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Are Genes Patentable? Myriad Revisited

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Biologics, which can be defined as substances that are produced by or extracted from a biological source, are increasingly important therapeutic agents. Recombinant DNA technology allows for the production of biologic medicines, as well as replication of those medicines as “biosimilars.” The enactment of the Biosimilars Act in 2010 and the recent promulgation of an FDA pathway for approval of biosimilars have made accessible and affordable biologic medicines more than a theoretical possibility. As with their predecessors, new and generic small-molecule medicines, these biologic medicines have generated significant controversy, including patent litigation, some already attracting the attention of the Supreme Court.

In *Association for Molecular Pathology, et al., v. United States Patent and Trademark Office* (“*Myriad*”),[2]the courts considered “composition of matter” and “method” claims of patents assigned to Myriad Genetics, Inc. (“Myriad”) covering genetic sequences related to breast cancer susceptibility from the human *BRCA1* and *BRCA2* genes. The composition of matter claims set forth the inventors’ claims, for example, to an “*isolated DNA* coding for a *BRCA1* polypeptide, said polypeptide having [a specific] amino acid sequence,” and that same *isolated DNA* “wherein said DNA has [a specific] nucleotide sequence.”[3]

The method claims describe a method of screening drug compounds for their effectiveness in treating breast cancer. The claimed method involves growing “a transformed eukaryotic host cell containing an altered *BRCA1* gene,” where the altered *BRCA1* gene is one that is thought to “cause” or predispose an individual to breast cancer. The “transformed” cell is one that has been modified using the now conventional techniques described in the patent to cause the cell’s DNA to includethe “altered *BRCA1* gene” and that present a model system for studying breast tumor cells. The method then calls for growing the transformed cell “in the presence of a compound suspected of being a cancer therapeutic” and, using techniques described in the patent specification, “determining the rate of growth” of the cell and comparing that rate to the rate of growth of the same cell in the absence of the suspected therapeutic compound.[4]If the growth rate is slower, inferentially the suspected therapeutic could be deemed “effective.”

The plaintiffs, the Association for Molecular Pathology (“AMP”) and others claimed they were restrained by the patents from using similar methods in the diagnosis and treatment of breast cancer.[5]

Previous Court Proceedings

Prior to trial, the district court construed a number of the terms in the challenged patent claims, including the terms “DNA” and “isolated DNA.”[6]The trial court held that the “isolated DNA” composition of matter claims were outside the statutory subject matter eligible for patenting under § 101 of the Patent Act. Relying on the “machine-transformation” test enunciated by the Federal Circuit *en banc* decision in *In re Bilski,* a test that was later modified (or rejected) by the Supreme Court,[7]the trial court also held the method claims to be invalid.

Myriad appealed to the Court of Appeals for the Federal Circuit. In April 2011, the Federal Circuit held the challenged claims to be patent-eligible under 35 U.S.C. § 101. In a divided opinion, the court held both “isolated DNA" and cDNA to be patent-eligible subject matter, predicated on an understanding of the chemical differences between DNA and “isolated DNA” or cDNA, and rejecting the“informational” definition of DNA offered by the plaintiff-appellees.[8]Neither party directly challenged the district court’s claim construction on appeal, particularly its construction of the terms “DNA” and “isolated DNA.” None of the three opinions in the Federal Circuit’s initial review of *Myriad* quoted, relied on or criticized the unchallenged district court construction of the claim terms “DNA” or “isolated DNA.”[9]

The plaintiff-appellees petitioned the Supreme Court for review, raising the question, “Are human genes patentable?”[10]

