Feeling Funk-y:
Human Gene Patents in AMP v. Myriad
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In a stunning reversal of the long-standing practice of the U.S. Patent & Trademark Office permitting the patenting of human DNA, the Supreme Court unanimously held on June 13, 2013, in Association for Molecular Pathology v. Myriad Genetics, Inc., that an isolated segment of human DNA, such as a gene, is not eligible for patent protection under 35 USC §101. The decision suggests that more human intervention beyond mere cleaving of this naturally occurring molecule from its natural environment is required. The Court did not prevent patent protection on all genetic materials, however, as it also held that a type of non-naturally occurring molecule known as complementary DNA was patent eligible.

The Court’s analysis of these DNA-based claims was guided by two precedents, Funk Brothers Seed Co. v. Kalo Inoculant Co. \(^1\) and Diamond v. Chakrabarty \(^2\), which addressed the patent eligibility of biological organisms. In this article, we examine these two precedents, how the Supreme Court applied them in its decision in Myriad, and some potential implications of the Myriad decision.

BACKGROUND ON PATENT ELIGIBILITY OF COMPOSITION OF MATTER CLAIMS

The range of patent eligible subject matter is set forth in 35 USC §101, which provides:

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 therefor, subject to the conditions and requirements of this title.

The Supreme Court has held that this broad statutory language extends patent protection to “include anything under the sun that is made by man.” \(^3\)

The Supreme Court has held, however, that the broad statutory language is limited by an implicit exception: “laws of nature, natural phenomena, and abstract ideas” are not patentable. \(^4\) These natural laws, principles, and ideas are viewed as the basic tools of scientific and technological innovation. \(^5\) As such, courts have recognized that there is a danger that patents on these basic tools would “tie up” their use and inhibit “more future invention than the underlying discovery could reasonably justify.” \(^6\)

The Court has also recognized, however, that all inventions “at some level embody, use, rest upon, or apply laws of nature, natural phenomena, or abstract ideas.” \(^7\) For this reason, the exception has the potential to swallow the rule and essentially exclude all discoveries and developments from the patent system. Courts have thus sought to limit the scope of the exception and strike the appropriate balance between creating “incentives that lead to creation, invention and discovery” and avoiding exclusivity in areas that “can impede the flow of information that might permit, indeed spur, [more] invention.” \(^8\)

At times, courts have struggled to define the limits of the natural law/abstract idea exception and to determine whether it applies in a particular case. \(^9\) A clear, easy-to-apply standard has proved elusive. Nonetheless, in Funk Brothers and Chakrabarty, the Supreme Court set forth two guideposts for analyzing whether a claim directed to a biological composition was patent eligible. These two cases, described in greater detail below, helped mark the general boundaries of §101.

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7. Id. at 309.
8. Id. at 1305.
and the natural phenomenon/abstract idea exception with respect to biological inventions.

A. Funk Brothers Seed Co.

In *Funk Brothers*, the Court was faced with the issue of the scope of the product-of-nature exception to patent eligibility.10 The claims at issue covered certain combinations of bacteria that beneficially infect the roots of leguminous plants, forming nodules and giving the plants the ability to fix nitrogen from the air. There were several species in this genus of root-nodule bacteria, and no one species of bacteria could infect the roots of all species of leguminous plants. Generally, when different species of these root-nodule bacteria were mixed, the bacteria would exert a mutually inhibiting effect, reducing their efficacy. This meant that a farmer seeking to give his crops this beneficial trait often had to buy separate products, containing a different species of bacteria, for each type of leguminous crop the farmer planted.

The patentee discovered that certain strains of certain species of root-nodule bacteria could be combined without causing this mutual inhibition. Thus, particular combinations of different species of bacteria could be combined into a single product, which a farmer could use to inoculate all of his or her leguminous crops. This was more convenient and cost-effective for the farmer. The patentee claimed all combinations of root-nodule bacteria strains that could be mixed without exhibiting a mutually inhibitory effect.

