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Fed. Circ.'s Arduous Legal Landscape For Diagnostic Patents

By **Vanessa Yen, Evan Diamond and Julia Kolibachuk** (August 20, 2019, 3:53 PM EDT)

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On Aug. 9, 2019, the U.S. Court of Appeals for the Federal Circuit issued a public opinion in Genetic Veterinary Sciences Inc. v. Laboklin GmbH & Co. KG, finding claims directed to methods for detecting a genetic marker for a canine hereditary disease to be patent-ineligible under 35 U.S.C. Section 101.[1]

This decision continues the trend of the Federal Circuit invalidating claims to diagnostic inventions as being directed to patent-ineligible natural phenomena under U.S. Supreme Court precedent and highlights the continuing challenges facing innovators attempting to protect technology related to diagnostic inventions.

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Patent Eligibility and "Diagnostic" Inventions

With its decisions in Mayo Collaborative Services v. Prometheus Laboratories Inc. and Alice Corporation Party Ltd. v. CLS Bank International, the Supreme Court established a two-step test to assess whether claimed subject matter is eligible for patenting under 35 U.S.C. Section 101.[2] In the first step, the court determines whether the claims at issue are "directed to" patent-ineligible subject matter — i.e., a law of nature, a natural phenomenon or an abstract idea.[3]

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If so, then under the second step, the court must determine whether the claims nonetheless recite an "inventive concept," i.e., whether the "elements of each claim both individually and as an ordered combination ... transform the nature of the claim into a patent-eligible application."[4] If they do not, the challenged claims will be found invalid as patent-ineligible.

With respect to "diagnostic" inventions involving, e.g., the detection of diseases or genetic conditions using newly discovered biological phenomena, the Mayo/Alice two-step test has almost universally been applied by the Federal Circuit to find claims patent-ineligible under Section 101. In Mayo, the Supreme Court struck down claims to a "method of optimizing therapeutic efficacy" based on the exact correlation between the levels of a drug metabolite in patients' blood and the safety and efficacy of the drug — finding the claims at issue to be directed to a patent-ineligible natural law.[5]

The court in Mayo further found that, beyond the "natural law" (i.e., the correlation between metabolite levels and biological effects) — the claims' "additional steps consist[ed] of well-understood,

routine, conventional activity already engaged in by the scientific community," and thus did not confer patentability under step two of the test.[6]

Following the two-step test of Mayo, the Federal Circuit has found a range of different diagnostic inventions to be patent-ineligible, including, e.g., (1) methods for noninvasive prenatal testing using cell-free fetal DNA from maternal serum;[7] (2) methods for assessing risk of cardiovascular disease based on detection of a particular enzyme;[8] and (3) methods for diagnosing a neurological disorder based on detection of autoantibodies to a membrane protein.[9]

While recognizing the value and novelty of diagnostic inventions and the importance of incentivizing their development, the majority of judges on the Federal Circuit have noted that the Supreme Court's precedent in Mayo leaves little room to uphold typical "diagnostic" claims that couple the observation of a newly discovered natural phenomenon with conventional laboratory techniques.[10] In contrast, the Federal Circuit has upheld "method of treatment" claims in the face of patent-eligibility challenges where the claims require the administration of a specific drug to treat a specific disease in specific patients.[11]

The Genetic Veterinary Sciences Decision

In Genetic Veterinary Sciences, the Federal Circuit affirmed the district court's ruling that claims "directed to ... the discovery of the genetic mutation linked to HNPK" — a hereditary canine disease — were directed to a patent-ineligible natural phenomenon under Section 101.[12]

As described in the opinion, independent claim one recited "an in vitro method for genotyping a Labrador Retriever" comprising three steps: (1) "obtaining a biological sample" from a dog; (2) "genotyping" (i.e., examining the sequence of) the relevant gene, SUV29H2; and (3) "detect[ing] the presence of a replacement of a nucleotide" relative to the normal sequence at a specific position in the gene.[13] Dependent claims two and three further recited technical methods for genotyping SUV29H2.[14]

Assessing these claims under the Mayo/Alice framework, the Federal Circuit found that claim one was "directed to nothing more than observing or identifying the natural phenomenon of a mutation in the SUV39H2 gene" and that the dependent claims "add only generic methods of detecting the natural phenomenon."[15]

Under the second step of the Mayo/Alice analysis, the Federal Circuit found that the claimed steps, viewed individually or as an ordered combination of elements, failed to "recite an inventive concept that transforms the observation of a natural phenomenon into a patentable invention," because the described genotyping used only "conventional or known laboratory techniques to observe the newly discovered mutation."[16] Referencing Mayo, the Federal Circuit reiterated its prior holding that "a natural phenomenon, together with well-understood conventional activity, is not patent-eligible under § 101."[17]

Analysis and Implications

Genetic Veterinary Sciences confirms the current challenging legal landscape for patent protection of diagnostic inventions. Since Mayo, claims to diagnostic methods centered on an observed correlation between a natural characteristic and a disease state, coupled with routine or conventional technical means for detection, have been held patent-ineligible under Section 101. Genetic Veterinary Sciences

continues this pattern, wherein diagnostic claims are invalidated despite recognition that such inventions may provide a "positive and valuable contribution" to the public.[18]

While "method of treatment" claims have generally been upheld under Section 101, such claims are unlikely to provide adequate protection for companies that develop diagnostic inventions, because such "treatment" claims may be difficult to enforce against competing diagnostics companies that do not treat disease or direct their end users to do so.[19]