The Supreme Court Intervenes: *Prometheus*

In the interim, the Supreme Court decided *Mayo Collaborative Services v. Prometheus Laboratories Inc.*(“*Prometheus*”).[11]The Supreme Court found that the claims challenged in *Prometheus*—which relate to calibrating the dosage of a type of drug in response to the patient’s metabolism of the drug—simply appended “conventional steps, specified at a high level of generality, to laws of nature, natural phenomena, and abstract ideas,” and that this addition “cannot make those laws, phenomena, and ideas patentable.”[12] The Supreme Court granted the petition for certiorari in *Myriad*, vacated the opinion of the Federal Circuit and remanded the case for reconsideration in light of *Prometheus*.[13] The same day, the Federal Circuit ordered that briefs on the merits and amicus briefs be filed simultaneously on June 15, 2012, confined to the question: “What is the applicability of the Supreme Court’s decision in *Mayo* to Myriad’s isolated DNA claims and to method claim 20 of the ’282 patent?” Oral argument was scheduled for and held on July 20, 2012.[14]

Supplemental briefs were filed by Myriad Genetics and the plaintiffs. Amicus briefs were filed by a dozen or more interested parties including several involved in the development of biologic medicines and biosimilars.

Myriad’sOral Argument (The Second Time Around)

In effect, the Supreme Court’s action placed the *Myriad* case before the Federal Circuit again, as if its first decision had never been written. The arguments on July 20 were not made on a “clean slate,” but differed from those presented a year ago, when the Federal Circuit first heard the case.[15]Counsel for Myriad argued that, since the claims at issue in *Prometheus* were method claims, the Supreme Court’s decision in *Prometheus* did not and should not change the analysis of patent eligibility of composition of matter claims. Such claims, Myriad’s counsel argued, have been and should continue to be governed by the Supreme Court’s earlier decision in *Diamond v.*

Chakrabarty(“*Chakrabarty*”),[16]because the composition of matter recited in the representative composition claims was “markedly different” from something found in nature, and was the product of an “enormous amount of human judgment” or “inventive judgment.” This “inventive judgment,” he said, was the selection of the starting and ending points of the *BRCA1* gene. Pointing to the patent specification's definition of “regulatory sequences,” a definition that referred to DNA sequences as “normally” within 100,000 base pairs “of the coding region of a locus,” such as the *BRCA1* locus, counsel for Myriad stated that the selection of the starting and ending points of the genomic sequence of the *BRCA1* gene, depicted in Figure 10 in the patent, was the product of human ingenuity and an inventive scientific contribution.

Judge Lourie, who wrote the opinion for the majority in the initial *Myriad* decision, clearly agreed with Myriad's counsel, obviously suggesting through his questions that the nontrivial nature of this selection process was important in determining the eligibility of the claimed invention for patenting.

However, the argument that “inventive judgment” should be a test for patent eligibility presented an opportunity for intense questioning by both Judge Bryson, who dissented from the initial Federal Circuit opinion, and Judge Moore, who wrote a separate opinion concurring in part.

Neither *Chakrabarty* nor *Prometheus* announces any such test. Instead, *Prometheus* provided that the pertinent question is 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?”[17] *Chakrabarty* concerned a “human-made, genetically engineered bacterium” that was “capable of breaking down multiple components of crude oil,” a property, the Court said, “which is possessed by no naturally occurring bacteria.” Recognizing that the “Congress intended statutory [patentable] subject matter to “include anything under the sun that is made by man,” the Supreme Court found Chakrabarty’s new cell to be eligible for patenting because it was a “nonnaturally occurring manufacture or composition of matter – a product of human ingenuity ‘having a distinctive name, character [and] use.’"[18]The patentee, *Chakrabarty* said, "has produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility.” His discovery, the Court found, “is not nature's handiwork, but his own; accordingly it is patentable subject matter under § 101.”

However difficult it may be to apply the tests announced in *Prometheus* or *Chakrabarty* in a particular case, Myriad’s suggested test of “inventive judgment” offers no greater certainty. How much and what kind of “inventive judgment” is “enough” to distinguish a mere discovery from a product of real human ingenuity?