In an opinion authored by Justice Douglas, the Supreme Court held that this claim was not a protectable “invention” under the patent statutes.11 Patents cannot issue on the discovery of the phenomena of nature, according to the Court, because these natural qualities “like the heat of the sun, electricity, or qualities of metals, are part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none.”12 Instead, one may obtain a patent only on an “application of the law of nature to a new and useful end.”13

The Court reasoned that the discovery that certain strains of these bacteria could be mixed without causing an inhibitory effect was “no more than the discovery of some of the handiwork of nature and hence [was] not patentable.”14 The Court found that, however ingenious the discovery of this natural property might have been, the application in this case was simply an improvement in the packaging of a mixture of bacteria, which was well-known in the art at the time.15 Although this new product was more convenient and might have been an important commercial advance, these facts alone were not sufficient to make the claimed combination a patentable invention.16

The Court emphasized the fact that the patentee had not produced a new bacterium or altered the properties of any of the bacteria used in the claimed combination. Rather, “each species has the same effect it always had,” serving “the ends nature originally provided.”17 The Court thus distinguished between an act of “discovery” of a natural principle and an act of “invention,” with only the latter being eligible for patent protection.18

B. Chakrabarty

About 30 years later, the Court in *Diamond v. Chakrabarty* again faced the limits of the law-of-nature exception to patent eligibility.19 The patent applicant in this case had inserted foreign genetic material—at least two stable, energy-generating plasmids—into a bacterium that gave the organism the new ability to break down multiple components of crude oil. The inventor maintained that this invention would have significant benefits in treating oil spills.

In addition to method claims for producing the bacteria and claims to a delivery system, the inventor included claims directed to the bacteria themselves. The issue was whether this microorganism constituted a “manufacture” or “composition of matter” within the meaning of §101.

In an opinion authored by Chief Justice Burger, the Court concluded that the claimed bacteria fell within the scope of patent-eligible subject matter under §101. First, the Court observed that the statute used broad terms, which signaled that Congress intended the patent laws to have wide scope.20 Next, the Court examined the legislative history, finding that this, too, supported a broad construction of §101.21

The Court also discussed the exception to patentability for natural discoveries but found that the claimed bacteria qualified as patent-eligible subject matter.22 It reasoned that “the claim [was] not to a

10333 U.S. 127 (1948).
11*Funk Brothers* was decided in 1948, four years before the passage of the Patent Act and the current embodiment of §101.
12*Funk Bros. Seed Co.*, 333 U.S. at 130.
13*Id.* (citation omitted).
14*Id.* at 131.
15*Id.* at 131–32.
16*Id.*
17*Id.* at 131.
18*Id.* at 132.
20*Chakrabarty*, 447 U.S. at 308.
21Later in the opinion, the majority also rejected the arguments that Congress’s understanding that living organisms were not covered under §101 was implied by its passage of a pair of plant patent acts and that microorganisms cannot qualify as patentable subject matter until Congress expressly authorizes such protection. See *id.* at 310–18.
22*Id.* at 309 (“Thus, a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated law that E = mc²; nor could Newton have patented the law of gravity.”).
hitherto unknown natural phenomenon, but to a non-naturally occurring composition of matter—a product of human ingenuity “having distinctive name, character, and use.”23 The Court expressly contrasted the claims in Funk Brothers with those at issue here, stating that “[h]ere...the patentee has produced a new bacterium with markedly different characteristics from any found in nature....His discovery is not nature’s handiwork, but his own; accordingly it is patentable subject matter under §101.”24 Thus, the modified bacterium fell outside the boundaries of the product-of-nature exception.

APPLICATION IN MYRIAD

These two precedents guided the Supreme Court’s analysis of Myriad’s patent claims on isolated genes. Myriad discovered the location and sequences of the BRCA1 and BRCA2 genes. Mutations in these genes are associated with an increased risk of certain breast and ovarian cancers. This discovery enabled Myriad to develop diagnostic genetic tests to detect these mutations, which allowed individuals to better assess their risk of developing these cancers and make more informed treatment decisions.

Myriad sought and obtained several patents based on its discovery of the BRCA genes, including nine composition claims directed to the genes themselves.25 Myriad used two basic approaches to claim this genetic material. First, it claimed isolated DNA molecules that encode polypeptides having specified amino acid sequences. Claims of this type encompassed DNA molecules that have nucleotide sequences identical to those of the naturally occurring BRCA genes. The difference is that the claimed DNA molecule had been “isolated”—that is, not covalently bound to a much longer chromosomal DNA strand—and removed from its natural cellular environment. Second, Myriad claimed isolated DNA molecules that had a specified nucleotide sequence—forming a molecule known as complementary DNA—that encoded the given BRCA amino acid sequences. cDNA contains only the protein-coding portions of genes (exons) and does not typically exist in nature except as a very short-lived intermediate.26 Rather, cDNA is created in a laboratory, often from a template of mRNA, which does not contain the non-protein-coding portions (introns) typically found in mammalian genes.

