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Supreme Court Limits What Biotechnology Can be Patented

What types of innovations can be patented? To meet the patentability requirements of the Patent Act, an invention must be useful, novel and non-obvious. The invention must be described in sufficient detail to permit one of ordinary skill in the art to make and use the invention. Are there any other limitations on what can be patented? Should there be? A recent Supreme Court opinion says yes, limiting the types of inventions that may be patented, particularly in the field of biotechnology.

Background

Subject matter that may be eligible for a patent is set forth in 35 U.S.C. § 101:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

Over 30 years ago, in *Diamond v. Chakrabarty*, the Supreme Court decided

genetically modified organisms could be patented. The inventor had developed a bacterium capable of breaking down crude oil that could be used in cleaning up oil spills. The United States Patent and Trademark Office (PTO) rejected his patent application on the basis that living things are not patentable subject matter.

The Supreme Court reversed, holding that the bacterium was not naturally occurring and qualified as patentable subject matter as a “manufacture” or “composition of matter” under the § 101. The Court cautioned that limitations should not be read into the statute that Congress has not expressed.

In what is now considered the high point of the permissiveness of patentable subject matter, the Court quoted the legislative history of § 101 that patentable subject matter includes “anything under the sun made by man.”

Chakrabarty is widely viewed as the case that spurred the nascent field of biotechnology. The PTO took the Supreme Court’s injunction literally and began issuing patents on isolated

human DNA and similar discoveries. Isolating DNA sequences has permitted biotechnology companies to develop tests for genetic diseases and to create research tools to permit us to learn more about the human body and how to treat various diseases. These inventions are leading to personalized medicine, including customized medical decisions, practices and products tailored for individual patients.

While patents may have been the incentive to spur on these advances in biotechnology and medicine, patents also permit their owners to exclude use of the claimed technology for the term of the patent. This has raised the debate on access to these new medical breakthroughs.

More than 30 years later, the Supreme Court has waded into the field once more and decided that isolated DNA is a product of nature and is therefore not eligible to be patented.

Association for Molecular Pathology v. Myriad Genetics

Genes set forth genetic characteristics of humans and other organisms. Each gene is encoded as DNA that occurs within the organism. Scientists can extract and isolate DNA from the genes for research, as mentioned above. Through manipulation, they can develop synthetic DNA in

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the laboratory known as complementary DNA (cDNA); this cDNA is also useful for research and further innovation.

Inventors at Myriad discovered the precise location and sequence of two human genes, known as BRCA1 and BRCA2, mutations of which can substantially increase the risks of breast and ovarian cancer in those patients in which the mutations are present. The inventors isolated the genes from the human genome and developed tests to determine if individuals have the genetic mutations and therefore the increased cancer risk. The tests require the DNA to be isolated before testing can occur.

Myriad obtained a number of patents based on this discovery, including patents claiming the isolated DNA coding and isolated cDNA coding for the BRCA1 and BRCA2 genes. With these patents, Myriad asserted the exclusive right to administer the genetic tests for the mutations of these genes that would indicate an increased cancer risk.

The PTO has been issuing these types of patents since *Chakrabarty*. Specifically, isolated DNA and cDNA do not exist in nature separated and isolated from the remainder of the human genome. Therefore, they are not naturally occurring and qualified for patents as “manufactures” or “compositions of matter.”

A group of doctors and patients, led by the American Civil Liberties Union, sued Myriad and the PTO, seeking a declaration that the claims of the patents were invalid and that these inventions were not eligible for patent protection. If the court agreed with the plaintiffs, they would be free to administer the tests at facilities not administered by Myriad, and they would not have to pay license fees to Myriad for performing such tests.

Supreme Court Opinion

When the case finally reached the Supreme Court, Justice Thomas wrote for a unanimous Court that claims to isolated DNA are not patent eligible, while claims to the synthetically created cDNA are.

His analysis started with the text of § 101, but then recognized several judicially created exceptions to the broad wording of the statute: laws of nature, natural phenomena and abstract ideas.

Without this exception, there would be considerable danger that the grant of patents would “tie up” the use of [basic tools of scientific and technological work] and thereby “inhibit future innovation premised upon them.”

In its reasoning regarding the isolated DNA, the Court reasoned that Myriad did not create anything. Its principal contribution was uncovering the precise location and genetic sequence of the BRCA1 and BRCA2 genes. The Court determined that “separating [those] gene[s] from [the] surrounding genetic material is not an act of invention.” The extensive effort indicated by Myriad does not warrant a patent under § 101.

The Court did recognize that cDNA is a different matter. Isolated cDNA sequences do not exist within nature or the human body. They retain some characteristics of naturally occurring DNA, but are sufficiently distinct to warrant patent eligibility.

Implications

One thing to note about this case is the fact that the plaintiffs did not acquire the relief initially sought. In the original complaint, the plaintiffs also challenged Myriad’s claims to methods of screening cancer patients. It pursued these claims through most of the litigation, arguing that they were directed to abstract ideas and were thus not patent eligible. The Federal Circuit upheld these method claims and the Supreme Court declined to review that decision. Thus, the win is in a sense a Pyrrhic victory: the claims to methods of screening cancer patients for the genetic mutation remain in force. Nobody else can practice these methods without infringing the claims.

The historical underpinnings for a patent system generally stem from the desire to encourage investment in innovation and also to encourage disclosure of innovative discoveries and advancements. In exchange for disclosure of new

inventions, patents permit innovators to exclude competition for a limited time and to charge monopoly profits during the limited term of the patent. The *Myriad* opinion instead seems to suggest that patents inhibit rather than encourage research.

How will this opinion affect the biotechnology industry? Given the extensive costs of research in these areas, will companies continue to make large scale investments? Following recent Supreme Court opinions on patentable subject matter, including *Myriad*, it seems that patents in the area of personalized medicine will be difficult to obtain and enforce. Further, many biotechnology companies are working on ways to grow organs that can be transplanted into the human body to replace defective organs. The goal is for these organs to be as similar to the natural organs as possible. This opinion seems to indicate that such organs could not be patented.

As far as specific guidance, the Supreme Court opinion did not provide a great deal of help. The Court specifically noted that it was not considering the patent eligibility of DNA where the order of the naturally occurring nucleotides has been altered. Where is the line? How different, how “inventive” does the new molecule or sequence need to be to be eligible?

The Court also noted that no method claims were at issue. Innovative methods of manipulating genes would appear to still be patent eligible. Further, no applications of knowledge about the genes were at stake. If the claims were limited to such applications, they would presumably also be patent eligible.

The Supreme Court has been reviewing a number of recent cases regarding patent eligibility. It has come down on the side of ineligibility in each one, thereby limiting the subject matter that can be patented. Will the Court continue to limit what can be patented or will it now let the dust settle for a while? 