Judge Moore asked whether Myriad's argument was that the *BRCA1* gene is patentable because human ingenuity is involved in deciding where to “clip” it, when extracting it from DNA. Myriad’s counsel responded affirmatively. Judge Moore appeared to ask whether the determination of where to cut was Myriad's “whole case,” commenting that the “inventive judgment” test “makes no sense.”

Judge Bryson, following up, questioned whether, if a surgeon exercising judgment determined the best way to remove a kidney to maximize its effectiveness in a kidney transplant, would be entitled to claim, in a patent, the isolated kidney as an invention because he determined where best to cut? Myriad's counsel responded that he would not be entitled to a patent, distinguishing the *Myriad* case by the assertion that DNA extraction is far more complex. Judge Bryson asked whether, if the kidney extraction question was equally complicated, would it make a difference? Rescued by Judge Lourie’s intervening question, which noted the difference between an organ and a well-defined chemical composition, Myriad's counsel ultimately retreated to his argument that the isolated DNA claimed in

the *Myriad* patents is patentable subject matter because it is man-made. He added that it is man-made because Myriad scientists decided where to start and stop the molecule.

The panel also questioned Myriad's counsel regarding the impact of *Prometheus* on the single method claim identified by the Federal Circuit prior to argument (Claim 20). The method claims struck down in *Prometheus*, he said, started with an abstract idea and applied it with a "trinity" of "well understood, routine and conventional" analytical steps. In contrast, he added, the claim in *Myriad* starts with a "new manufacture," that is, a host cell that is itself man-made, and then applies steps to that new manufacture. After arguing that some "transformation" is explicitly required by the claim, and faced with Judge Moore's comment that "transformation is somewhat irrelevant at this point," Myriad's counsel distinguished the method claim by acknowledging that its critical feature was the use of something not found in nature.

At the end of the argument, counsel for Myriad concluded by stating that, "Simply put, *Chakrabarty* drew the line, this court applied that line [in its initial decision in *Myriad*] … and nothing in [*Prometheus*] changed that line."

The Plaintiff's Oral Argument

Counsel for the Association of Molecular Pathology fared no better in questioning than Myriad's counsel. He began with the proposition that the isolated DNA claims in *Myriad* had "stunning breadth." He argued that, by itself, under the logic announced in *Prometheus*, the breadth of the challenged composition of matter claims should cause the court to be concerned with their "preemptive effects."[19]Judge Lourie commented that claim breadth is a matter for determination under 35 U.S.C. § 112, and not a matter of patent eligibility, under 35 U.S.C. § 101. He suggested that "by definition," the *Prometheus* holding concerning method claims is simply irrelevant to analysis of composition claims. AMP's counsel suggested that the "law of nature" doctrine, presumably described in *Prometheus*, was meant to ensure that laws and products of nature are free for all to use, whether the subject matter is defined as a method or as composition of matter.

Judge Moore, evincing a negative reaction, stated that AMP's argument about claim breadth undermined its argument about preemption, adding that "our cases have not distinguished among different laws of nature according to whether or not the principles they embody are sufficiently narrow." She characterized AMP's argument about the breadth of Myriad's isolated DNA claims as "a waste of time." AMP's counsel took the hint and moved on.

Turning to the method claim, Claim 20, AMP's counsel analogized the "host cell" described in the claim to an off-the-shelf test tube. He stated that all that the method claim required is the insertion of a BRCA1 "gene" into the host cell and then "seeing what happens." Judge Moore asked whether the "host cells" used in the method were themselves not found in nature and were man-made? AMP's counsel ultimately acknowledged that the transformed "host cell" described in Claim 20 was not naturally occurring. He attempted to distinguish the use of such a "host cell" by stating that it was not itself "inventive" and that anyone using the method described in Claim 20 could simply purchase such a "host cell" as an off-the-shelf product.[20]

In light of AMP's argument that methods of using biological substances were, at least under some circumstances, not eligible for patenting, Judge Lourie questioned whether the use of penicillin as an antibacterial agent was a patent-eligible method. AMP's counsel replied that, although he was not fully familiar with the history of penicillin, the answer to Judge Lourie's question probably depended on whether a "transformation" occurred during the process and whether it was "markedly different."

