Bloomberg BNA

BNA's Patent, Trademark & Copyright Journal®

PATENTS

The authors look at recent views of the Supreme Court, Federal Circuit and PTO on patent eligibility and identify three principles to help practitioners seeking patent protection for medical diagnostics and treatments.

Patent Eligibility and Medical Diagnostic and Treatment Methods: Principles to Apply

BY COREY M. BEAUBIEN AND SHANNON K. SMITH

Section 101 of the Patent Act defines patent eligible subject matter.[1] Practitioners in many technology areas overlook it, since many inventions plainly fulfill the condition. But those who work with medical diagnostic and treatment methods encounter less certainty under Section 101.

The Supreme Court, the Federal Circuit and the Patent and Trademark Office (PTO) have all recently addressed patent eligibility as to medical diagnostics and treatments. While greater clarity is wanting, several principles are presented that may lessen the uncertainty met by practitioners.

Background

Courts hold that Section 101 contains an implicit exception making laws of nature, natural phenomena and abstract ideas ineligible for patent protection.[2] Rather, it is their application to a structure or process that satisfies Section 101.[3] The rationale underlying the exception is a concern that tying up basic tools of science will impede innovation more than promote it.[4]

Against this is the reality that all inventions at some level embody laws of nature, natural phenomena and abstract ideas.[5] Claimed medical diagnostic and treatment methods can recite one of the implicit exceptions and, when they do, are scrutinized under the jurisprudence governing patent eligibility.

The Supreme Court

In 2006 in *Laboratory Corp. of America Holdings v. Metabolite Laboratories Inc.*, the Supreme Court foreshadowed its later review of medical diagnostic and treatment methods.[6] Several justices joined in a dissent in which they asserted that the claim at issue was not

[1] 35 U.S.C. § 101 (2012) (defining ''any new and useful process, machine, manufacture, or composition of matter'' as patentable subject matter).

Corey M. Beaubien is a shareholder and Shannon K. Smith is an associate at the intellectual property law firm Reising Ethington P.C., at its Troy, Mich. office. Views expressed in this article are those of the authors.

[2] *Diamond v. Diehr*, 450 U.S. 175, 185, 209 U.S.P.Q. 1 (1981).

[3] *Id.* at 187.

[4] *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1293, 2012 BL 66018, 101 U.S.P.Q.2d 1961 (2012) (83 PTCJ 727, 3/23/12).

[5] *Id.*

[6] 548 U.S. 124, 79 U.S.P.Q.2d 1065 (2006) (72 PTCJ 208, 6/23/06).

 ISSN 0148-7965

patent eligible because it merely recited a natural phenomenon without a patent-eligible application.[7] Although the writ of certiorari in the case was dismissed as improvidently granted, the justices delivered their dissent nonetheless.

The claim concerns a process of diagnosing vitamin deficiencies.[8] In the claim, the level of homocysteine is first examined and then correlated with a vitamin deficiency of cobalamin or folate. The dissent contended that the claim simply embodies the correlation between homocysteine and vitamin deficiency, and that this is no more than an instruction to read some numbers in light of medical knowledge.[9]

Then in 2012, the Supreme Court took up the issue again, this time without dismissal. In *Mayo Collaborative Services v. Prometheus Laboratories Inc.*, the Court considered whether claims concerning a correlation between blood concentrations and drug dosage were eligible for patent protection.[10] It held the claims were not. The implicit exception at issue involved the correlation between concentrations of certain metabolites in blood and the likelihood that the accompanying drug dosage would be too low or too high—viewed as a law of nature.[11] The Court found that the law of nature was not properly applied and therefore the claims' subject matter did not satisfy Section 101.[12]

In its analysis, the Court looked at the claimed steps individually and then at the claim as a whole with the steps in combination.[13] The representative claim recites a method of optimizing therapeutic efficacy for treating an immune-mediated gastrointestinal disorder. A first step calls for administering a drug with 6-thioguanine to a subject having the disorder. The Court found that this step merely limits the method to the relevant environment, namely doctors who treat patients.[14] A second step calls for determining the level of 6-thioguanine in the subject. The Court read this step as instructing doctors to determine the relevant metabolite levels in the patient by any process they choose—that is, to engage in well-understood, routine and conventional activity.[15] Here, the Court referred to the patent's description that methods for determining metabolite levels were well known.[16]

The last two phrases of the claim are ''wherein'' clauses. One recites that a level of 6-thioguanine less than a specified value indicates a need to increase the amount of the drug, and the other recites that a level more than a specified value indicates a need to decrease the amount. The Court viewed the clauses as simply informing doctors about the relevant law of nature for the treatment.[17] And the steps in combination added nothing to support eligibility, as anyone who wanted to use the law of nature must follow the claimed steps.[18]

