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The *Myriad* Appeal: Is Isolated Human DNA Patentable?

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Today, in what could be a landmark biotechnology patent case, the Federal Circuit heard oral argument in *Association for Molecular Pathology, et al. v. United States Patent and Trademark Office, et al.* If the plaintiffs are able to survive the lack of standing challenge, the Court will decide whether isolated human DNA is patent-eligible. A district court in the Southern District of New York invalidated under 35 U.S.C. § 101 (section 101) certain patents to genes known to be risk-indicators for breast cancer owned by Myriad Genetics, Inc. (Myriad). This decision is in stark contrast to the stated policy and actions of the United States Patent and Trademark Office (Patent Office), which has traditionally granted patents to isolated DNA. The United States Department of Justice, representing the federal government in the case, has taken the position that certain isolated gene patents should be invalidated but that other gene patents, where the genetic product does not exist in nature, should be upheld.

The Federal Circuit is addressing two questions on appeal: 1) whether plaintiffs had standing to file a declaratory judgment action against Myriad seeking to invalidate its patents; and, if so, 2) whether isolated DNA is patent-eligible subject matter. A decision affirming the district court and finding that isolated human DNA is not patent-eligible subject matter would be a substantial shift in patent law.

In 2001, the Patent Office published revised examination guidelines concerning the patent eligibility of isolated genes and stated that an isolated and purified gene may be the basis for a patent as long as the patent discloses that the specified gene expresses a useful protein. This case challenges those guidelines and the validity of Myriad's patents. At issue are fifteen claims from seven patents relating to the human genes known as Breast Cancer Susceptibility Genes 1 and 2 (BRCA1 and BRCA2, respectively). Mutations in these genes are associated with significantly increased risks of breast and ovarian cancer. Myriad is the holder, or exclusive licensee, of these patents. In practical terms, this makes Myriad the only company in the United States able to produce and derive results from tests of these genes.

The plaintiffs in this case are a range of doctors, scientists, patients, and organizations related to breast cancer research and testing. They argue that they are being injured by the improperly granted patents. The doctors, scientists, and clinics argue that they cannot continue their research or treat their patients. The patients argue that they are being denied testing and treatment because of the restrictions imposed by Myriad. If the patents are invalidated as ineligible patent subject matter, the plaintiffs argue that their issues will be resolved.

There are two types of patent claims in this case: composition claims and method claims. The composition claims are directed to isolated DNA that translates into a certain protein. The method claims are directed to a process of comparing a subject's DNA with a baseline sample to identify the specific mutations in the DNA that signal an increased risk of breast or ovarian cancer.

Client Alert.

District Judge Robert Sweet, in a 152-page opinion, declared the subject matter of the claims of the patents-in-suit ineligible for patenting. The district court's inquiry focused on whether or not the claimed invention fell within the "products of nature" exception to patentable subject matter, which excepts naturally occurring phenomena from being patentable.

Judge Sweet found both the composition claims and the process claims were invalid. Citing Supreme Court precedent that patentable "products of nature" must be markedly different from natural phenomena to be patent-eligible, the court found there was no change in what occurred in nature by simply removing a section of DNA from the entire genome but not otherwise altering the DNA. Judge Sweet reasoned that purification, by itself, did not render the isolated DNA patent-eligible because the basic structure and function of the DNA remained the same. As for the method claims, the court found that they were only directed to the abstract process of "comparing" and "analyzing" gene sequences, and did not contain the transformative act necessary for patenting because preparatory physical transformations do not qualify for patenting.

Myriad appealed Judge Sweet's decision to the Federal Circuit. As to the composition claims, Myriad argues that isolated DNA molecules are "compositions of matter eligible for patenting" and that "products of nature" are not categorically ineligible for patenting. As to the method claims, Myriad argues that the extracting, processing, and analyzing of the DNA creates a transformation sufficient for patentable subject matter.