He added, appearing to surprise at least some of the judges, that merely using penicillin and seeing what happens “is clearly not patentable.”

The Argument of the United States

The United States, as *amicus curiae*, also argued before the court. Noting that there may have been “lots of discovery" in this case, counsel for the United States added that the patentees “did not bestow the utility” of the claimed isolated DNA, “they just uncovered it.” Responding to questions by Judge Lourie, counsel for the United States appeared to support AMP's arguments, expressing concerns about “preemption,” and arguing that old products and laws of nature should remain free for public use.

Counsel for the United States commented that it has been difficult, if not impossible, to find a “principled line” that would allow isolated DNA claims to be eligible for patenting, but that would prohibit eligibility of things like isolated coal or tungsten for patenting. The government's counsel suggested, by analogy, that coal does not become patent-eligible upon extraction, simply because someone was able, by “inventive judgment” or otherwise, to distinguish coal from the surrounding rock, even if many of the natural properties of coal cannot be exploited until it is extracted from its surrounding environment.

The government stated that, in its view, this is not a “close case.” As a further analogy, counsel for the United States suggested that breaking apart a proton to isolate a quark would not yield a patent-eligible invention. The line between discovery and invention, the United States suggested, cannot be drawn by reference to changes in a substance that are merely incidental to its extraction from a larger environment. In this sense, the United States took issue with majority opinion and Judge Moore's opinion in the initial *Myriad* decision. Both opinions relied on what Judge Moore described as “chemical considerations” as follows:

DNA is a chemical polymer. In principle, a polymeric DNA sequence is no different than any other well known polymer, for example, nylon. … When they are assembled into a DNA sequence, … monomers are chemically bonded to each other. The process of polymerization of the monomer units—whether carried out by chemical or biological means—results in a new molecule.[21]

Observations About the Judges’ Positions

It was not apparent, from the questioning, that any of the judges agreed with the positions taken by the United States, or that they agreed fully with the positions taken by any of the parties in the case.

It appeared that Judge Lourie adhered to his view, stated in the Federal Circuit's initial majority opinion, that Myriad's claims to “isolated DNA” were eligible for patent under 35 U.S.C. § 101 because, a result of the severing of covalent bonds in the DNA backbone in order to obtain “isolated DNA,” the claimed isolated DNA is a “chemical species” that markedly differs from “native DNA,” and is therefore patent-eligible subject matter.[22]

It was also clear from the questioning that Judge Bryson was not deterred by argument or responses to questions from adhering to the position in his initial dissenting opinion in *Myriad:*

Myriad is claiming the genes themselves, which appear in nature on the chromosomes of living human beings. The only material change made to those genes from their natural state is the change that is necessarily incidental to the extraction of the genes from the environment in which they are

found in nature. While the process of extraction is no doubt difficult, and may itself be patentable, the isolated genes are not materially different from the native genes.[23]

“[T]here is no magic,” Judge Bryson said in that dissent,“to a chemical bond that requires us to recognize a new product when a chemical bond is created or broken, but not when other atomic or molecular forces are altered.…” A chemical bond, he continued, “is merely a force between two atoms or groups of atoms strong enough ‘to make it convenient for the chemist to consider [the aggregate] as an independent molecular species.…’“[24]

Whether Judge Moore will continue to adhere to her initial concurring view seems less certain. Judge Moore again recognized, in her questions, the need for patent certainty and she expressed sincere concern about disrupting the “settled expectations” of holders of patents on “genes,” like Myriad. Nevertheless, the United States persuasively argued that other cases decided by the Supreme Court, including, for example, *Bilski v. Kappos*,[25]significantly altered or disrupted the “settled expectations” of patent holders, and that this consideration should not be determinative in arriving at general rules about the interpretation of the “law of nature” exception to patent eligibility under 35 U.S.C. § 101. Judge Moore's questions of Myriad's counsel strongly suggest that she may now have less comfort with the line between “invention” and mere ”discovery” that may have been drawn in the initial round of opinions, particularly if that line depends upon a vague concept like “inventive judgment.”

