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Intellectual Property Alert

CAFC Delivers Another Decision on Patentability of Myriad Patents

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In *Univ. of Utah Res. Foundation et al. v. Ambry Genetics Corp*., No. 2014-1361 (Fed. Cir. Dec. 17, 2014), the Federal Circuit once again has weighed in on the patent eligibility of Myriad Genetics, Inc.'s patents related to BRCA1 and BRCA2 genes. In this case, a panel of three judges of the Federal Circuit considered claims of patents that were not previously before this court and were also not considered by the Supreme Court in *Molecular Pathology v. Myriad*, 133 S. Ct. 2107 (2013) ("*Myriad*").

In 2013, Myriad sued Ambry Genetics Corporation in the U.S. District Court for the District of Utah alleging infringement of sixty-six claims across fifteen different patents. This case came before the Federal Circuit on appeal of the district court refusal to grant Myriad a preliminary injunction against Ambry. Myriad's motion asserted six claims in three patents: claims 7 and 8 of US patent 5,753,441 ("the '441 patent"), claims 16 and 17 of US patent 5,747,282 ("the '282 patent"), and claims 29 and 30 of US patent 5,837,492 ("the '492 patent"). *See* slip op. at 2-4. Claims 16 and 17 of the '282 patent, and claims 29 and 30 of the '492 patent are directed to "DNA primers"; claims 7 and 8 of the '441 patent are directed to a method of screening "alteration of a BRCA1 gene." *See* slip op. at 6, 10. The District Court denied Myriad's motion for a preliminary injunction finding that "Myriad was unlikely to succeed on the merits because the claims were likely drawn to ineligible subject matter." Slip op. at 4-5. On appeal, the Federal Circuit affirmed. *See* slip op. at 19.

Claims directed to primers of the '282 patent and the '492 patent are patent-ineligible under *Myriad.*

In finding the claimed primers patent-ineligible, the panel rejected Myriad's structurally based arguments that the primers were patent eligible because they were (a) synthetically replicated and/or (b) single stranded, both of which do not occur in the human body. Slip. op. at 8. The court found that the primers were structurally indistinguishable from the isolated DNA found to be patent ineligible because they contained the same sequence. The court further noted that the primers were structurally distinguishable from cDNA found to be patent eligible by the Supreme Court in *Myriad*. *See* slip op. at 7.

The panel also rejected Myriad's functionally based argument that the claimed primers "have a fundamentally different function than when they are part of the DNA strand." Slip op. at 9. Rather, the panel observed that "[o]ne of the primary functions of DNA's structure in nature is that complementary nucleotide sequences bind to each other. It is the same function that is exploited here . . . ." Slip op. at 9. Thus, the panel held that "[a] DNA structure with a function similar to that found in nature can only be patent eligible as a composition of matter if it has a unique structure, different from anything found in nature." Slip op. at 9 (internal citations omitted). And because the panel concluded that the claimed primers "do not have such a different structure" than DNA found in nature, claims 16 and 17 of the '282 patent, and claims 29 and 30 of the '492 patent, directed to primers, are patent ineligible. *See* slip op. at 9.

Method of screening claims 7 and 8 of '441 patent are patent-ineligible under *Alice*

The method of screening claims 7 and 8 were directed to "screening germline of a human subject for an alteration of a BRCA1 gene." *See* slip op. at 10. Relying on the recently issued Supreme Court decision in *Alice Corp. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2354 (2014), the panel applied a two-step test: First, whether "the

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comparison of wild type genetic sequences with the subject's genetic sequence" corresponds to a patent-ineligible concept; and second, whether the steps in the claim reciting "techniques to be used in making the comparisons," "either in isolation or combination with other non-patent-ineligible elements, are sufficient to 'transform the nature of the claim' into a patent-eligible application." Slip op. at 13, 14 (internal citations omitted).

Applying the first step of *Alice*, the panel concluded that the claims would "impede a great swath of research relating to the BRCA genes" because "[t]he covered comparisons are not restricted by the purpose of the comparison or the alteration being detected. Because of its breadth, the comparison step covers detection of yet-undiscovered alterations, as well as comparisons for purposes other than detection of cancer." Slip op. at 15, 16. Therefore, the panel held that claims 7 and 8 are directed to unpatentable abstract ideas. Slip op. at 16. And applying the second step of *Alice*, the panel concluded that the additional features, such as the techniques used in making the comparison of alteration in the BRCA gene with its wild-type counterpart, "do nothing more than spell out what practitioners already knew," and, therefore, the techniques failed to transform the nature of the claim into a patent-eligible application. Slip op. at 17. In effect, the broad scope of the claims appears to have led the panel to find these claims patent-ineligible.

The panel, however, left open the possibility that the outcome could have been different if other claims in the patent, for example claim 21 of the '441 patent, were challenged. *See* slip op. at 17, 18. Distinguishing claims 7 and 8 from claim 21 of the '441 patent, the panel observed that unlike claims 7 and 8, which "are significantly broader and more abstract, as they claim all comparisons between the patient's BRCA genes and the wild-type BRCA genes," "the detection in claim 21 is limited to the particular mutations the inventors discovered: detecting ten specific mutations from the wild-type, identified as '[p]redisposing [m]utations,' for the specific purpose of identifying increased susceptibility to specific cancers." Slip op. at 19. Thus, patent eligibility of method of screening claims directed to detecting "particular mutations the inventors discovered" remains a possibility.

Notably, the panel did not rely on *Mayo Collaborative Services v. Prometheus Labs, Inc.*, 132 S. Ct. 1289 (2012) ("*Mayo*") in holding the method claims invalid. The panel explained that because the method claims "recite abstract ideas," they did not need to reach the issue of whether *Mayo* is directly on point. Slip op. at 13. Ambry had asserted that such method claims here "simply identify a law of nature . . . and apply conventional techniques," and, therefore, under the Supreme Court decision in *Mayo*, are patent ineligible. *See* slip op. 13.

Note: While Myriad Genetics is a Mintz Levin client, we did not represent the company in this litigation.

If you have any questions about this topic, please contact the author(s) or your principal Mintz Levin attorney.

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