WSGR ALERT

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DISTRICT COURT INVALIDATES CLAIMS DRAWN TO ISOLATED DNA AS CLAIMING UNPATENTABLE SUBJECT MATTER UNDER SECTION 101

On March 29, 2010, the U.S. District Court for the Southern District of New York issued a decision in *Association for Molecular Pathology v. U.S. Patent and Trademark Office*, No. 09 Civ.4515 (S.D.N.Y 2010), holding that several claims in patents drawn to isolated DNA sequences encoding the *BRCA1* and *BRCA2* genes, and methods of using those sequences to detect or screen for cancer, are invalid because the claims were not drawn to statutory subject matter under 35 U.S.C. §101. Although this decision has drawn a great deal of press, upon closer inspection, it should not affect well-counseled diagnostics companies.

Several particulars regarding this decision render it of limited importance. First, this decision was issued by a district court and, as such, is not binding precedent on either the U.S. Patent and Trademark Office (PTO) or any other court in the U.S. outside of the Southern District of New York. Additionally, of the claims invalidated, those drawn to isolated DNA are not relied upon by most diagnostics companies. Similarly, the method claims invalidated in this decision do not recite any machine, apparatus, or transformative step—limitations that post-*Bilski* claims typically contain. Furthermore, decisions by courts of appeal are likely to curtail the holding or modify the legal underpinnings of the decision. Therefore, in light of the limited precedential effect of this decision, the limited relevance of the claims that were invalidated, and the lengthy appeal process that will almost certainly follow this decision, diagnostics companies will typically be in the same legal position they were prior to this decision.

Overview

35 U.S.C. §101 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 therefore, subject to the conditions and requirements of this title."

U.S. Supreme Court cases addressing this statute have ruled that the language is to be given broad scope and applicability; however, the scope of patentable subject matter is not unlimited. A long-standing limitation on this scope was provided in *Diamond v. Chakrabarty*, where the Supreme Court held that laws of nature, physical phenomena, and abstract ideas fall outside the scope of patentable subject matter. Under this rule, unmodified living organisms, pure elements, and mathematical algorithms are not patentable. Under current law, which regards isolated DNA as a patentable purified chemical, the PTO grants patents on isolated genes or other sequences, but denies patents on genes or sequences naturally occurring, and still intact, within a living organism.

Brief Case Summary

BRCA1 and *BRCA2* are forms of a human gene that are linked to the development of breast cancer. Myriad, the owner of several patents drawn to isolated *BRCA1* or *BRCA2* sequences and their use in diagnostic and research tests, is the sole provider of clinical and other tests for *BRCA1* and *BRCA2*. The *Association for Molecular Pathology* case was initiated by multiple plaintiffs, including several non-profit associations and individual doctors and scientists, to challenge the Myriad patents. The multiple plaintiffs in the case alleged that the claims in suit from seven Myriad patents are invalid under Section 101 and alleged that the PTO practice of allowing such claims is unconstitutional.

Holding Regarding Isolated DNA Claims

Two basic types of claims were at issue in the case. The first of these is a composition claim drawn to isolated DNA exemplified by claim 1 of U.S. Patent No. 5,747,282, which recites:

"An isolated DNA coding for a BRCA1 polypeptide, said polypeptide having the amino acid sequence set forth in SEQ ID NO:2."

In addressing the validity of the composition claims at issue, Judge Sweet examined the two requirements under Section 101: 1) Does the claimed invention posses utility?, and 2) Does the claimed invention constitute statutory subject matter? After determining that the inventions recited by the claims satisfied the utility requirement, the judge next addressed the question of whether the claims were drawn to statutory subject matter. Multiple Supreme Court cases were analyzed and the judge concluded that the controlling cases required that if a patent claim is drawn to a naturally occurring substance, the invention must possess "markedly different characteristics" to constitute statutory subject matter.

In determining that the claimed isolated DNA was not "markedly different," the judge rejected the argument that DNA is simply a

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chemical that has been altered by extraction from the source and purified. Instead, the judge noted that DNA's primary function of carrying protein-encoding information is not altered whether the DNA is in the body or isolated from the body. Thus, the DNA was not sufficiently altered from the "product of nature" by being isolated. Myriad relied on language from a case from the same district (written by Judge Learned Hand in *Parke-Davis & Co. v. H.K. Mulford Co.*) that stated that there was no rule that naturally occurring products extracted without change from a naturally occurring source were not patentable. Judge Sweet rejected this argument, considering the language to be both dicta and contrary to Supreme Court and appellate court precedents. Relying on these holdings, the judge ruled that the claims drawn to isolated DNA were invalid under 35 U.S.C. §101, as the isolated DNA did not possess such markedly different characteristics from the human *BRCA1* and *BRCA2* sequences that are a "product of nature."

Observations on the Holding Regarding Isolated DNA Claims

Although this decision regarding the validity of isolated DNA claims represents a divergence from the current understanding of the law, even if upheld, it will have little, if any, impact on most diagnostic companies. One reason the decision will have limited effect is that many patents with claims drawn to particular isolated sequences are older patents with little term left. For example, the Myriad patents at issue have only four to five years of term remaining. As the *Association for Molecular Pathology* decision is likely to be appealed to the Federal Circuit, any potential shift in the law regarding claims other than those of the patents-in-suit will not be known for more than a year. This delay may last even longer if the Federal Circuit decision is appealed to the Supreme Court. Additionally, many patents (and applications) with claims drawn to isolated DNA have been abandoned. Thus, even if upheld on appeal to the Federal Circuit—which is unlikely—this decision will not have a broad-ranging effect for most diagnostics companies.

