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Federal Circuit Patent Bulletin: *Univ. of Utah Research Found. v. Ambry Genetics Corp.*

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"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. Primers do not have such a different structure and are patent ineligible."

On December 17, 2014, in *Univ. of Utah Research Found. v. Ambry Genetics Corp.*, the U.S. Court of Appeals for the Federal Circuit (Prost, Clevenger, Dyk*) affirmed the district court's denial of Myriad's motion for preliminary injunction seeking to enjoin Ambry from infringing U.S. Patents No. 5,753,441, No. 5,747,282, and No. 5,837,492, which related to compositions of matter and methods involving the BRCA1 and BRCA2 genes and their relationship to breast and ovarian cancer, because the claims were directed to ineligible subject matter under 35 U.S.C. § 101. The Federal Circuit stated:

Claim 16 of the '282 patent is . . . directed to: A pair of single-stranded DNA primers for determination of a nucleotide sequence of a BRCA1gene by a polymerase chain reaction, the sequence of said primers being derived from human chromosome 17q, wherein the use of said primers in a polymerase chain reaction results in the synthesis of DNA having all or part of the sequence of the BRCA1 gene. . . . The primers before us are not distinguishable from the isolated DNA found patent-ineligible in Myriad and are not similar to the cDNA found to be patent-eligible. Primers necessarily contain the identical sequence of the BRCA sequence directly opposite to the strand to which they are designed to bind. They are structurally identical to the ends of DNA strands found in nature.

Authors

Lawrence M. Sung
Partner
202.719.4181
lsung@wiley.law

Contrary to Myriad's argument, it makes no difference that the identified gene sequences are synthetically replicated. As the Supreme Court made clear, neither naturally occurring compositions of matter, nor synthetically created compositions that are structurally identical to the naturally occurring compositions, are patent eligible. After all, as the district court in the earlier Myriad case and our opinion in Myriad made clear, isolated DNA is routinely synthetically created.

Myriad argues that primers are in fact not naturally occurring because single-stranded DNA cannot be found in the human body. But, as the Supreme Court made clear, "separating [DNA] from its surrounding genetic material is not an act of invention." The Supreme Court held ineligible claims directed to segments as short as 15 nucleotides, the same length as the primer claims at issue here, suggesting that even short strands identical to those found in nature are not patent eligible. . . .

Myriad also argues that the sequences, when extracted as primers, have a fundamentally different function than when they are part of the DNA strand. When part of the naturally occurring genetic sequence, DNA "stores the biological information used in the development and functioning of all known living organisms," but when isolated as a primer, the DNA fragment "prime[s], i.e., . . . serve[s] as a starting material for a DNA polymerization process." In fact, the naturally occurring genetic sequences at issue here do not perform a significantly new function. Rather, the naturally occurring material is used to form the first step in a chain reaction—a function that is performed because the primer maintains the exact same nucleotide sequence as the relevant portion of the naturally occurring sequence. One of the primary functions of DNA's structure in nature is that complementary nucleotide sequences bind to each other. It is this same function that is exploited here—the primer binds to its complementary nucleotide sequence. Thus, just as in nature, primers utilize the innate ability of DNA to bind to itself.

We do not read the Supreme Court's opinion in Myriad as conferring patent eligibility on composition of matter claims directed to naturally occurring DNA strands under such circumstances. 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. Primers do not have such a different structure and are patent ineligible.

We next address the two asserted method claims, claims 7 and 8 of the '441 patent. While we addressed some of the method claims of the '441 patent in our Myriad decision, the Supreme Court did not address any method claims. . . . Laws of nature are not the only implicit exception to patentable subject matter identified by 35 U.S.C. § 101.Natural phenomena and abstract ideas are also not patentable. Recently in Alice the

Supreme Court reiterated its two-step test to determine patent eligibility for any claims that allegedly encompass abstract ideas. First, "we determine whether the claims at issue are directed to [a]patent-ineligible concept[]. If so, we then ask, 'what else is there in the claims before us?'" That is, we next ask whether the remaining elements, either in isolation or combination with the other non-patent-ineligible elements, are sufficient to "'transform the nature of the claim' into a patent-eligible application." Put another way, there must be a further "inventive concept" to take the claim into the realm of patent-eligibility. . . .

We have already addressed the first paragraphs—the comparison step—in our own 2012 Myriad decision. . . . Here, under our earlier decision, the comparisons described in the first paragraphs of claims 7 and 8 are directed to the patent-ineligible abstract idea of comparing BRCA sequences and determining the existence of alterations. The methods, directed to identification of alterations of the gene, require merely comparing the patient's gene with the wild-type and identifying any differences that arise. The number of covered comparisons is unlimited. The 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. Even with respect to cancer, the comparisons are not limited to the detection of risk of breast or ovarian cancer. Similar concerns to the ones the Supreme Court expressed in Myriad with respect to isolated DNA exist here: allowing a patent on the comparison step could impede a great swath of research relating to the BRCA genes, and it is antithetical to the patent laws to allow these basic building blocks of scientific research to be monopolized. The first paragraphs in claims 7 and 8 are therefore unpatentable abstract ideas, as we held in Myriad.

Having determined that the comparison steps of claims 7 and 8 are abstract ideas, we move to the second step of Alice and ask whether the particular mechanism for the comparisons added by claims 7 or 8 renders the claims patent-eligible. For this step, Alice dictates that we ask whether the remaining elements, either in isolation or combination with the other non-patent-ineligible elements, are sufficient to "'transform the nature of the claim' into a patent-eligible application." There must be a further inventive concept to take the claim into the realm of patent-eligibility. . . . The non-patent-ineligible elements of claims 7 and 8 do not add "enough" to make the claims as a whole patent-eligible. The district court found, and Myriad does not challenge, that the elements of the second paragraphs of claims 7 and 8 "set forth well-understood, routine and conventional activity engaged in by scientists at the time of Myriad's patent applications." Moreover, "[a] ny scientist engaged in obtaining the sequence of a gene in a patient sample would rely on these techniques." Myriad does not challenge the district court's finding that "the claims contain no otherwise new process for designing or using probes, primers, or arrays beyond the use of BRCA1 and BRCA2 sequences in those processes." The second paragraphs of claims 7 and 8 do nothing more than spell out what practitioners already knew—how to compare gene sequences using routine, ordinary techniques. Nothing is added by identifying the techniques to be used in making the comparison because those comparison techniques were the well-understood, routine, and conventional techniques that a scientist would have thought of when

instructed to compare two gene sequences. . . . The claims, therefore, are directed to patent-ineligible subject matter.