None of the judges, in their questioning, appeared concerned that the Supreme Court's recent *Prometheus* decision affected the outcome of the Federal Circuit's analysis of the remaining method of use claims, particularly Claim 20. To the contrary, even Judge Bryson seemed to refrain from criticizing Myriad’s position that use of a man-made “host cell” in the claimed method was “enough” to distinguish that method from the “determining” steps claimed in *Prometheus*.

Conclusions

Many conclusions might be drawn from the questions propounded by the Court in the recent reargument of the *Myriad* case. What seems clear is that the court will continue to search for a principled basis on which to distinguish an “invention” that may apply a "law of nature" or that results in the creation of a new substance, from a mere “discovery” of a product of nature. The *Myriad* case may not be the best vehicle for the Court’s refinement of the blurry line set forth in *Chakrabarty* that distinguishes a natural product from one that is "markedly different" and man-made. Indeed, it might be argued that, despite the failure of the parties to concentrate their arguments on patent eligibility in light of the unchallenged construction of claims by the district court, the eligibility of the “isolated DNA” claims in *Myriad* might be determined with greater ease simply by recognizing that those claims are, in fact, limited in scope, perhaps solely to cDNA, and that those claims are not, as the plaintiffs suggested, “stunningly broad.” It might be argued that the large questions generated by the parties’ briefs, evident in the Federal Circuit’s questions, need not be reached in order to resolve the specific dispute between the parties and that, instead, this is *not* the “right” case for re-drawing of arguably blurry lines.

Whatever the court may decide, it would seem that *Myriad* is likely destined for another visit to the Supreme Court. Whether the Supreme Court may decide to entertain review of the important questions debated in the most recent *Myriad* briefs and oral argument in the Federal Circuit will likely depend on the nature of the Federal Circuit’s disposition and opinion in the case. At the end of the argument, after thanking counsel for their argument, Judge Lourie stated that the court would take the case under advisement and, with obvious good humor, acknowledged that “it remains to be seen

whether we'll be back."

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[1]This client alert has been prepared by members of Schiff Hardin's Intellectual Property Group, who concentrate their practices in biologics and pharmaceutical products, including D. Christopher Ohly (Washington, D.C.), Sailesh K. Patel (Chicago), George Yu (San Francisco) and Steven Hankins. For further information about the contents and specific subject matter of this client alert, please contact Chris Ohly, in our D.C. office, George Yu, in our San Francisco office, or Sal Patel, in our Chicago office. For additional information about our IP practice, please contact Steve Hankins, in our San Francisco office.

[2]702 F.Supp. 2d 181 (S.D.N.Y. 2010), *rev'd* 653 F.3d 1329 (Fed. Cir. 2011), *cert. granted*, *vacated and remanded*, 2012 WL 1500104 (April 30, 2012).

[3]*See* U.S. Patent No. 5,747,282, claims 1 and 2. In the trial court, the plaintiffs also challenged certain claims that referred to "cDNA" as also drawn to patent-ineligible subject matter under 35 U.S.C. § 101. *See Myriad*, 653 F.3d at 1334 (noting, for example, that the plaintiffs sought a declaratory judgment of invalidity with respect to claim 1 of U.S. Patent No. 5,753,441). Claim 1 of the '441 patent refers to cDNA. *Myriad*, 702 F.Supp.2d at 213, n.34. Claims 1 and 2 of the '282 patent were said to be "representative composition claims." *Myriad*, 653 F.3d at 1334.