The plaintiffs respond by arguing that DNA is a natural phenomenon found in nature and isolating a product of nature does not make it eligible for patenting under Supreme Court precedent because the changes made to the DNA in the lab do not give isolated DNA a distinctive name, character, or use.

On appeal, the Solicitor General's Office of the United States has taken the almost unprecedented step of filing its own *amicus curiae* brief in support of neither party. . The United States' brief divides the types of claims at issue differently. It argues that Judge Sweet correctly invalidated the isolated DNA claims, but incorrectly invalidated the engineered DNA molecule claims. Arguing that all "human-made inventions" are patentable, the United States would have the Federal Circuit reverse the district court in part and validate the claims limited to cDNA, a human-engineered molecule.

There is a chance the Federal Circuit will not reach the merits of the patentable subject matter issue. The Federal Circuit may decide the plaintiffs lack standing to challenge Myriad's patents because there is no actual "case or controversy," rather than a hypothetical dispute, between the parties.

The Federal Circuit's "case or controversy" jurisprudence requires examination of "all the circumstances" to determine whether or not the court may consider an action for declaratory judgment of invalidity. To establish an actual case or controversy, the Federal Circuit requires that the defendant must take an affirmative action relating to enforcing its patent rights and the plaintiff must have taken meaningful steps towards conducting potentially infringing activity. District Judge Sweet found that these requirements were met, but the Federal Circuit may revisit his finding.

Today, the parties argued their positions before the three judge panel of Circuit Judges Lourie, Bryson, and Moore. Myriad, the plaintiffs, and the Department of Justice each argued. The court appeared to be very interested in the parties' position on standing stating that it is a "threshold issue" that must be taken up in the first instance.

Myriad stated that the case should be dismissed due to a lack of standing because the plaintiffs could not meet the "actual or threatened injury" prong of the standing inquiry. Myriad argued that the last affirmative action it took to enforce its patents was sending a 1998 cease and desist letter to the University of Pennsylvania. Judge Moore queried whether the University is still under the threat of the cease and desist letter and whether it was realistic for it to believe that such a

Client Alert.

threat existed. Myriad countered that it was unreasonable for the University to believe that the threat still existed and, in any event, if that is the case why did the plaintiffs wait twelve years to file a declaratory judgment action.

The plaintiffs argued that Myriad has conceded that there is standing because it has acknowledged that there are scientists and labs that are ready, willing, and able to perform research and testing on the BRCA 1 and BRCA 2 genes. Judges Moore and Lourie pointed out that the evidence submitted by plaintiffs in support of Myriad being “ready, willing, and able” to perform the research and testing argument was not strong in that the researchers said they would “consider” doing the research and testing, not that they “were going to affirmatively do” so. The plaintiffs responded by arguing that once the researchers received Myriad’s cease and desist letter in 1998, they altered their behavior and stopped all research and testing on the BRCA1 and BRCA2 genes. According to the plaintiffs, this alone provides the plaintiffs with standing.. Moreover, plaintiffs state that they routinely isolate and sequence genes every day and could do the same with the BRCA1 and BRCA2 genes but for Myriad’s patents. Because of the cease and desist letter, the plaintiffs state that they “know Myriad would sue them as soon as they starting such testing.”

Turning to the merits of the appeal, Myriad argued that isolated DNA does not exist in nature and would not exist but for human ingenuity. Therefore, patents claiming isolated DNA must be valid and survive the inquiry under section 101 set forth in the Supreme Court’s *Chakrabarty* and *Funk Brothers* line of cases. Judge Bryson asked whether he could sequence his own genome or whether he would have to get licenses from all the patentees owning the patents to each individual gene sequence. Myriad replied that Judge Bryson could sequence his own genome as long as he did not isolate any one gene that had been patented. Judge Moore asked whether a mineral stuck in a rock that required excessive means for extraction was patentable. Myriad stated that if human ingenuity was required to extract the mineral from the rock, then the mineral would be patentable under section 101. However, Myriad added that such a mineral may not be patentable under the novelty and obviousness tests. Judge Lourie added that DNA is different because one is changing it when one takes it out of the entire genomic sequence; whereas, the mineral will be unchanged when it is removed from the rock. Myriad analogized its extraction of genes to the production of a baseball bat. Myriad stated that a tree exists in nature and inside the tree is a baseball bat. Due to human ingenuity, the tree is turned into a baseball bat and therefore, the bat is patentable. According to Myriad, the bat exists in nature as a tree, but human manipulation makes it take the form of the bat, which is patentable.

