Washington Legal Foundation

On the Merits:

ASSOCIATION FOR MOLECULAR PATHOLOGY, et al.,

Petitioners,

v.

MYRIAD GENETICS, INC., et al.,

Respondents.

U.S. Sup. Ct. No. 12-398

On Writ of Certiorari to the United States Court of Appeals For the Federal Circuit

Oral Argument: April 15, 2013

Question Presented: Whether human genes are patent-eligible subject matter under the Patent Act.

Summary of the Case: Myriad Genetics, Inc. is a research firm that engages in genetic research. Myriad isolates genes by taking a blood sample, fragmenting the extracted genes, and then looking for mutations or other variants. Among other things, this process of isolation and fragmentation helps determine whether a patient's genes are predisposed to a potential cancer risks and makes a patient's genetic information more accessible for study in laboratories or by medical professionals. Myriad obtained patents from the U.S. Patent Office on "isolated" forms of two genes that are correlated with a higher risk of breast or ovarian cancer in their "isolated" state. Myriad's patents claimed exclusive control over the genes once they were removed from the body and from human cells.

Several organizations representing doctors, genetic scientists, researchers, clinicians, health professionals, and patients filed suit challenging the patents. They claim that Myriad's patent claims are merely an attempt to secure a monopoly over natural phenomena, since the isolated genes are in no way altered from their characteristics when in the body. They also contend that Myriad's claims are so broad that they include "every single natural variation" of the genes, "including those that have not yet been isolated." The U.S. Court of Appeals for the Federal Circuit upheld Myriad's patents against challenge.

On The Merits:
Judgment for Respondents
Aaron Stiefel
Kaye Scholer LLP

The Patent Act defines patent-eligible subject matter broadly to encompass "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof." 35 USC § 101. This Court has recognized the use of "any" in the statute as reflecting that "Congress plainly contemplated that the

patent laws would be given wide scope" and that Congress intended statutory subject matter to "include anything under the sun that is made by man." *Diamond v. Chakrabarty*, 447 U.S. 303, 308, 309 (1980) (citations omitted).

We have articulated only three exceptions to what is patentable subject matter under §101—"laws of nature, physical phenomena, and abstract ideas." *Diamond v. Diehr*, 450 U.S. 175, 185 (1981). In *Mayo Collaborative Services v. Prometheus Laboratories, Inc.,* 132 S. Ct. 1289, 1293 (2012), we explained that these "implicit" exceptions preclude patenting "basic tools of scientific and technological work," but cautioned that "too broad an interpretation of this exclusionary principle could eviscerate patent law" because "all inventions at some level embody, use, reflect and rest upon, or apply laws of nature, natural phenomena, or abstract ideas."

In *Mayo*, we tested the patentability of method claims by asking whether the claims "do significantly more" than simply describe laws of nature, and held that merely adding steps consisting of "well-understood, routine, conventional activity" is not sufficient to reach that threshold. *Id.* at 1297-98. That test is consistent with the framework previously set out in *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), for evaluating composition of matter claims such as those presented in the instant case. There, we drew a distinction between compositions that, even if combined or altered in a manner not found in nature, have characteristics similar to those found in nature versus compositions that human intervention has given "markedly different" or "distinctive" characteristics. 447 U.S. 303, 309-10. The *Chakrabarty* test, consistent with *Mayo*, thus demands that a patentable invention apply human ingenuity to produce something significantly beyond what exists in nature.

Applying the *Chakrabarty* test to the isolated DNA at issue in this case, we conclude that the challenged claims are drawn to patentable subject matter because they cover molecules that are markedly different—have distinctive chemical identity and nature—from molecules that exist in nature. The same considerations that lead us to that conclusion, demonstrate that the claims satisfy *Mayo*'s command that patentable claims do "significantly more" than simply describe a law—or product—of nature. Through human ingenuity, Myriad produced isolated molecules having structure and utilities different than anything found in nature. Inside the body, DNA is hidden in chromosomes—strands of millions of base pairs of DNA that contain many genes—where the DNA is bound to proteins that are integral to the structure of the chromosome. Although the DNA "codes for" the multitude of proteins that the body manufactures, native DNA contains inoperative non-coding sequences as well. Thus, in nature, DNA is unknown, unavailable, and unusable.

Isolated DNA on the other hand results from human intervention to cleave or synthesize a portion of a native chromosomal DNA, imparting to the isolated DNA a chemical identity distinct from that possessed by native DNA. The fact that the claimed isolated DNA retains the same nucleotide sequence as native DNA does not undermine the isolated DNA's "markedly different" characteristics and chemical structure. The amino acid sequence of DNA is merely a shorthand description that falls far short of completely characterizing a DNA molecule. The isolated DNA molecules at issue here have different structural characteristics and bring with them functional utilities (e.g., as probes or primers) that do not exist in native DNA. A claim to such "markedly different" molecules describes "significantly more" than what exists in nature.

Prior to the invention, neither the claimed isolated molecules themselves nor any genetic diagnostic applications utilizing those molecules were available to the public. The patent's public disclosure of the invention allowed thousands of researchers to publish papers on these new molecules and their uses. The inventors were appropriately rewarded for their disclosure with a limited term of exclusivity for the commercialization of their invention. The preemptive force of the awarded claims is limited to the newly created molecules and their diagnostic application and thus does not "[foreclose] more future invention than the underlying discovery could reasonably justify." 132 S. Ct. at 1301.

