to another party, when that party is bringing something to market that the public really needs – such as a cancer screening test that would allow patients to get a second opinion. The patentee has an obligation to license on fair terms," Dreyfuss said.

The US does not limit patent rights in this manner. "We used to think we had this essential facilities doctrine, but the Supreme Court said in [Verzion v. Trinko](#) [pdf] that we don't," Dreyfuss noted.

The US, in short, provides few legal means for protecting the public or the economy from patentees seeking to exploit their government-granted monopolies. "Patents should be exploited with the public in mind, but we don't have that," Dreyfuss said. "There are virtually no controls on what a patentee can do once it gets a patent."

Thus when a patent produces some detrimental effects for society (as apparently occurred in this case), US courts are pressured to protect the public, but they are constrained in what they can do. This pushes the courts to use the legal remedy that is available – to strike down the patent on the grounds that the underlying invention is not patent-eligible, according to Dreyfuss.

This remedy creates two problems. First, there is the danger of overkill. Too many inventions might be rendered unpatentable, removing the financial incentive for companies to engage in potentially

important research.

Second, the patent-eligibility standard may not suffice to protect the public interest; too many inventions may slip past. This could well be the result from *Myriad*, if the Supreme Court adopts the Justice Department's legal standard. By patenting cDNA, processes for using BRCA1/2, and uses of BRCA1/2, Myriad may be able to maintain its monopoly and to stifle both researchers and rivals. Other owners of gene patents might similarly evade the patent-eligibility limit, leaving the public without effective protection.

A better approach, according to Dreyfuss, would be for the US to adopt European-type limits on patent rights. She said, "Isolated genes should be patent-eligible, and there should be a really strong research-use defence. If we had that, a lot of the problems of researchers would go away. If patentees could not refuse to licence their patents to others, many problems caused by lack of competition would go away. Myriad could licence its patents but couldn't prevent patients from getting second opinions."

That might be a better result, but it would require a dramatic shift in US law. And the Supreme Court is highly unlikely to mandate such a radical change. The court has weakened antitrust law repeatedly in recent years, and there is no reason to think the court would suddenly reverse course and impose new antitrust limits on laissez faire capitalism.

The Supreme Court's decision in *Myriad* may thus strike down patents on isolated genes, but it may be far less significant than many biochem companies fear or many patients hope. "Will it make a difference?" said Dreyfuss. "I don't know."

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