The plaintiffs made an interesting economic-based argument that the Myriad patents are invalid under section 101. They argued that it is Myriad’s business to test genes and let people know whether they have an increased risk of cancer. Therefore, the genes as they exist in a person must be the same as the isolated DNA that is tested in order for Myriad to give accurate test results. Myriad thus is merely taking what already exists in nature and is attempting to patent it. Judges Bryson and Lourie pointed out that in order to isolate DNA, covalent bonds are broken and a portion of the DNA is removed from the entire genome, so the isolated DNA must be different than what occurs in nature. Judge Moore added that there are many things that one can do with isolated DNA that cannot be done with an entire genome. The plaintiffs responded by arguing that the isolated DNA as it exists separate from the entire genome is the exact DNA that exists in the entire genome. According to the plaintiffs, removing the mineral from the rock is an apt analogy to the isolated DNA – both occur in nature and under Supreme Court precedent, this is not patentable subject matter.

The federal government stated that the court should look at DNA under what it calls a “magic microscope.” The government argues that when you look through the magic microscope and see DNA as it exists in nature, even if you are focusing only on one specific gene, then it is not patentable subject matter. However, if you are looking through the magic microscope and see DNA that does not exist in nature, such as cDNA, then it is patentable because cDNA is not found in

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nature. The government analogized isolated DNA to lithium, the third element on the Periodic Table. According to the government, lithium is attached to other chemicals in nature. When lithium is isolated from the other chemicals by breaking the covalent bonds between them, the isolated lithium does not become patentable — lithium has been known for centuries and therefore it cannot be patented. The government states that the Court must look at the difference between a product of nature and a human-made invention — the latter, it argues, is patentable. Judge Lourie further stated that the inventors of Myriad's patents did not purify DNA in the sense that they got rid of impurities like with lithium. Instead, they extracted a portion of a large genome to come up with a new product — an isolated piece of DNA. The government conceded that a process patent directed to this method might be appropriate, but remained firm in its belief that the resulting DNA is not itself patentable.

Judge Moore stated that should the Federal Circuit find isolated DNA is not patentable, there would be a dramatic shift in patent law. Judge Moore pointed out that the Patent Office has been granting isolated DNA patents for thirty-five years and to this day has guidelines on its website stating its policy is to grant such patents. Judge Moore noted the diametrically opposed positions within the federal government — pitting the Department of Justice on one side against the Patent Office on the other side. The government responded that following several court opinions issuing on the patentability of isolated DNA, the government took a “comprehensive look at whether [isolated DNA] was patentable.” The government concluded that “the vast majority of DNA patents that have been granted are valid because they are not solely directed to isolated DNA.” However, the Patent Office was “wrong” in granting those patents that are directed to isolated DNA and the guidelines set forth by the Patent Office dealing with this subject matter are also “wrong.”

Myriad concluded the argument by stating that section 101 is consistently understood as encompassing isolated DNA molecules. The Patent Office has been granting patents directed to this subject matter for decades. The entire biotech industry is moored on the notion that isolated DNA is patentable. This notion, Myriad adds, is supported by the Patent Office guidelines. According to Myriad, if the Federal Circuit were to invalidate all of the patents directed to isolated DNA, the foundation of the biotech industry would be significantly damaged.

While it is uncertain how the Federal Circuit will decide either issue on appeal, ultimately either or both issues in the case may end up before the Supreme Court.

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