Myriad’s patents gave it the right to exclude others from isolating these genes, which gave it the power to control BRCA testing. The plaintiffs were a group of institutions and individuals who wanted to engage in BRCA testing or research but were allegedly blocked by Myriad’s patents. The plaintiffs sought a declaration that these claims were invalid under §101, arguing that they were drawn to ineligible products of nature.

A. Isolated DNA Claims

Myriad’s claims that covered isolated but otherwise unmodified segments of naturally occurring DNA fell somewhere between the claims in Funk Brothers and those in Chakrabarty. Unlike the claimed combination in Funk Brothers, where the patentee had done nothing to alter the bacteria but had simply mixed certain species, Myriad claimed that its molecule had been altered from its natural state. Particular segments of DNA, such as genes, Myriad argued, typically do not exist in isolated form in nature. Rather, some human intervention and manipulation is required to cleave the targeted segment from the longer chromosomal DNA to which it is attached or to synthesize an isolated molecule directly.27 The basic question in this case was whether this alteration was enough to move Myriad’s claims to isolated DNA segments outside the product-of-nature exception and render the isolated molecule patent eligible. In other words, had Myriad met the Chakrabarty standard and claimed a new molecule with “markedly different characteristics from any found in nature”?28

Writing for the majority at the Federal Circuit, Judge Lourie held that Myriad’s claims met this standard. Isolated DNA was patent eligible, according to Judge Lourie, because it “results from human intervention to cleave or synthesize a discrete portion of a native chromosomal DNA, imparting on that isolated DNA a distinctive chemical identity as compared to native DNA.”29 An isolated DNA molecule is much shorter and has different ends than the native DNA from which it came. Judge Lourie ruled that this distinctive characteristic of isolated DNA was sufficient to render it “markedly different” from its natural counterpart, and that the fact that the two molecules contained identical genetic information was irrelevant to this inquiry.29

The Supreme Court disagreed. Writing for a unanimous Court, Justice Thomas rejected the argument that claims to isolated DNA were claims to a new, non-naturally occurring molecule. The Court stated that “Myriad’s claims are simply not expressed in terms

23 Id. at 309–10 (citation and internal editing marks omitted).
24 Id. at 310.
25 These nine composition claims were the sole claims at issue before the Supreme Court.
26 Myriad also had claims covering partial segments of these claimed isolated DNA and cDNA molecules, as well as common mutations of these sequences.
27 The Federal Circuit noted in its opinion that isolated DNAs can also be chemically synthesized directly as isolated DNAs. This is a process that also clearly involves human intervention and manipulation. See Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 689 F.3d 1303, 1329 (Fed. Cir. 2012).
28 Id. at 1328.
29 Id. at 1330.
of chemical composition, nor do they rely in any way on the chemical changes that result from the isolation of a particular section of DNA.”\textsuperscript{30} Rather, the claims focused on the genetic information encoded in the \textit{BRCA} genes. The Court reasoned that adopting such a strict chemical-based approach could lead to absurd outcomes. For example, “if the patents depended on the creation of a unique molecule, then a would-be infringer could arguably avoid infringing [the entire gene claims] by isolating a DNA sequence that included the [genes] and one additional nucleotide pair.”\textsuperscript{31} According to the Court, such a molecule would not be chemically identical to the molecule claimed by Myriad.

Instead, the Court found that, unlike the patentee in \textit{Chakrabarty}, Myriad did not create anything; nature created these genes. Myriad only discovered a natural product. The Court recognized that this discovery was an important medical breakthrough, but it asserted that “[g]roundbreaking, innovative, or even brilliant discovery does not by itself satisfy the \textsection 101 inquiry.”\textsuperscript{32} The Court found that Myriad’s claims were more analogous to the claims in \textit{Funk Brothers} and concluded that just as the \textit{Funk Brothers} claims “fell squarely within the law of nature exception,” so did Myriad’s.\textsuperscript{33} It held that Myriad’s claims to isolated natural DNA were not to new compositions of matter that were patent eligible under \textsection 101.

