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DECODING PATENT-ELIGIBILITY OF DIAGNOSTIC METHODS

Is an Invention Patent-Worthy?

The Law of Nature or IP Challenge

Figuring out whether an invention is patent-worthy has become a bit easier, thanks to the Federal Circuit's clarifications in *Genetic Technologies, Ltd. v. Merial, LLC*. A universal inherent feature of human DNA is an ineglible law of nature, while the second prong of the *Mayo/Alice* test is not met where the claim sets forth no new physical techniques and relies instead on known, routine, and conventional steps. Law of Nature or Patentable Subject Matter?

In *Genetic Techs.*, Genetic Technologies, Ltd. sued Merial LLC and Bristol-Myers Squibb, alleging infringement of U.S. Patent. No. 5,612,179.[1] This patent claims methods of analyzing sequences of genomic DNA using the principle of "linkage disequilibrium."[2]

Linkage disequilibrium was discovered in the 1980's by Dr. Malcom J. Simons, the named inventor on this patent. Dr. Simons found that coding and non-coding regions of the human genome "appear 'linked' together in individuals' genomes more often than probability would dictate" and, regardless of their chromosomal locations.[3] Dr. Simons concluded that alleles of a particular gene may be detected by amplifying and analyzing non-coding regions of the genome known to be linked to the coding region. He filed several patent applications relating to this discovery.[4] The patent at issue in this litigation arose out of one of those applications.[5]

Merial and Bristol-Myers Squibb moved to dismiss under Rule 12(b)(6) for failure to state a claim, arguing the claims of the patent covered ineligible subject matter under § 101.[6] The district court agreed, deciding claim 1 of the patent is "invalid for claiming a law of nature, which is patent-ineligible subject matter."[7]

On appeal, the parties stipulated that claim 1 of the patent is representative of claims 2-25 and 33-36 with respect to eligibility under § 101.[8] The Federal Circuit analyzed claim 1 by following the two-step test for patent-eligibility set forth by the Supreme Court in *Mayo* and *Alice*: 1) Determine whether

1. *Genetic Technologies Ltd. v. Merial LLC,* --- F. App'x ---, at 1 (Fed. Cir. April 8, 2016).
2. *Id.*
3. *Id.* at 4.
4. *Id.*
5. *Id.*
6. *Id.* at 5.
7. *Id.*
8. *Id.* at 6.

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the claims at issue are directed to a patent-ineligible concept and, if so, 2) Examine the claim elements to see if it contains an inventive concept sufficient to transform the claimed abstract idea or law of nature into a patent-eligible application.[9]

Claim 1 Failed Step 1 of the *Mayo/Alice* Test

The Federal Circuit decided claim 1 failed the first step of the *Mayo/Alice* test because it was directed to patent-ineligible subject matter.[10] The Federal Circuit explained claim 1 is "directed to the relationship between non-coding and coding sequences in linkage disequilibrium and the tendency of such non-coding DNA sequences to be representative of the linked coding sequences," that this is "indisputably a universal inherent feature of human DNA," and, thus, is an ineligible law of nature.[11] The Federal Circuit further noted that the "product of the method of claim 1 is information about a patient's natural genetic makeup."[12]

"The Federal Circuit further noted that the 'product of the method of claim 1 is information about a patient's natural genetic makeup.'"

The Federal Circuit also compared claim 1 to the claims invalidated in *Mayo* and *Ariosa* and found them to be "quite similar."[13] It agreed with the district court that "just as the relationship at issue in *Mayo* was entirely a consequence of the body's natural processes for metabolizing thiopurine, so too is the correlation here (between variations in the non-coding regions and allele presence in the coding regions) a consequence of the naturally occurring linkages in the DNA sequence."[14]

In *Ariosa*, the Federal Circuit invalidated claims directed to a method of detecting, amplifying, and analyzing cell-free fetal DNA because they were "directed to matter that is naturally occurring" and "the inventors there did not purport to 'create[ ] or alter[ ] any of the genetic information encoded in the cffDNA.'"[15]

In this case, claim 1 "involves no creation or alteration of DNA sequences, and does not purport to identify novel detection techniques," and "broadly covers essentially all applications, via standard experimental techniques, of the law of linkage disequilibrium to the problem of detecting coding sequences of DNA."[16] The similarity of claim 1 to the claims in *Mayo* and *Ariosa* "requires the conclusion that claim 1 is directed to a law of nature."[17]

Claim 1 Also Failed Step 2 of the *Mayo/Alice* Test:

Next, the Federal Circuit considered whether claim 1 "contains an inventive concept sufficient to transform the claimed abstract idea [or law of nature] into a patent-eligible application" and found it did not.[18] The Federal Circuit looked at the "physical steps by which claim 1 implements the natural law

9. *Id.* at 7-8.
10. *Id.* at 11-12.
11. *Id.* at 8-9.
12. *Id.* at 9.
13. *Id.* at 9-10.
14. *Id.* at 10.
15. *Id.* at 11 (citations omitted).
16. *Id.* at 9 & 11 (citations omitted).
17. *Id.* at 11.
18. *Id.* at 12-13.