[4]*See* U.S. Patent No. 5,747,282, claim 20. This claim was not one of the "representative" method claims, but was singled out as different from several other representative claims, which "cover methods of 'analyzing' or 'comparing' a patient's BRCA sequence with the normal, or wild-type, sequence to identify the presence of cancer-predisposing mutations." *Myriad*, 653 F.3d at 1334. Interestingly, claim 20 of the '282 patent was the only method claim identified by the Federal Circuit for further briefing after the Supreme Court's remand. http://www.cafc.uscourts.gov/images/stories/opinions-orders/10-1406%20order.pdf.

[5]In *Myriad* patents were challenged under 35 U.S.C. §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.

[6]The trial court construed the term "DNA" to mean "a sequence of nucleic acids, also referred to as nucleotides" therefore constituting a "nucleotide sequence" or a "polynucleotide." It construed the term "isolated DNA," in light of the explicit, lexicographer's definition of the term included in the patent specification, to mean "a segment of DNA nucleotides existing separate from other cellular components normally associated with native DNA, including proteins and other DNA sequences comprising the remainder of the genome, and includes both DNA originating from a cell as well as DNA synthesized through chemical or heterologous biological means." *See Myriad,* 702 F.Supp.2d at 216 - 17.

[7]*Bilski v. Kappos*, 130 S.Ct. 3218 (2010).

[8]More recently, in connection with the re-argument of the *Myriad* case after its remand by the Supreme Court, Dr. James Watson, the acknowledged co-discoverer of the double-helical structure of the DNA molecule and, while at NIH, a contemporaneous decoder of the entire human DNA

sequence, submitted a brief as *amicus curiae*. In his eloquent description of DNA and his opposition to the patenting of DNA materials, Dr. Watson acknowledged that “DNA is little more than two strands of a nucleotide polymer together in a double helix formation. The nucleotide polymer consists of various sequences of A, T, G, and C bases.”

However, Dr. Watson argued, unlike other chemical moieties, DNA has a unique “informational role in life.” He argued that “[a] human gene, which is a product of nature, is useful because it conveys vital information.” The human genome’s “ability to be our instruction book on life,” he said, “distinguishes it from other chemicals covered by the patent laws.” As a result, he contended, “we would not want one individual or company to monopolize the legal right to the beneficial information of a human gene—information that should be used for the betterment of the human race as a whole.”

[9]“According to Myriad,” the Federal Circuit opinion said, the “district court failed to recognize the transformative nature of the claims by (1) misconstruing the claim term “sequence” as just information, rather than a physical molecule …” Myriad, 653 F.3d at 1355. Curiously, the district court’s opinion does not list the term “sequence” as a disputed claim term. Myriad, 702 F.Supp.2d at 216 – 17.

[10]See Association for Molecular Pathology Petition for Certiorari, at page i, http://www.aclu.org/files/assets/association_of_molecular_v__myriad_petition_for_writ_of_certiorari.pdf.

A gene is commonly defined as a “DNA segment that contributes to phenotype/function. In the absence of demonstrated function a gene may be characterized by sequence, transcription or homology.” HUGO Gene Nomenclature Committee, http://www.genenames.org/guidelines.html. A gene is also defined as a “DNA segment that *reveals* an *‘image’*of a DNA-derived molecule that is *hypothesized* to exist and function.” E.J. Rogers, *Can You Patent Genes? Yes and No,* 93 J. Pat. & Trademark Off. Soc'y 19 (2011). In either event, a “gene” includes segments of both complimentary strands of DNA at a particular location or sequence.

None of the ‘282 composition of matter claims explicitly set forth a claim for “cDNA.” Strictly speaking, the relevant patent claims to *isolated DNA*only recite the “nucleotide sequence [of 5914 base pairs is] set forth in SEQ ID NO:1.” This sequence is *not* the *entire* “gene.” One skilled in the art might well understand the claim, in light of the patent specification, to claim the *cDNA* that corresponds to the BRCA1 “gene,” especially because SEQ ID NO:1 describes the “Molecule Type” it enumerates as “cDNA,” while other sequences identified in the patent specification label molecules as “DNA (genomic).”

