WSGR ALERT

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FEDERAL CIRCUIT VALIDATES CLAIMS DRAWN TO ISOLATED DNA, INVALIDATES CLAIMS DRAWN TO ANALYZING OR COMPARING DNA WITHOUT TRANSFORMATION STEP

On July 29, 2011, the U.S. Court of Appeals for the Federal Circuit issued a decision in *Association for Molecular Pathology v. U.S. Patent and Trademark Office,* No. 2010-1406, holding that several claims drawn to isolated DNA sequences encoding the BRCA1 and BRCA2 genes, as well as methods of using those sequences to screen for cancer, were valid as being drawn to statutory subject matter under 35 U.S.C. § 101. The decision overturns the lower court's decision for these claims, but the Federal Circuit upheld the lower court's holding that claims drawn to methods of using those sequences to detect cancer that did not recite any machine, apparatus, or transformative step were invalid. The much-awaited decision confirmed the expectation that the Federal Circuit would hold isolated DNA sequences as patentable. These holdings by the Federal Circuit should not affect well-counseled diagnostics companies.

Several factors in this case mean that it is "business as usual" for claims involving isolated DNA sequences. First, the claims drawn to isolated DNA were upheld as valid, so older patents with such claims are still valid and newly filed or pending applications with such claims will continue to be examined by the U.S. Patent and Trademark Office (PTO) under the same rules that have been in place for decades. Second, the method claims held invalid in this decision do not recite any machine, apparatus, or transformative step—limitations that post-*Bilski* claims typically contain. Thus, diagnostic companies typically will be in the same legal position as they were prior to this decision.

Overview

Under 35 U.S.C. § 101, "[w]hoever 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 longstanding 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.

The Supreme Court also recently addressed patentable processes in *Bilski v. Kappos*, rejecting the so-called "machine-or-transformation" test developed by the Federal Circuit as the only test to define a patentable process. Under the machine-or-transformation test, a process is patentable if it is tied to a machine or apparatus, or if it has a transformative step. However, the Supreme Court held that the machine-or-transformation test offers "a useful and important clue, an investigative tool, for determining whether some claimed inventions are processes under §101."

Brief Case Summary

BRCA1 and BRCA2 are forms of a human gene linked to the development of breast cancer and ovarian cancer. Myriad, the owner of several patents drawn to isolated BRCA1 and BRCA2 genes 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 nonprofit associations and individual doctors and scientists, in order 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 they further alleged that the PTO practice of allowing such claims is unconstitutional.

Holding Regarding Isolated DNA Claims

At issue were two basic types of claims: composition claims and method claims. The type of composition claim drawn to isolated DNA is exemplified by claim 1 of U.S. Patent

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No. 5,747,282, which recites:

> "An isolated DNA coding for 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, the panel examined whether the isolated DNA is a product of nature and therefore not patent-eligible subject matter, or if it is a human-made invention and therefore patent-eligible subject matter. Judge Alan Lourie applied a test based on the Supreme Court drawing "a line between compositions that, even if combined or altered in a manner not found in nature, have similar characteristics as in nature, and compositions that human intervention has given 'markedly different,' or 'distinctive,' characteristics." Applying this test, the majority concluded that the composition claims are drawn to patentable subject matter, as the claimed molecules are markedly different, with a distinctive chemical identity and nature from molecules that exist in nature.

In determining that the claimed isolated DNA was markedly different, the three judges on the panel, Judge Lourie, Judge Kimberly Moore, and Judge William Bryson, all agreed that cDNA is patentable. However, while both Judge Lourie and Judge Moore agreed that isolated DNA and not just cDNA is patentable, the reasonings provided by Judge Moore and Judge Lourie differ. Judge Bryson, on the other hand, dissented, stating that while cDNA is patentable subject matter, fragments of genes are not.

The majority concluded that isolated DNA has been cleaved or synthesized to consist of a fraction of a naturally occurring DNA molecule. Thus, the isolated DNA is not the same molecule as exists in the body, imparting the fragment with a distinctive chemical identity from that of native DNA. The majority also made the distinction between isolated DNA and purified DNA, in that the claimed isolated DNA molecules do not exist in nature, where it occurs within a physical mix that needs to be purified. The isolated DNA in question must be chemically cleaved, not simply purified. Thus, the court concluded that isolated DNA, as a portion of a native DNA molecule, has a markedly different chemical structure than native DNA and is therefore patentable subject matter.

Both the majority opinion and Judge Moore's concurrence further noted that the PTO has been granting patents directed to isolated DNA molecules for almost 30 years, and that the Supreme Court has consistently held that any changes to longstanding practice should come from Congress and not the courts. Judge Moore's concurrence also added that Congress is well aware of this issue and has chosen not to amend Section 101 to exclude isolated DNA from patentable subject matter.

