LOCKE LORD® QUICKStudy
Intellectual Property Practice
December 22, 2014

Myriad Loses Again – Method Claims Are Invalid Under *Alice*

By: Alan B. Clement and Paul B. Sudentas

By now, the patent and biotech communities are well-versed in the line of Supreme Court and Federal Circuit decisions concerning Myriad Genetics, Inc. et al.'s (Myriad) patents concerning human genes. To add another blow at Myriad's attempts to save its patents, the Federal Circuit recently affirmed the denial of a preliminary injunction on six claims (not previously considered by the Supreme Court or the District Court) because the claims were directed to ineligible subject matter under 35 U.S.C. § 101. *See In re BRCA1- and BRCA2-Based Hereditary Cancer Test Patent Litigation*, Nos. 2014-1361, -1366, --- F.3d ----, 2014 WL 7156722 (Fed. Cir. Dec. 17, 2014).

The six asserted claims were directed either to compositions of matter or methods. The compositions of matter claims were directed to primers, *i.e.*, "short, synthetic, single-stranded DNA molecule(s) that bind[] specifically to . . . intended target nucleotide sequences." Not surprisingly, the Supreme Court's 2013 Myriad decision (*Association for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013)) guided the Federal Circuit's decision as to these primer claims and concluded that "it makes no difference that the identified gene sequences are synthetically replicated[,] . . . neither naturally occurring compositions of matter, nor synthetically created compositions that are structurally identical to the naturally occurring compositions are patent eligible."

Notably, the Federal Circuit was faced with addressing patent eligibility for claims that were not composition of matter claims similar to those previously before the Supreme Court in the prior actions. These additional claims were method claims (*e.g.*, "A method for screening germline of a human subject for an alteration of a BRCA1 gene which comprises comparing . . . wherein a germline nucleic acid sequence is compared by hybridizing a BRCA1 gene probe . . ."). In its decision, the Federal Circuit followed the two-step test for patent eligibility for claims that allegedly encompass abstract ideas as set forth in *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347 (2014):

1. Are the claims at issue directed to a patent-ineligible concept? If yes, what else is claimed in the claims at issue?
2. Are the remaining elements, in isolation or in combination with non-patent-ineligible elements, sufficient to "transform the nature of the claim into a patent-eligible application"?

In applying the first step of the *Alice* test, the Federal Circuit held that the first clause of the method claims at issue – the comparisons – "are directed to the patent-ineligible abstract idea of comparing BRCA sequences and determining the existence of alterations" wherein the number of covered comparisons is unlimited and "not restricted by the purpose of the comparison or the alteration being detected."

Next, moving to the second step of the *Alice* test, the Federal Circuit held that the remaining elements of the claims at issue "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 comparisons techniques were the well-understood, routine, and conventional techniques that a scientist would have thought of when instructed to compare two gene sequences."

The Federal Circuit also discussed Myriad's argument based on Judge Bryson's prior *dicta* that method Claim 21 of Myriad's '441 patent might present patentable subject matter. While Claim 21 was not before the Court, the Federal Circuit disposed of Myriad's argument, distinguishing Claim 21 from the method claims at issue because Claim 21 was limited to detecting ten specific mutations while the method claims at issue were not so limited.

This decision serves as further guidance for applying the two-step test for patent eligibility as set forth by the Supreme Court in *Alice*, especially in the biotech world. In knowing how the Federal Circuit applies the *Alice* test, companies should be able to properly analyze the patentability of claims that encompass abstract ideas.

For more information on the matters discussed in this *Locke Lord QuickStudy*, please contact the authors:

Alan B. Clement | 212-812-8318 | aclement@lockelord.com
Paul B. Sudentas | 646-217-7716 | psudentas@lockelord.com