

Chicago Daily Law Bulletin®

Volume 160, No. 193

Game on: Biotech gene patents find renewed life in Australia

At the end of betting in Monte Carlo casinos, the croupiers announce, "Les jeux sont faits. Rien ne va plus." Gamblers remain transfixed as they wait for the white ball to drop into a numbered slot of the roulette wheel.

Biotech companies have a lot in common with these Monegasque gamblers. In June 2013, they watched the U.S. Supreme Court in *Association for Molecular Pathology v. Myriad Genetics Inc.*, 569 U.S. 2013, eliminate patent protection for isolated DNA.

Fortunately, the international biotech ball kept rolling. In September in Australia, it finally stopped. Those who bet on DNA won.

The decision in *D'Arcy v. Myriad Genetics Inc.* by the Federal Court of Australia, that country's top court, reminds us that international harmonization is not an absolute value.

One of the overarching themes of international intellectual property protection over the past 20 years has been the goal of harmonization. Like harmonies in music, harmonization in IP rights allows for variations in the notes played, while maintaining measured intervals among a range of predictable choices.

The most significant international representation of IP harmonization may be the Agreement on Trade-Related Aspects of Intellectual Property Rights. Established in 1994, TRIPS set a wide range of substantive obligations for the international protection of IP rights. For example, Article 27 established a mandatory tripartite test for patentability.

Subject to various limitations, inventions "in all fields of technology" under Article 27 are patentable if they are "new, involve an inventive step and are capable of industrial application." This test necessarily allows for variations in surrounding issues, such as the role of grace

periods in establishing invalidating prior art.

In the case of the BRCA gene at the heart of the *Myriad* cases, it also allows countries to establish differing gateway limitations for the protection of inventions related to natural-occurring phenomenon. What is notable about the recent decision by the Australian Federal Court is that it expressly rejected the U.S. court's gateway analysis in *Myriad*.

Briefly, the U.S. Supreme Court held in *Myriad* that isolating the BRCA1 and BRCA2 genes, whose presence is used to test for breast cancer, did not qualify as patentable subject matter under U.S. law.

Although the isolated gene might not necessarily occur in nature, the court did not believe that the act of isolation itself was a sufficiently inventive act to alter the fact that a patent would serve only to protect "the genetic information encoded in the BRCA1 and BRCA2 genes."

Unlike U.S. practices, the Australian Federal Court did not restrict its patentability examination to domestic precedents. To the contrary, the *D'Arcy* court considered the decisions of both the U.S. Supreme Court and the U.S. Court of Appeals for the Federal Circuit in *Myriad*.

In fact, it found the opinions of Judges Kimberly A. Moore and Alan D. Lourie of the Federal Circuit to be "consistent with patent law, and persuasive." This persuasiveness lay in their "analysis of the products [isolated genes] as products and not on the information that they contain."

Ultimately, the Australian Federal Court upheld the lower court's decision that the BRCA gene patent was valid. At the heart of the distinctions between the U.S. and Australian courts' patentability decisions regarding the BRCA isolated gene is the role of exclusions for naturally occurring phenomenon.

Over the past several years, U.S. Supreme Court precedent has raised a gate to patentability

GLOBAL IP



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based on the critical issue of whether the proposed invention is simply an abstract idea, a law of nature, or as in the *Myriad* case, naturally occurring phenomenon. This gateway treatment has been the subject of heated debate in the patent community.

Myriad did not eliminate patent protection for BRCA gene therapies since process and other claims remained untouched by the decision. It also did not eliminate biotech patents. But it did suggest that early breakthroughs, including mapping activities related to the brain, may not be patentable in the United States.

By contrast, *D'Arcy* clearly emphasized the biotech-friendly nature of Australian patent law. The court unreservedly rejected any barriers based on U.S. natural phenomenon exceptions. It declared: "In Australia, there is no statutory or jurisprudential limitation of patentability to exclude 'products of nature.'"

The Australian court, however, went beyond stressing distinctions between Australian and U.S. patent law to criticizing *Myriad* on its own grounds. It began by questioning how *Myriad* could be reconciled with

earlier Supreme Court precedent in *Chakrabarty* recognizing the patentability of modified bacteria.

The Australian court then directly challenged the U.S. court's failure to consider the chemical differences between isolated and natural occurring DNA: "With respect, the Supreme Court's emphasis on the similarity of 'the location and order of the nucleotides' existing within the nucleic acid in nature before *Myriad* found them is misplaced. It is the chemical changes in the isolated nucleic acid which are of critical importance, as this is what distinguishes the product as artificial and economically useful."

Underscoring a fundamental philosophic difference between the two patent systems, the court in *D'Arcy* included as a factor in its analysis the specific recognition that the "isolation of the nucleic acid ... leads to an economically useful result." In clear terms, in the penultimate paragraph of this 50-page decision, the Australian court stressed its fundamental disagreement with *Myriad*: "The U.S. Supreme Court ... accepted wrongly, with respect, that the isolated nucleic acid is a 'product of nature.'"

D'Arcy demonstrates the continuing power of U.S. precedents as a guiding force in the role of international patent harmonization.

However, it also reminds us that global knowledge of U.S. patent precedents does not guarantee their adoption as international protection standards.

In the game of international biotech patentability, the bets are not over until the roulette wheel has stopped spinning. Where the ball will ultimately land is hard to predict.

But it is a good bet that the country that provides stronger protection for biotech innovators could end up winning a bigger share of the pie. Only time and the rolling ball itself will tell.