

To: The Honorable Jon Dudas
Under Secretary, Commerce for Intellectual Property
Director, United States Patent and Trademark Office
Mail Stop Comments
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Re: Response to Request for Comments on Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility, 71 Fed. Reg. 34307 (June 14, 2006).

Date: July 31, 2006

Dear Under Secretary Dudas:

The Institute for Science, Law & Technology (“ISLAT”) submits the following response to the United States Patent and Trademark Office’s (“USPTO”) request for comments regarding the Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility (“Interim Guidelines”) published at 71 Fed. Reg. 34307. ISLAT has extensive experience in conducting legal and empirical analyses regarding patents, particularly gene patents and nanotechnology patents. ISLAT has participated in Congressional briefings, scientific conferences, and academic meetings dealing with § 101 Subject Matter Eligibility and has advised governmental agencies on this issue. Over the past decade, ISLAT has received grants from the U.S. Department of Energy, the

National Science Foundation, and the Robert Wood Johnson Foundation to analyze the proper scope of patents involving genes and nanotechnology. (See, for example, Jordan Paradise, Lori Andrews, and Timothy Holbrook, "Patents on Human Genes: An Analysis of Scope and Claims," 307 Science 1566-1567 (2005)). The research of ISLAT has shown that it is crucial that patents not be granted on laws of nature and products of nature because such patents 1) run afoul of existing law; 2) discourage innovation; and 3) overcompensate the applicant by allowing a patent on a process or product that he did not invent, but that existed prior to any intervention on his part.

The policy intent of patent law is to encourage invention and to assure that the public receives a new benefit in exchange for the grant of patent rights. Patents are not allowed on products of nature and laws of nature because the public would not be gaining anything new if an individual were allowed to, say, patent air (or the process for inhaling) and charge people a patent royalty whenever they breathed.

For over 150 years, the U.S. Supreme Court has steadfastly held that laws of nature and products of nature are not patentable. Increasingly, though, patent applicants are crossing the line and, in fact, some patents have been granted that improperly cover products of nature or laws of nature. The USPTO should be applauded for drafting Interim Subject Matter Eligibility Guidelines to deal with this problem.

The Interim Guidelines were drafted, however, before the U.S. Supreme Court heard oral argument, received input from the Solicitor General, and issued an opinion in Laboratory Corporation of America Holdings v. Metabolite Laboratories, Inc., 548 U.S. ___, 2006 WL 1699360 (2006). In that litigation, both the Solicitor General speaking for the Administration and various justices of the U.S. Supreme Court during oral argument

indicated that the prohibition of patents on laws of nature and products of nature was still clearly in effect and that the USPTO and the Federal Circuit had misinterpreted where the line should be drawn. Because of new criticisms that came to light during that litigation, the Interim Guidelines need to be revised. Currently, they improperly focus on implementing a Federal Circuit case, State Street Bank & Trust Co. v. Signature Financial Group Inc., 149 F.3d 1368, 47 U.S.P.Q.2d 1447 (Fed. Cir. 1999), rather than on implementing the more proper U.S. Supreme Court precedents. If the Interim Guidelines are not amended, examiners will be granting patents that run afoul of the Patent Act, the policy behind the Patent Act, and U.S. Supreme Court precedent. Given the U.S. Supreme Court's apparent willingness to strike down patents based on a law of nature/products of nature challenge (if that challenge is raised in the lower courts), it is of the utmost importance for examiners to understand the U.S. Supreme Court precedents and the policies underlying those precedents in order to assure that they issue valid patents.

The USPTO has expressed particular interest in comments that take into consideration the recent case, Laboratory Corporation of America Holdings v. Metabolite Laboratories, Inc., 548 U.S. ___, 2006 WL 1699360 (2006). The patent at issue in that case covered the following process: use any test (whether patented or unpatented) to measure the level of an amino acid called homocysteine in a body fluid and then, if the level is elevated above the norm, conclude that vitamin deficiency is likely. It is worth noting that in the oral argument in the Metabolite case, none of the justices indicated that he or she thought the patent was rightly granted. The reason that a majority of the justices did not rule the claim at issue invalid on 35 U.S.C. § 101 grounds was that the §

101 challenge had not been raised below. This is an indication that the patent examiners might already have gone too far in granting patents on laws of nature and products of nature.