We note that our decision in this case is consistent with well-settled expectations that follow from the Patent and Trademark Office's longstanding practice to allow claims to isolated DNA sequences. Such established patent eligibility has allowed researchers to devote significant resources to discovering such DNA and has yielded monumental advances in the treatment and prevention of disease. Any categorical rule excluding isolated genes from patent eligibility is, therefore, neither in the public interest nor consistent with applicable legal precedent. We thus affirm the ruling of the United States Court for the Federal Circuit finding Myriad's composition claims to isolated DNAs patent eligible.

Dissenting View:
John Hendricks
Reed & Scardino LLP

In *Mayo* we reaffirmed that patent eligible subject matter under § 101 is limited by exclusions for natural phenomena, laws of nature, and abstract ideas, "'as they are the basic tools of scientific and technological work.' And monopolization of those tools through the grant of a patent might tend to impede innovation more than it would tend to promote it." *Mayo*, 132 S. Ct. at 1293 (quoting *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972)). Although the majority today claims to embrace these principles, its analysis effectively makes every composition of matter patent eligible. Consequently, the decision will impede the goals of innovation underlying the patent laws, even though Respondents adduce no empirical studies to support their argument that exclusion of human genes from patentable subject matter will diminish incentives for genetic research and innovation in the field. In contrast, substantial empirical research indicates that gene patents have already impeded medical research and patient access.

The majority appears to endorse the Federal Circuit's argument that isolated DNA sequences are patentable by virtue of being "isolated"—i.e. a composition has "markedly different characteristics" from the same sequence as it occurs in the genome solely because isolation of DNA entails breaking covalent bonds at each end of a gene segment. *Association for Molecular Pathology v. USPTO*, 689 F.3d 1303, 1328. (Fed. Cir. 2012). Although the majority invokes the language of *Chakrabarty*, it deviates from the analytic approach used by this Court. Rather than assessing whether human ingenuity has resulted in a composition having "markedly different characteristics," the majority substitutes a rigid test of whether human intervention has resulted in *any* structural change to a molecule. This test will apply to any composition regardless of the patent claim language, the description of the alleged invention, or the field of art or science at issue. (The challenged patent claims do not teach the importance or value of the isolated DNA's terminal points. Rather, the claims, which cover numerous compositions having differing molecular structures at their terminal points, underscore the irrelevance of these granular changes.)

The majority's preoccupation with *de minimis* structural changes incidental to isolation of gene sequences is contrary to the approach taken in *Funk Bros.* and *Chakrabarty* and ignores the established canons of claim construction. Instead of addressing structural changes, the Court in *Funk Bros.* observed that "the bacteria *perform* in their natural way. Their use in combination does not improve in any way their natural functioning. They serve the ends nature originally provided and act quite independently of any effort of the patentee." *Funk Bros. Seed Co. v. Kalo Inoculent Co.*, 333 U.S. 127, 131 (1948) (emphasis added). Likewise, in *Chakrabarty* instead of addressing chemical or structural differences, the Court observed that the bacteria had a petroleum degrading capability "which is possessed by no naturally occurring bacteria." *Chakrabarty*, 447 U.S. at 305. The analysis of organic compositions in both cases turned on whether the claimed subject matter revealed any functional advantages beyond those inherent in the natural components.

In *Mayo*, we considered how much change is "marked" and sufficient to be transformative. Addressing a method claim, we asked whether "the patent claims add *enough* to their statements of the correlations to allow the processes they describe to qualify as patent-eligible processes that *apply* natural laws?" *Mayo*, 132 S. Ct. at 1297. The correlative question here is whether the process of isolating DNA and the attendant changes that occur as a consequence of isolation make it different *enough* to *transform* it in any defining way. Based on this Court's reasoning in *Funk Bros.*, *Chakrabarty*, and *Mayo*, the answer is clearly no.

Myriad's claims are directed to natural genomic sequences which are isolated through routine processes into a conventional format. "Isolation of interesting compounds is a mainstay of the chemist's art. If it is known how to perform such an isolation, doing so 'is likely the product not of innovation but of ordinary skill and common sense.'" *Aventis Pharma Deutschland GmbH v. Lupin, Ltd.*, 499 F.3d 1293, 1302 (Fed. Cir. 2007) (citing *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007)). Even if the process or method of isolation were not routine, the molecular changes incidental to the process have no bearing on what DNA is or does and do not alter defining *properties* of DNA as described in the patent or as interpreted by a person of skill in the art of genetics.

Read in conjunction with *Funk Bros.* and *Chakrabarty*, *Mayo* compels the conclusion that merely isolating a natural sequence of nucleotides from the human genome by a routine process into a scientifically conventional format does not alter the natural properties of DNA "*enough*" to qualify "isolated DNA" as patentable subject matter. This is consistent with what this Court said over a century ago:

> There are many things well known and valuable in medicine or in the arts which may be extracted from . . . substances. But the extract is the same, no matter from what it has been taken. A process to obtain it from a subject from which it has never been taken may be the creature of invention, but the thing itself when obtained cannot be called a new manufacture.

American Wood-Paper Co. v. Fibre Disintegrating Co., 90 U.S. (23 Wall.) 566, 593-94 (1874).

The majority opinion abrogates this long standing precedent and introduces confusion in this Court's jurisprudence. Beyond this, the Court's decision today authorizes commercial practices that have proven themselves damaging not only to the goals of innovation that underpin our patent laws but also to the health and welfare of Americans who will suffer as a consequence of private monopolies on their genetic code.

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