

***Association for Molecular Pathology et al. v. Myriad Genetics, Inc. et al.*, 569 U.S. 12-398 (13 June 2013)**

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Case summary

The U.S. Supreme Court (hereinafter: the Court) decided on 13 June 2013 unanimously that isolated naturally occurring genes are not patent eligible subject matter. Synthetically created composite DNA, however, is patent eligible.

The facts

Respondents Myriad Genetics, Inc. (hereinafter: Myriad) had discovered the precise location and sequence of two human genes, mutations of which can increase the risks of breast and ovarian cancer. In relation to this discovery, Myriad was granted several patents. These patents would give Myriad the exclusive right to isolate an individual's BRCA1 and BRCA2 genes (the above mentioned genes), as well as the exclusive right to synthetically create BRCA cDNA.¹ In the present case, three claims were relevant: those concerning the isolated genes, the diagnostic method and the screening methods identifying potential drug candidates. Petitioners Association for Molecular Pathology filed suits against these claims, holding that they were invalid under 35 U.S.C. §101 (i.e. lack of a patentable invention).

On 29 March 2010, the District Court granted summary judgment to petitioners and agreed with their suit, holding Myriad's claims invalid because they merely covered products of nature and standard scientific procedure.

On 29 July 2011, the Federal Circuit overturned the District Court's judgment in part and affirmed it in part. Reversing the District Court's ruling, it held that isolated DNA as well as methods for screening cancer therapeutics can be patent eligible. However, methods for comparing DNA were held to be patent ineligible.

On 26 March 2012 the Supreme Court vacated the Federal Circuit's judgment and remanded the case back to the Federal Circuit, asking it to reconsider its decision in the light of the Court's recent ruling in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*. In this decision, the Court had held that certain kinds of claims in medical diagnostics patents, for example natural phenomena, were patent ineligible.²

On 16 August 2012, the Federal Circuit issued its judgment, containing a nearly identical reasoning to its first decision.

On 13 June 2013, the Supreme Court decided the case and affirmed in part and reversed in part. It held that isolated DNA was a naturally occurring product and therefore patent ineligible. The creation of cDNA, however, was judged to not be a product of nature and therefore patent eligible.

¹ See p. 6 of the judgment. cDNA is a composite DNA; synthetically created exons-only strands of nucleotides. cDNA contains only the exons that occur in DNA, omitting the intervening introns.

² See the summary of that decision in this database.

The legal issues

The legal issues concerned (1) isolated DNA, (2) the creation of cDNA and (3) indirectly, matters untouched by this judgment.

(1) Isolated DNA

The Court affirmed the importance of its ruling in *Chakrabarty*, which concerned the patentability of a highly useful bacterium created by human intervention.³ Contrasting this invention with the isolation of DNA as achieved by Myriad, the Court found that Myriad did not create anything new and that isolated DNA is a naturally occurring product and therefore generally patent ineligible. It stated that a brilliant discovery by itself does not satisfy the §101 inquiry (patentable subject matter).⁴ Referring to its judgment in *Funk Brothers Seed Co. v. Kalo Inoculant Co.* the Court also established that the isolation did not constitute a new composition of matter.⁵

The Court in this context also dismissed the Respondents' argument that the Patent and Trademark Office's prior practice of awarding gene patents is entitled to deference.

(2) Creation of cDNA

The Court found that cDNA is to be considered a non-naturally occurring molecule and that its creation is the creation of something new.⁶ cDNA therefore is not a product of nature and thus patent eligible under 35 U.S.C. §101. Eligibility may, however, be denied in case of very short series of DNA without intervening introns, in which case the cDNA may be indistinguishable from the natural DNA.

(3) Matters untouched by the judgment

First, the Court noted that the case did not involve "method claims".⁷ Respondents did not create a new innovative method of manipulating genes but rather used well established and widely known processes.

Secondly, the Court held that the decision neither involved patents on new applications of knowledge about the concerned genes.

Lastly, it stated that the decision did not concern the patentability of DNA in which the order of the naturally occurring nucleotides has been altered.

Points of significance:

- Contrary to prior and accepted practice in patent law, the Court dismissed in this case the granting of gene patents for isolated DNA, finding them to be products of nature. It emphasized, however, that it did not rule on the

³ See the summary in this database.

⁴ See p. 12 of the judgment.

⁵ See p. 13, *ibid.*.

⁶ See p. 17, *ibid.*.

⁷ See part III of the judgment.

patentability of DNA in which the order of the naturally occurring nucleotides has been altered.

- All in all, the Court's decision can be considered a relatively narrow one albeit one with consequences on a number of existing patents and patent claims. The Court's decision simply holds that "genes and the information they encode are not patent eligible under §101 *merely* because they have been isolated from the surrounding genetic material." (emphasis added). Thus, claims concerning genes may still be patentable; however, they need to define the concerned DNA sequences more precisely, or differently, than simply with the word "isolated".
- In a certain way, the above is confirmed by the Court's present ruling that cDNA is patent eligible. As explained in footnote no. 1 in this case summary, cDNA is produced by taking natural DNA but omitting certain parts of it. It is therefore possible to obtain patents on parts identical or similar to elements of naturally occurring DNA, as long as the process is more than the mere isolation thereof.
- For a good overview of the current approach in US case law on the patentability of natural substances and phenomena, the *Myriad* decision should be consulted in conjunction with the Supreme Court's decision in *Mayo* and the decision by the US Court of Appeals for the Federal Circuit in *iNO Therapeutics LLC v. Praxair Distribution Inc.*⁸

Key words:

Pre- Grant Flexibilities, patentability, subject matter, patent-eligibility, gene, gene patent, novelty, DNA, cDNA, product of nature, composite matter, method, application.

Available at: <http://supreme.justia.com/cases/federal/us/569/12-398/>

⁸ See the summaries of both decisions in this database.