Holding Regarding Method Claims

The second type of claim at issue—method claims—is exemplified by claim 1 of U.S. Patent No. 5,709,999, which recites:

"A method for detecting a germline alteration in a BRCA1 gene, said alteration selected from the group consisting of the alterations set forth in Tables 12A, 14, 18 or 19 in a human which comprises analyzing a sequence of a BRCA1 gene or BRCA1 RNA from a human sample or analyzing a sequence of BRCA1 cDNA made from mRNA from said human sample with the proviso that said germline alteration is not a deletion of 4 nucleotides corresponding to base numbers 4184-4187 of SEQ ID NO:1."

These method claims relate to processes for using isolated DNA sequences to compare and test patient or experimental samples to determine if the *BRCA1* and *BRCA2* mutations are present in the samples, but do not recite a particular apparatus or transformative step. The judge analyzed the claims using the "machine-or-transformation" test from the Federal Circuit *In re Bilski* case. To qualify as statutory subject matter under the machine-or-transformation test, a method claim must either be tied to a particular machine or transform a particular article into a different state or thing to be patentable under Section 101. The judge first noted that none of the method claims were drawn to use with a particular machine or apparatus and next turned to the question of whether there was a transformation of the isolated DNA, as claimed.

The judge held that the claims at issue were drawn to simply analyzing or comparing sample DNA sequences with isolated DNA sequences and that the claims did not require anything about the isolated DNA to be altered or changed. He further stated that analyzing or comparing as recited in the claims was the equivalent of claiming an abstract mental process. The judge also analogized the use of the isolated DNA as a comparison for clinical or experimental samples to the use of a mathematical algorithm to analyze collected data. Upon reaching these conclusions, Judge Sweet held that no transformation occurred and that the method claims failed to meet the requirements of Section 101. Having invalidated the claims under Section 101, the judge declined to address the constitutional questions.

Observations on the Holding Regarding Method Claims

This decision provides a straightforward application of the machine-or-transformation test from *Bilski*. Again, like the decision regarding the isolated DNA claims, this part of the decision is not likely to have broad-ranging effects for diagnostics companies or the biotechnology industry in general. First, the machine-or-transformation test from *Bilski* may soon be altered or struck down by an imminent decision by the Supreme Court. Any application of this test for patentable subject matter that is contrary to that adopted by the Supreme Court will be overturned on appeal of Judge Sweet's decision.

Even if *Bilski's* machine-or-transformation test is upheld by the Supreme Court—and Judge Sweet's analysis holds—it is important to remember that the *Bilski* decision has altered the way well-counseled diagnostics companies approach method claims for some time now. In distinction from the method claims of Myriad's patents, which recite no apparatus or transformation, post-*Bilski* claims link diagnostic methods to a particular apparatus or provide some transformative limitation that satisfies the machine-or-transformation test. Claims incorporating such limitation should satisfy the *Bilski* test.

Summary

Although touted in the press as drastically altering the DNA patent landscape, potentially affecting tens of thousands of patents and sounding the death knell for the entire biotechnology industry, closer inspection of the decision shows that it is, at best, of limited importance. First, this decision was made by a district court judge.

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As such, the decision holds no weight with the PTO and the PTO is unlikely to change its approach to examining and issuing pending claims drawn to isolated DNA based on this decision. Additionally, another judge in the same or a different district can reach the opposite conclusion. Thus, the decision should not be interpreted as indicating a wholesale change in existing law.

Second, the Federal Circuit's *Bilski* decision has been appealed to the Supreme Court and a decision is imminent. It is likely that the Supreme Court will strike down or modify the machine-or-transformation test utilized to invalidate the method claims under Section 101. If struck down by the Supreme Court, the analysis applied to the method claims by Judge Sweet is likely to be an inapplicable test when the decision is appealed. However, even if the machine-or-transformation test of *Bilski* remains the law, claims that tie a diagnostic method to a particular apparatus or transformation of the DNA should pass the *Bilski* test.

Finally, this decision will undoubtedly be appealed by Myriad to the Federal Circuit. During the appeal—which may take more than one year—it is possible that the decision will be suspended or stayed. By the time the Federal Circuit hears the appeal, the Supreme Court's *Bilski* decision will be issued and will guide their analysis of the validity of the method claims under Section 101. The Federal Circuit in turn is likely to curtail the holding with regard to the isolated DNA claims as an inappropriate narrowing of the scope of Section 101. However, even if the Federal Circuit affirms Judge Sweet's decision, factors such as limited remaining patent term for isolated DNA claims and limited reliance by diagnostic companies on such claims will diminish the real-world effects of such a change in the law.

Further Guidance

For further guidance on how to evaluate your patent portfolio and patent strategy in light of this decision and its potential implications, please contact Vern Norviel, Peter Munson, or one of the other attorneys in the intellectual property practice at Wilson Sonsini Goodrich & Rosati.

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