The “coding sequence for a BRCA1 polypeptide,” the patent specification states “is shown in SEQ ID NO:l.” It is a portion of the “BRCA1 locus” that itself may or may not be *the entire* BRCA1 “gene.” *See Myriad*, 653 F.3d at 1376 (Bryson, J., dissenting: “Aside from Myriad’s cDNA claims, its composition claims are not defined by any particular chemical formula. For example, claim 1 of the ?282 patentcovers all isolated DNAs coding for the BRCA1 protein, with the protein being defined by the amino acid sequence encoded by the naturally occurring BRCA1 gene. From a molecular perspective, that claim covers a truly immense range of substances from the cDNA that is 5,914 nucleotides long to the isolated gene that contains more than 120,000 nucleotides. And the patent does not define the upper end of that range because the patent does not identify a unique nucleotide sequence for the 120,000–nucleotide–long isolated BRCA1 gene. …”)

It is also noteworthy that, in his dissenting opinion after the Federal Circuit’s initial hearing of *Myriad*,

Judge Bryson commented on AMP's (appellees) argument "that the BRCA1 cDNA can be isolated from nature." Judge Bryson noted that AMP referred "to a BRCA1 pseudogene called BRCA1P1 that is found in the human genome." However, Judge Bryson said, "the appellees have failed to demonstrate that the pseudogene consists of the same sequence as the BRCA1 cDNA." As a result, in his dissent, Judge Bryson said "I agree with the court that the claims to BRCA cDNA are eligible for patenting. The cDNA cannot be isolated from nature, but instead must be created in the laboratory." *Myriad*, 653 F.3d at 1378, n.5. Absent *factual* proof that the BRCA1 cDNA identified in the patent, in "SEQ ID NO:1" recited in the "isolated DNA" claims, can be found "in nature," a disposition of the appellees' argument that those "isolated DNA" claims do not cover subject matter eligible for patenting under 35 U.S.C. § 101 might be somewhat clearer, at least under the *Chakrabarty* standard.

[11]132 S.Ct. 1289, 1304 (2012).

[12]In *Prometheus*, the Supreme Court also reiterated that the "machine-or-transformation" test, frequently employed by the Federal Circuit in determining whether a claim covers patentable subject matter, is merely an "important and useful clue" to patentability, adding that the test does not trump the "law of nature" exclusion. *Id.*, 132 S.Ct. at 1301, *citing Bilski v. Kappos*, 561 U.S. ——, 130 S.Ct. 3218, 177 L.Ed.2d 792(2011). The Supreme Court found that the "machine-or-transformation" test failed in *Prometheus*. *Id.*, 132 S.Ct. at 1303.

Without explicitly extending its reasoning to other cases, in *Prometheus* the Supreme Court held that certain patent claims, covering methods for determining the optimal dosage of thiopurine drugs, including 6–mercaptopurine (6–MP) and azathiopurine (AZA), used to treat gastrointestinal and non-gastrointestinal autoimmune diseases, were invalid because they claimed non-patentable subject matter. In particular, the Supreme Court held those method claims unpatentable under §101 of the Patent Act, because they "effectively claim the underlying laws of nature themselves." The Supreme Court said:

We need not, and do not, now decide whether were the steps at issue here less conventional, these features of the claims would prove sufficient to invalidate them. For here, as we have said, the steps add nothing of significance to the natural laws themselves. *Unlike, say, a typical patent on a new drug or a new way of using an existing drug, the patent claims do not confine their reach to particular applications of those laws.* The presence here of the basic underlying concern that these patents tie up too much future use of laws of nature simply reinforces our conclusion that the processes described in the patents are not patent eligible, while eliminating any temptation to depart from case law precedent. *Prometheus*, 132 S.Ct at 1302 (emphasis added).