This ruling follows on the heels of the Federal Circuit's highly anticipated decision last month in Athena Diagnostics Inc. v. Mayo Collaborative Services LLC, where, in a 7-5 split decision, the court denied rehearing en banc of a 2-1 split panel decision invalidating a patent directed towards diagnosing neurological disorders by detecting certain autoantibodies in patients' bodily fluid.[20]

The denial of en banc review in Athena Diagnostics generated a remarkable four concurring opinions and four dissenting opinions, which, as one opinion remarked, illustrates "how fraught the issue of § 101 eligibility, especially as applied to medical diagnostics patents, is."[21]

The concurring opinions in Athena Diagnostics expressed that the court was bound by Mayo to find diagnostic inventions to be patent-ineligible in many cases but acknowledged as a policy matter that the law "should leave room for sufficiently specific diagnostic patents"[22] and even invited the Supreme Court or Congress to change the current state of the law,[23] while the dissenting opinions generally expressed that the Federal Circuit has been overreading Mayo in finding nearly all diagnostic patents to be ineligible subject matter.[24]

The current standards for patent eligibility of diagnostic patents may still be subject to change. Draft legislation proposed in May 2019 by Senators Chris Coons, D-Del., and Thom Tillis, R-N.C., would abrogate the Mayo/Alice test entirely and extend patent eligibility to "any invention or discovery that provides specific and practical utility in any field of technology through human intervention."[25]

The 7-5 split decision in Athena Diagnostics is also ripe for a potential petition for certiorari to the Supreme Court. The diagnostics and pharmaceuticals industries should monitor developments in this area closely, as changes in legal precedent or new legislation could have a dramatic impact on patent protection for medical diagnostic tools.

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[1] Genetic Veterinary Scis., Inc. v. LABOKLIN GmbH & Co. KG, No. 2018-2056 (Fed. Cir. Aug. 9, 2019).

[2] Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66 (2012); Alice Corp. Pty. v. CLS Bank Int'l, 573 U.S. 208 (2014).

[3] Alice v. CLS, 573 U.S. at 217 (citing Mayo, 566 U.S. at 77-78).

[4] Id. (internal quotation and citation omitted).

[5] Mayo at 76-80.

[6] Id. at 79-80.

[7] Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371 (Fed. Cir. 2015), reh'g en banc denied, 809 F.3d 1282 (Fed. Cir. 2015).

[8] Cleveland Clinic Found. v. True Health Diagnostics LLC, 859 F.3d 1352 (Fed. Cir. 2017); Cleveland Clinic Found. v. True Health Diagnostics LLC (Fed. Cir. 2019).

[9] Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC ("Athena I"), 915 F.3d 743 (Fed. Cir. 2019); reh'g en banc denied, 927 F.3d 1333 (Fed. Cir. 2019).

[10] Athena I, 915 F.3d at 753, n. 4 (dicta) ("[I]n our view, providing patent protection to novel and non-obvious diagnostic methods would promote the progress of science and useful arts. But . . . the Supreme Court has effectively told us in Mayo that correlations between the presence of a biological material and a disease are laws of nature, and purely conventional or obvious pre-solution activity is normally not sufficient to transform an unpatentable law of nature into a patent-eligible application of such a law.") (internal quotations and citations omitted); see also Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC ("Athena II"), 927 F.3d 1333, 1339 (Fed. Cir. 2019) (Dyk, J., concurring) ("Although the Supreme Court's decision in Mayo did not make all diagnostic claims patent ineligible . . . Mayo left no room for us to find typical diagnostic claims patent eligible, absent some inventive concept at Mayo step two.") (citation omitted).

[11] See, e.g., Vanda Pharm. Inc. v. West-Ward Pharm. Int'l Ltd., 887 F.3d 1117 (Fed. Cir. 2018); Endo Pharm. Inc. v. Teva Pharm. USA, Inc., 919 F.3d 1347 (Fed. Cir. 2019).

[12] Genetic Veterinary Scis., Inc. v. LABOKLIN GmbH & Co. KG, No. 2018-2056, at 20 (Fed. Cir. Aug. 9, 2019).

[13] Id. at 19, 22-23.

[14] Id. at 19-20, 23.

[15] Id. at 23 (internal quotation omitted).

[16] Id. at 23-25.

[17] Id. at 24 (citing Mayo, 566 U.S. at 73, 79-80).

[18] Id. at 26.

[19] See Cleveland Clinic, 859 F.3d at 1363-64 (after finding diagnostic claims patent-ineligible under § 101, affirming dismissal of infringement allegations based on method-of-treatment claims for failure to meet pleading requirements for contributory and induced infringement).

[20] See generally Athena II, 927 F.3d 1333.

[21] See id., 927 F.3d at 1337 (Hughes, Prost, Taranto, JJ., concurring).

[22] See id. at 1339 (Dyk, Hughes, Chen, JJ., concurring).

[23] See, e.g., id. at 1337 (Hughes, Prost, Taranto, JJ., concurring) ("[Further] explication might come from the Supreme Court. Or it might come from Congress, with its distinctive role in making the factual and policy determinations relevant to setting the proper balance of innovation incentives under patent law."), at 1341 (Dyk, J., concurring) ("[I]t would be desirable for the Supreme Court to refine the Mayo framework to allow for sufficiently specific diagnostic patent claims with proven utility.").

[24] See generally id. at 1352-73 (Moore, O'Malley, Wallach, Stoll, Newman, JJ., dissenting).

[25] May 22, 2019 draft bill available at https://www.tillis.senate.gov/services/files/E8ED2188-DC15-4876-8F51-A03CF4A63E26.