"In sum, the Federal Circuit concluded that claim 1's physical steps 'do not, individually or in combination, provide sufficient inventive concept to render claim 1 patent eligible.'"

of linkage disequilibrium" to determine whether they provide "more than 'well-understood, routine, conventional activity' already engaged in by those in the field."[19]

Claim 1 one involves two steps.[20] The Federal Circuit said the first step (amplifying DNA with a primer pair) was "indisputably well known, routine, and conventional in the field of molecular biology" when the precursor application of the patent was filed.[21] The Federal Circuit pointed out that Genetic Technologies argued "amplification was a technique readily practiced by those in skill at the time the application was filed" to overcome a § 112 rejection for lack of enablement.[22]

The Court also said the second step (analyzing amplified DNA) was "well known, routine, and conventional at the time the '179 patent was filed," and Genetic Technologies conceded this point.[23] The Federal Circuit noted "[i]n this regard, claim 1 of the '179 patent is directly comparable to the claims invalidated in *Ariosa*."[24] The Federal Circuit noted Genetic Technologies admitted "during prosecution of the '179 patent that it did not invent any new physical techniques."[25]

In sum, the Federal Circuit concluded that claim 1's physical steps "do not, individually or in combination, provide sufficient inventive concept to render claim 1 patent eligible."[26]

Genetic Technologies had argued that claim 1 "is inventive because it involves the analysis of *man-made* amplified DNA" that has an "altered methylation status" of naturally occurring DNA.[27] The Federal Circuit, however, rejected this argument because claim 1 "is concerned primarily with the information contained in the genetic *sequence*" of DNA, "not with the specific chemical composition of a particular molecule."[28] The sequence of the man-made DNA is "identical to that of naturally occurring DNA," which is distinguishable from "the cDNA held to be patent-eligible in *Myriad*."[29]

Genetic Technologies also argued that "no one had [] analyzed man-made non-coding DNA in order to detect a coding region allele" prior to patent filing, and this additional feature "provides sufficient inventive concept to pass step two of the *Mayo/Alice* test."[30] Again, the Federal Circuit disagreed, saying the term "to detect the allele" is "a mental process step" that "does not create the requisite inventive concept" to be patent-eligible under § 101 "because it merely sets forth a routine comparison that can be performed

19. *Id.* at 13 (citations omitted).
20. *Id.* at 13-14.
21. *Id.* at 13.
22. *Id.* at 14.
23. *Id.*
24. *Id.* at 15 (citing *Ariosa*, 788 F.3d at 1377 ("Using methods like PCR to amplify and detect cffDNA was well-understood, routine, and conventional activity in 1997.")).
25. *Id.* at 14 & 15.
26. *Id.* at 14-15.
27. *Id.* at 15, fn. 3.
28. *Id.* (emphasis in original).
29. *Id.* (citing *Myriad*, 133 S. Ct. at 2119).
30. *Id.* at 16.

by the human mind."[31] The Federal Circuit added, "The novelty of looking to non-coding DNA to detect a coding region allele of interest resides in the novelty of the newly discovered natural law of linkage disequilibrium…and adds little more than a restatement of the natural law itself."[32]

What to Expect from § 101 Moving Forward

The *Genetic Techs.* opinion reinforces patent-eligibility challenges to claims drawn to data processing, analysis, or steps that could be carried out by the human mind. It continues the trend of finding patent-ineligibility of claims whose novelty lies in data analysis.

It also emphasizes the importance of drafting claims so that they are distinguished from prior art and cannot fall into the "mental step" trap described by the Federal Circuit in this case.

Ongoing uncertainty about subject matter eligibility might have a chilling effect on innovation and the transfer of technology among firms, universities, and research institutions. Indeed, David Kappos, former director of the U.S. Patent and Trademark Office, recently called for abolition of § 101, stating, "Europe doesn't have 101 and Asia doesn't have 101 and they seem to be doing just fine in constraining patent-eligible subject matter."[33]

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Sequenom presented the question: "Whether a novel method is patent-eligible where: (1) a researcher is the first to discover a natural phenomenon; (2) that unique knowledge motivates him to apply a new combination of known techniques to that discovery; and (3) he thereby achieves a previously impossible result without preempting other uses of the discovery?"[35]

The USPTO also recently issued subject matter eligibility guidance on May 4, 2016, that provides hope for life sciences inventions.[36] It is too early to tell whether this guidance improves the chances that life science claims will be allowed by examiners or upheld by courts.

In the meantime, courts may be more likely to find patent eligibility if claims recite the use of a new technology, rather than the application of existing and well-known techniques to newly discovered natural phenomena. Also, methods may be patent-eligible if they require modifying or creating a new naturally derived product (like cDNA in *Myriad*).

31. *Id.* at 16.
32. *Id.* at 19.
33. http://www.law360.com/articles/783604/kappos-calls-for-abolition-of-section-101-of-patent-act.
34. *Sequenom, Inc. v. Ariosa Diagnostics, Inc.,* No. 15-1182, 2016 WL 1105544 (March 21, 2016).
35. *Id.*
36. http://www.uspto.gov/patent/laws-and-regulations/examination-policy/2014-interim-guidance-subject-matter-eligibility-0.