A year after *Mayo*, the Supreme Court addressed whether DNA was patent eligible in *Association for Molecular Pathology v. Myriad Genetics, Inc.*[19] While *Myriad* did not deal with method claims directly, a prominent question became whether the process of isolating DNA from an organism was patent eligible.[20]

The Court held that the process was not ''an act of invention,'' despite the extensive research conducted.[21] In the final section of the opinion, however, the Court noted that if the claims had recited an innovative method of manipulating genes while searching for the genes at issue, a method patent could have been sought.[22] The Court emphasized that the ineligible claims did not recite a new application of knowledge about the genes, nor a scientific alteration of the naturally occurring genetic code.[23]

The Court of Appeals for the Federal Circuit

Soon after *Mayo* and before the substantive holding in *Myriad*, the Federal Circuit addressed patent eligibility and medical diagnostics in *PerkinElmer, Inc. v. Intema Ltd.*[24] Although the case is unreported, it cites *Mayo* in its analysis and demonstrates the Federal Circuit's understanding of the Supreme Court case.[25] In *PerkinElmer*, the Federal Circuit held that the claims at issue were not eligible for patent protection.[26] The claims concern a noninvasive method of assessing whether a fetus is at risk of having Down syndrome. One representative claim calls for measuring the level of screening marker(s) from the first trimester of pregnancy, measuring the level of screening marker(s) from the second trimester, and then determining the risk of Down syndrome by comparing these measurements with statistical information.[27]

The Federal Circuit observed two implicit exceptions in the claim. One was a law of nature involving the relationship between screening marker levels and the risk of fetal Down syndrome, and the other involved the mental process of comparing data to determine a risk level.[28]

To decide whether the claims were eligible, the Federal Circuit looked at the claimed steps individually and then at the claim as a whole with the steps in combination—the approach taken in *Mayo*. The measuring steps merely recited well-understood, routine and conventional activity, and the determining step recited statistical information that is well understood and conventional information.[29] The combination did not save the claims, the Federal Circuit found, as anyone who wanted to use the implicit exceptions must employ the claimed method.[30]

---

[7] *Id.* at 125–26.
[8] *See id.* at 129.
[9] *Id.* at 137.
[10] 132 S. Ct. at 1294–95.
[11] *Id.* at 1296.
[12] *Id.* at 1297.
[13] *See id.* at 1297–98.
[14] *Id.* at 1297.
[15] *Id.* at 1298.
[16] *Id.*
[17] *Id.* at 1297.
[18] *Id.* at 1298.
[19] 133 S. Ct. 2107, 2013 BL 155804, 106 U.S.P.Q.2d 1972 (2013) (86 PTCJ 332, 6/14/13).
[20] *Id.* at 2111.
[21] *Id.* at 2117–18.
[22] *Id.* at 2119
[23] *Id.* at 2120.
[24] 496 Fed. App'x 65, 66, 2012 BL 305806, 105 U.S.P.Q.2d 1960 (Fed. Cir. 2012) (85 PTCJ 177, 12/7/12).
[25] *See, e.g., id.* at 69 (''The Supreme Court's decision in *Mayo* and this court's recent decision in *Ass'n for Molecular Pathology v. PTO*, 689 F.3d 1303 (Fed. Cir. 2012) [hereinafter *Myriad*] dictate the result we reach today.'').
[26] *Id.* at 73.
[27] *Id.* at 67–68.
[28] *Id.* at 70.
[29] *Id.* at 71.
[30] *Id.*

  PTCJ ISSN 0148-7965

The Patent and Trademark Office

In March 2014, the PTO turned to patent eligibility and medical diagnostics and treatments when it published its *Guidance For Determining Subject Matter Eligibility Of Claims Reciting Or Involving Laws of Nature, Natural Phenomena, & Natural Products*.[31] Among its aims, the *Guidance* seeks to address the Supreme Court's holdings in *Mayo* and *Myriad*.

The *Guidance* presents a set of factors for determining whether a claim that recites one of the implicit exceptions is eligible for patent protection. Several of the factors echo reasoning from *Mayo*, including: i) the claimed elements/steps narrow the scope of the claim so that others are not substantially foreclosed from using the judicial exception (weighs for eligibility), ii) the claimed elements/steps do more than describe the judicial exception with general instructions to apply or use the exception (for), and iii) the claim calls for elements/steps that add something that is more than well understood, conventional or routine in the relevant field (for).[32]

The *Guidance* also applies the factors in examples. One example sets forth two claims concerning a medical treatment method—one claim is not eligible for patent protection and the other is.[33] Both recite a method of treating a mood disorder in a patient with white light. The natural phenomenon involves the effect of white light on neuronal activity. The first claim simply calls for exposing the patient to a synthetic source of white light, with the exposure altering the patient's neuronal activity and mitigating the mood disorder. According to the *Guidance*, the factors weigh against eligibility.[34] The claim covers substantially all practical applications of using white light to effect neuronal activity, the step of exposing a patient to white light is no more than a general instruction to apply the natural phenomenon, and the step is well-understood, conventional, and routine in the art of treating mood disorders.