[13]*See Myriad, cert. granted*, *vacated and remanded*, 2012 WL 1500104 (April 30, 2012).

[14]*See* Note 1, *supra*.

[15]A transcript of the arguments is not yet available. A recording of the arguments became available on the afternoon of July 20, 2012. http://www.cafc.uscourts.gov/oral-argument-recordings/search/audio.html

[16]At issue in *Diamond v. Chakrabarty,* 447 U.S. 303 (1980)(*Chakrabarty*),was the eligibility of claims in a patent application to a "human-made, genetically engineered bacterium." The bacterium was "capable of breaking down multiple components of crude oil," a property, the Court said, "which is possessed by no naturally occurring bacteria. Because of this property "Chakrabarty's invention

[was] believed to have significant value for the treatment of oil spills."

The Court said that Chakrabarty's "micro-organism plainly qualifies as patentable subject matter. His claim is not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter - a product of human ingenuity 'having a distinctive name, character [and] use.'" *Chakrabarty,* 447 U.S. at 309 – 10.

[17]Focusing on method claims, *Prometheus* reiterated that laws of nature, physical phenomena, and abstract ideas are not patentable, expressing a concern that claims covering natural laws will inhibit, rather than promote, innovation. *Prometheus* held the challenged method claims unpatentable under §101 of the Patent Act, because they "effectively claim the underlying laws of nature themselves," and simply appended "conventional steps, specified at a high level of generality, to laws of nature, natural phenomena, and abstract ideas."

[18]*Chakrabarty,* 447 U.S. at 309 – 10.

[19]*Prometheus* considered what the Supreme Court characterized as "narrow laws that may have limited applications." However, the Supreme Court said, even those patent claims, that embody those "narrow" law of nature nonetheless implicate a concern "that the grant of patents that tie up their use will inhibit future innovation premised upon them, a danger that becomes acute when a patented process amounts to no more than an instruction to "apply the natural law," or otherwise forecloses more future invention than the underlying discovery could reasonably justify." These comments by the Supreme Court in *Prometheus* were apparently the basis for argument by AMP's counsel concerning the "stunning breadth" of the patent claims at issue in *Myriad*.

The argument by AMP's counsel about the breadth of the *Myriad* patent claims was based, at least in part, in an effort to import into the isolated DNA claims a portion of the patent specification that defined what he characterized as "DNA." The specification contains no specific definition of "DNA," leaving that to the understanding of one of ordinary skill in the art. The portion of the patent specification partially quoted by AMP's counsel says, in pertinent part, that "The polynucleotide compositions of this invention include RNA, cDNA, genomic DNA, synthetic forms, and mixed polymers, both sense and antisense strands, and may be chemically or biochemically modified or may contain non-natural or derivatized nucleotide bases, as will be readily appreciated by those skilled in the art." '282 Patent, col. 19, lines 51 – 56. As noted above, however, the patent claims only recite "isolated DNA," and not all "polynucleotide compositions." Further, as noted above, the patent specification contains a lexicographer's definition of the term "isolated." '282 Patent, col. 19, lines 8 – 18. Finally, as further noted above, the district court in *Myriad* actually construed the term "isolated DNA" in its opinion. All of this was apparently ignored by counsel for AMP in his answer to the court's questions.

[20]In later responses to questions, Myriad's counsel appeared to argue that the "host cell" was transformed by insertion of the altered BRCA1 "gene" into the cell, according to the method in Claim 20, but this argument was itself not entirely clear.

[21]*Id.,* 653 F.3d at 1361.

[22]*Id.,* 653 F.3d at 1352 - 53.

[23]*Id.,* 653 F.3d at 1375 B.

[24]*Id.,* 653 F.3d at 1375, *quoting* Linus Pauling, *The Nature of the Chemical Bond* 6 (3d ed. 1960).

[25]130 S.Ct. 3218 (2010).

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