The Court also rejected the argument that it should defer to the practice of the PTO, which had granted patents on isolated DNA molecules for more than 30 years. The Court noted that Congress had never expressly approved of this practice in any legislation and that the United States had taken a position opposed to this practice in its arguments to the Court.\textsuperscript{34}

\section*{B. cDNA Claims}

The Supreme Court held that cDNA, on the other hand, is eligible for patent protection. Because cDNA does not contain the non-protein-coding nucleotide sequences, as found in human genes, and does not typically occur in nature, it did not fall into the product-of-nature exception. The Court rejected the argument that cDNA should not be patent eligible because, although a cDNA molecule is composed only of the protein-coding portions of a gene, these exons and thus the structure of the cDNA molecule are dictated by nature. Although this may be true, the Court concluded that “the lab technician unquestionably creates something new when cDNA is made.”\textsuperscript{35} cDNA, according to the Court, was sufficiently distinct from the natural DNA from which it was derived to be said not to be a product of nature. Thus, the Court found, in essence, that claims to cDNA were more like the claims in \textit{Chakrabarty} than those in \textit{Funk Brothers}.

\section*{III. REMARKS}

The \textit{Myriad} decision further illuminated the scope of the product-of-nature exception to \textsection 101. \textit{Funk Brothers} showed that the exception applied to claims where the properties of the claimed natural materials had not been altered. \textit{Myriad} demonstrated that claimed natural materials could be subject to some amount of human modification—in this case, the cleaving of covalent bonds resulting in an isolated DNA segment—and still fall within the exception. \textit{Myriad} thus expanded the known boundaries of the product of nature exception.

It is clear from \textit{Myriad} that more human intervention and modification—beyond isolating a naturally occurring DNA molecule from its natural state—is needed to render a claim to that molecule patent eligible. It is also clear that the amount of human manipulation involved creating cDNA molecules is enough to create a new, patent-eligible molecule that is “markedly different” from the natural materials from which it was derived.

It is not clear, however, where the exact boundaries of the product-of-nature exception lies between these two reference points. In other words, the Court did not specify how much additional human modification was required to move a claim to a product derived from natural materials outside the scope of the exception. In fact, the court expressly declined to consider the patentability of DNA in which the order of naturally occurring nucleotides has been altered.\textsuperscript{36} This issue is left open for future cases.

For human DNA patents, the impact of \textit{Myriad} may be muted. The Human Genome Project was completed in 2003, raising obviousness issues under \textsection 103 for any subsequent claims to human DNAs, and many human DNA patents are close to their expiration dates. Indeed, Myriad’s patents expire in 2015.

The long-term impact of the \textit{Myriad} decision also remains unclear. The ostensible purpose of the product-of-nature exception is to prevent overbroad claims that hinder, rather than promote, further innovation. However sound this idea is in theory, it is difficult to know whether it actually achieves this result in practice. It is possible, as the plaintiffs in \textit{Myriad} argued, that more innovation in the area of genetic-based cancer research might result from the fact that researchers now have greater freedom.

\textsuperscript{30} Ass’n for Molecular Pathology v. Myriad Genetics, Inc., No. 12-398, 569 U.S. __, slip op. at 14 (June 13, 2013).
\textsuperscript{31} Id. at 15.
\textsuperscript{32} Id. at 12.
\textsuperscript{33} Id. at 12–13.
\textsuperscript{34} Id. at 15–16.
\textsuperscript{35} Id. at 17.
\textsuperscript{36} Ass’n for Molecular Pathology v. Myriad Genetics, Inc., No. 12-398, 569 U.S. __, slip op. at 18 (June 13, 2013).
to operate. On the other hand, it is possible that the expansion of the product-of-nature exception in *Myriad* could reduce the incentives to invest in such research, creating a chilling effect that results in less innovation. There is a widespread belief that the Court’s decision in *Chakrabarty*, which emphasized the expansive breadth of patent-eligible subject matter, contributed to the rapid growth of the biotechnology industry starting in the 1980s. The *Myriad* decision may be a catalyst in the opposite direction. Additional variables, such as a potential shift to greater reliance on trade secrets rather than patents, further complicate this inquiry. The net effect of these competing considerations and thus the ultimate impact of *Myriad* are difficult to predict.