Observations on the Holding Regarding Isolated DNA Claims

The decision regarding the patentability of claims drawn to isolated DNA represents an upholding of the longstanding practice of the PTO granting patents directed to DNA molecules. Though the decision was unanimous for cDNA, there was dissent as to the validity of claims directed to gene fragments. Given the split decision, the plaintiffs likely will request an *en banc* hearing or file a petition for a *writ of certiorari* with the Supreme Court.

Although it provides good news for holders of patents with claims to isolated DNA, the decision will have little impact on most diagnostic companies. 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 three to four years of their terms remaining. Additionally, many patents and applications with claims drawn to isolated DNA have been abandoned. Thus, this decision will likely not have a broad-ranging effect for most diagnostic companies even if it is overturned after further appeals.

Holding Regarding Method Claims

The second type of claims (method claims) was further divided into two categories by the court. The first category, which was held to be unpatentable under Section 101, contained no transformative step. This is exemplified by claim 1 of U.S. Patent No. 5,709,999 (the '999 patent), 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."

The panel was unanimous in holding that method claims to "analyzing" or "comparing" two gene sequences with no transformative steps, as exemplified by claim 1 of the '999 patent, fall outside the scope of patentable subject matter because they claim only abstract mental processes. Furthermore, the panel found that method claims to analyzing or comparing two gene sequences related to processes that use isolated DNA sequences to compare and test patient or experimental samples for BRCA1 and BRCA2 mutations do not recite a particular apparatus or transformative step. Myriad argued that these method claims satisfied the machine-or-transformation test because each requires a transformation of extracting and sequencing DNA molecules from a human sample before the sequences could be compared or analyzed. Myriad further stated that this is how the claim is interpreted, as the term "sequence" refers not to information, but rather to a physical DNA molecule whose sequence must be determined before it can be compared.

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The panel disagreed and stated that these method claims to analyzing or comparing two gene sequences recite nothing more than abstract mental steps for comparing nucleotide sequences. The panel noted that the claims do not specify any action prior to comparing or analyzing, and that the terms do not include or imply sample-processing steps. The panel also disagreed with Myriad's arguments that the term "sequence" refers exclusively to a physical DNA molecule, since the specification states that the sequences refer broadly to the linear sequence of nucleotide bases. The court noted that although the application of a formula or abstract idea to a process may constitute patentable subject matter, that was not the case in this instance because the entire process consists solely of the act of comparing two DNA sequences. Thus, the court held that this first category of method claim did not meet the patentability requirements of Section 101.

In contrast, the second category of method claim, which the panel held to be patentable, is exemplified by claim 20 of U.S. Patent No 5,747,282 (the '282 patent), which recites:

> "A method for screening potential cancer therapeutics which comprises: growing a transformed eukaryotic host cell containing an altered BRCA1 gene causing cancer in the presence of a compound suspected of being a cancer therapeutic, growing said transformed eukaryotic host cell in the absence of said compound, determining the rate of growth of said host cell in the presence of said compound and the rate of growth of said host cell in the absence of said compound and comparing the growth rate of said host cells, wherein a slower rate of growth of said host cell in the presence of said compound is indicative of a cancer therapeutic."

The panel was unanimous in overruling the lower court's decision that the second category of method claim is patent-ineligible subject matter. Instead, the panel found that the method claim directed to screening potential cancer therapeutics included transformative steps. Specifically, the court held that growing a host cell and determining the growth rate of the cell were transformative steps. The majority noted that both steps involve the physical manipulation of the cells, and that both steps are central to the purpose of the claimed process. The panel also noted that the claim was not so "manifestly abstract" as to claim only a scientific principle. Thus, the court held that these differences allowed this claim to meet the patentability requirements of Section 101.

Observations on the Holding Regarding Method Claims

This decision affirmed the lower court's holding that the method claims directed to comparing and analyzing sequences consist of an abstract mental process that is not drawn to patentable subject matter. As with the holding regarding isolated DNA, this part of the decision is not likely to have broad-ranging effects for diagnostic companies or the biotechnology industry post-*Bilski* because well-counseled diagnostics companies have been approaching method claims with the machine-or-transformation test in mind for some time now. Claims incorporating such limitations by linking diagnostic methods to a particular apparatus or providing some transformative limitation should fulfill the requirements under Section 101.

Summary

The holding in this case means business as usual for diagnostics companies and others with patents to isolated DNA sequences and their uses. Although it is likely that this ruling will be appealed, the ultimate outcome likely will have limited effects on diagnostics and other biotechnology companies regardless of whether the Federal Circuit's opinion is upheld or reversed. Because practitioners have been developing claims in light of the *Bilski* decision, most modern claims reciting uses of isolated DNA tie that use to a transformation or machine. Thus, those types of claims should be patentable under Section 101. However, even if the decision is reversed, factors such as limited remaining patent terms for isolated DNA claims and limited reliance by diagnostic companies on such claims diminish the real-world effects of a holding that results in such claims being found as unpatentable.

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 or another attorney in the intellectual property practice at Wilson Sonsini Goodrich & Rosati.

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