Patentable Subject Matter: The Supreme Court Speaks Again

After a long silence, the Supreme Court addresses a threshold requirement.

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The purpose of this short article, directed at pharmaceutical scientists, is to answer the question, "What is patentable subject matter?"[1] The answer is based on two recent Supreme Court decisions that examined the validity of patenting a clinical diagnostic test and isolated genes. It is hoped that this effort, though short, will help in demystifying for scientists this threshold requirement for patentability, and also promote more effective communication between scientists and patent attorneys, professionals with different backgrounds and perspectives,[2] who collaborate to capitalize on inventions through patent protection.

According to patent law, anyone who "invents or discovers any *new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof,* may obtain a patent therefor (emphasis added),"[1] provided the invention meets the requirements of novelty[3] and nonobviousness.[4] However, "laws of nature, natural phenomena, and abstract ideas" are not patentable[5] because patenting of such fundamental knowledge could hinder innovation and goes contrary to the policy reasons behind the constitutional basis for granting patent protection.[6]

THE *PROMETHEUS* CASE

In the first recent Supreme Court case[7] (hereinafter *Prometheus*), the Court determined that a patented method[8] to adjust dosages of a drug (6-thioguanine in this case) based on its therapeutic range (the range of blood drug concentrations over which a drug's therapeutic efficacy is optimal) is not patentable subject matter because the method merely states a law of nature. In arriving at this decision, the Court analyzed claim 1 of the '623 patent (assuming that "the other claims in this patent do not differ significantly from claim 1"[7]), described below:

A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:

(a) administering a drug providing 6-thioguanaine to a subject having said immune-mediated gastrointestinal disorder; and

(b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder, wherein the level of 6-thioguanaine less than about 230 pmol per 8×10^8 cells indicates a need to increase the amount of said drug subsequently administered to said subject, and wherein the level of 6-thioguanaine greater than about 400 pmol per 8×10^8 cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

The Court states that this claim is not patentable, because it merely "recite[s] a law of nature"[7] (i.e., the concept of the therapeutic range), and since the claim is clearly silent on how exactly to increase or decrease the dose, all it says is "apply the law."[7] The Court also identified two precedential cases involving methods that influenced its decision in *Prometheus*. In one case[5] decided in 1981, it had held that an invention (claims) which sought to apply the variables of the Arrhenius equation to improve a process for curing synthetic rubber was patentable, because it "did not seek to preempt the use of that equation"[5] by others. On the other hand, in the second case[9] decided in 1978, the Court held that "a method [just] for computing an 'alarm limit'"[9] which is "simply a number"[9] was not patentable because, though the method was related to catalytic conversion of hydrocarbons, the claims did not clearly explain how the alarm limit would be applied to optimize variables, such as temperature and pressure, associated with chemical process.

The Court added that a method would be patentable if it "has additional [new and useful] features that provide practical assurance that the [method] is more than a drafting effort designed to monopolize the law of nature itself."[7] However, adding such features can be challenging, because patent eligibility also requires overcoming the hurdles of novelty and nonobviousness (supra). Therefore, in this case, though including pharmacokinetic methods to adjust dose might make the claim overcome the "101 hurdle," it could be rejected on the basis of obviousness, since such methods are generally well known in the field. This point was discussed in the *AMP* case (infra).[10]

THE *AMP* CASE

In the second case[10] (hereinafter *AMP*), the Supreme Court decided on the validity of certain composition claims[11] in patents issued to Myriad. Some of these claims, which were directed at isolated gene segments, gave Myriad "the exclusive right to isolate an individual's BRCA1 and BRCA2 genes (or any strand of 15 or more nucleotides within the genes)."[10] The Court held that such isolated genes are not patentable subject matter because "[i]t is undisputed that Myriad did not create or alter any of the genetic information encoded in the BRAC1 and BRAC2 genes. The location and order of the nucleotides existed in nature before Myriad found them. Nor did Myriad create or

alter genetic structure of DNA,"[10] and "separating [a] gene from its surrounding genetic material is not an act of invention."[10] From a historical perspective, a 1911 appellate court, which was not cited in the Supreme Court opinion, had held that a purified form of adrenaline, extracted from animal glands, is patentable.[12]

On the other hand, the remainder of the Myriad claims directed at cDNA were deemed patentable because "creation of a cDNA sequence from mRNA results in an exons-only molecule that is not naturally occurring."[10] In a 1980 decision,[13] which the Court considers central to deciding *AMP,* it had approved the patenting of genetically modified organisms based on the broad congressional intent that "anything under the sun that is made by man"[13] should be patentable.

CONCLUSIONS

These two cases teach that (1) methods based on a natural law are patentable, provided they recite clearly how the law is applied practically, keeping in mind that application details should also meet the requirements of novelty and obviousness; (2) isolated or purified, but unmodified, forms of naturally occurring substances, such as an isolated gene segment, are no longer patentable; and (3) modified naturally occurring products of nature such as cDNA and genetically modified organisms are patentable.

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REFERENCES

1. Inventions patentable. 35 USC §101. ("The 101 hurdle," in patent law shorthand.)
2. Most, if not all, patent attorneys have an undergraduate or graduate degree in a scientific discipline.
3. Conditions for patentabilitiy: novelty and loss of right to patent. 35 USC §102.
4. Conditions for patentabilitiy: non-obvious subject matter. 35 USC §103.
5. *Diamond v Diehr,* 450 US 175, 195 (1981).
6. U.S. Constitution. Article 1. Section 8. Clause 8.
7. *Mayo Collaborative Services v Prometheus Laboratories Inc.* 566 US ___ (2012).
8. Seidman EG, Theoret Y, inventors. Method of treating IBD/CROHN's disease and related conditions wherein drug metabolite levels in host blood cells determine subsequent dosage. U.S. patent 6 355 623. March 12, 2002.
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10. *Association for Molecular Pathology v Myriad Genetics Inc.* US 569, ___ (2013).
11. Skolnick MH, Goldgar DE, Miki Y, et al, inventors. 17Q-linked breast and ovarian cancer susceptibility gene. US patent 5 747 282. May 5, 1998 (claims 1, 2, 5, 6 and 7); Shatuuck-Eidens, DM, Simard J, Durocher F, Emi M, Nakamura Y, inventors. Linked breast and ovarian cancer susceptibility gene. US patent 5 693 473. December 2, 1997 (claim 1); Tavtigian SV, Kamb A, Simard J, Couch F, Rommens JM, Weber BL, inventors. Chromosome 13-linked breast cancer susceptibility gene. US patent 5 837 492. November 17, 1998 (claims 1, 6 and 7).
12. *Parke Davis & Co. v H.K. Mulford & Co.,* 196 F. 496 (1912).
13. *Diamond v Chakrabarty,* 447 US 303 (1980).