The second claim has more to it. A first step calls for providing a light source that emits white light, a second step calls for filtering the ultra-violet rays from the white light, and a third step recites positioning the patient a distance of 30–60 cm from the light source for 30–60 minutes.[35] According to the *Guidance*, the factors weigh in favor of eligibility.[36] The claim does not substantially foreclose others from using white light to effect neuronal activity in other ways, as patients could be positioned at different distances for different durations. Further, the filtering and positioning steps are more than general instructions to apply the natural phenomenon, and it is not well understood, conventional and routine in the art to position a patient at the specified distance for the specified duration.

Principles to Apply

With the Supreme Court, Federal Circuit and PTO all recently turning their attention to the issue, several principles surface that may help practitioners determine whether medical diagnostics and treatments are eligible for patent protection. Stated in favor of eligibility, the principles are:

(1) recitations in the claim are more than well understood, routine or conventional activities,[37]

(2) recitations in the claim do not preclude all uses of the implicit exception, and

(3) recitations in the claim do more than simply recast the implicit exception.

The cases and the example looked at in this article illustrate the principles in practice.

Principle one is perhaps best exemplified in *Mayo*. The Supreme Court viewed the claimed step of determining the relevant metabolite levels in the patient as nothing more than actions performed by doctors in the past. Indeed, the patent itself described as much. This might also be said about the claimed step of administering the drug to the patient, although the Court read the step as merely narrowing the claim to its intended environment of doctors treating patients. While the remaining wherein clauses introduce a novel and unobvious correlation, according to the Court the clauses simply inform doctors about the law of nature. Accordingly, apart from the implicit exception, the claimed steps in *Mayo* recite well understood, routine and conventional activities.

Principle two is illustrated in *PerkinElmer*. The implicit exceptions involved the relationship between screening marker levels and the risk of fetal Down syndrome, and the mental process of comparing data. The claimed steps call for measuring screening marker levels and then determining the risk of Down syndrome by comparing the measurements to statistical information. The Federal Circuit found that the claim precluded all uses of the relationship and of the mental process and consequently was ineligible—the court cited *Mayo* for the notion. Put another way, for one to apply the relationship and the mental process, one must practice the claimed steps. All applications of the screening marker levels as they relate to the risk then, according to the court, are covered by the claim in *PerkinElmer*.

Principles two and three have a bit of overlap between them and relate to the idea of claiming more than the implicit exception itself. The last principle, number three, is illustrated in both *Laboratory Corp. of America Holdings* and *Myriad*. In *LabCorp*, the implicit exception involved the correlation between homocysteine and vitamin deficiency, and the claim calls for an assaying step that examines the level of homocysteine and a correlating step that associates the level of homocysteine with a vitamin deficiency. The dissent read the claim as simply describing the implicit exception in the

[31] Memorandum from Andrew H. Hirshfeld, Deputy Comm'r for Patent Examination Policy, to the Patent Examining Corps on the 2014 Procedure for Subject Matter Eligibility Analysis of Claims Reciting Or Involving Laws Of Nature/Natural Principles, Natural Phenomena, And/Or Natural Products (Mar. 4, 2014) (87 PTCJ 1012, 3/7/14), http://www.uspto.gov/patents/law/exam/myriad-mayo_guidance.pdf.

[32] *Id.* at 2–3 (''Judicial exception'' refers to a law of nature, natural phenomenon, or natural product for the purposes of the *Guidance*.).

[33] *See id.* at 15.

[34] *Id.* at 16.

[35] *See id.* at 15.

[36] *Id.* at 17.

[37] The apparent mingling of eligibility under Section 101 and novelty and nonobviousness under Sections 102 and 103 with this principle is noted but not discussed in this article.

patent-vernacular of a process with some steps, and nothing more. Indeed, the claim is broad and captures the correlation between homocysteine and vitamin deficiency in the mere two steps that it calls for. In *Myriad*, the implicit exception involved a natural product, namely, isolated, naturally occurring DNA. The ineligible claim essentially called for that natural product, and little else.

Concluding Remarks

Additional action from the legislature or the Supreme Court is unlikely anytime soon since the America Invents Act largely ignored Section 101, and *Mayo* and *Myriad* are still in their infancy. Practitioners are left to work with the current jurisprudence governing patent eligibility of medical diagnostic and treatment methods. The principles presented by that jurisprudence are imperfect, but might become illuminated as more cases make their way through the courts.

  PTCJ ISSN 0148-7965