The revisions to the Interim Guidelines should have three emphases:

1. The patent laws apply to human inventions, not discoveries of existing laws of nature or products of nature.¹

Even if a patent applicant exercised considerable innovation discovering a law of nature or product of nature, that law or product is not patentable. A person might expend money and creativity building a telescope, but he cannot patent the new planet he discovers through the telescope. Or he may invest time, money, and talent in learning the correlation between high blood pressure and a particular disease, but he cannot patent that relationship between high blood pressure and that disease (even if he cleverly drafts it as a process of measuring blood pressure and then correlating the result with the disease) because that would be a patent on a law of nature – a basic biological fact that predates the intervention of the patent applicant.

This logic is emphasized in U.S. Supreme Court cases. Funk Brother Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 131 (1948), involved a 35 U.S.C. § 101 inquiry, focusing on whether mixtures of certain bacteria were inventions or discoveries under the federal patent law. The Court held that the patent on a combination of six bacteria was invalid because “[p]atents cannot issue for the discovery of the phenomena of nature. . . .

¹Writing in 1889, a patent law scholar noted that the word “discovery,” as used in the Constitution, reached the level of patentability only where there is a human invention involved in the discovery. Albert A. Walker, Text-Book of the Patent Laws of the United States of America 2, at 2-3 (L.K. Strouse & Co., 2d ed. 1889). He pointed out that someone “may invent a machine, and may discover an island or law of nature. For doing the first of these things, that patent laws may reward him, because he is an inventor in doing it; but those laws cannot reward him for doing either of the others, because he is not an inventor in doing either.” Id.

The qualities of these bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none.” 333 U.S. at 130. In contrast, in Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980), an inventor introduced new genetic material into a bacterium cell, producing something that was not a product of nature and was thus patentable subject matter under 35 U.S.C. § 101. The case provided no break with precedent, though. In it, the U.S. Supreme Court emphasized that:

The laws of nature, physical phenomena, and abstract ideas have been held not patentable. Thus, a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated law that $E=mc^2$; nor could Newton have patented the law of gravity. Such discoveries are ‘manifestations of . . . nature, free to all men and reserved exclusively to none.’

Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980), *quoting* Funk Brothers Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948).

Dissenting Justices Breyer, Stevens, and Souter in Metabolite, 548 U.S. ___, 2006 WL 1699360, at *2-3, would have declared the test-plus-correlate patent invalid under § 101 even though the § 101 issue had not been raised by the petitioner in the courts below.

The dissenting justices pointed out that:

The justification for the principle does not lie in any claim that “laws of nature” are obvious, or that their discovery is easy, or that they are not useful. To the contrary, research into such matters may be costly and time-consuming; monetary incentives may matter; and the fruits of those incentives and that research may prove of great benefit to the human race. Rather, the reason for the exclusion is that sometimes *too much* patent protection can impede rather than “promote the Progress of Science and useful Arts,” the constitutional objective of patent and copyright protection. *U.S. Const., Art. I, § 8, cl. 8.*

2. Whether the patent application covers a machine, manufacture, composition of matter or a process, the examiner should assure that the invention claimed was “made by man.”

The prohibition on patenting a law of nature or product of nature is fairly easy to implement if the patent application includes a machine or manufacture that was invented by the applicant and would itself be patentable but for the fact that a law of nature was utilized. Patents that involve innovative *devices* that merely make use of laws of nature have been upheld by the U.S. Supreme Court. Mackay Radio & Telegraph Co. v. Radio Corp. of America, 306 U.S. 86 (1939); Corning v. Burden, 56 U.S. (15 How.) 252 (1854).

However, when the patent application is for a *process* that uses a law of nature, it is much more difficult for an examiner to determine whether the process is properly patentable. That is because laws of nature are generally themselves processes. The law of gravity is a process. The theory of relativity ($E=mc^2$) is a process that could be stated as: Find the mass of an object. Multiply it by the square of the speed of light. Determine the energy of the object.

The test for patentability of *processes* that the Interim Guidelines proposes is flawed. That test (based on an overly-broad reading of State Street) would allow a patent on the process involving a law of nature if the process produces a “useful, concrete, and tangible result.” *E.g.* Interim Guidelines at 1, 4, 19-22, 37-39. Elsewhere in the Interim Guidelines, the test is also referred to as producing practical results (*e.g.* Interim Guidelines at 1, 13, 18-21, 34-39) or having a real world function (Interim Guidelines at 4, 17, 21). This test is clearly overinclusive. It would allow patents on the laws of nature

themselves, with nothing more, because *most laws of nature are themselves processes that produce useful, concrete and tangible results and have a practical, real world function*. For example, the clearly unpatentable $E=mc^2$ would meet this test as would many other purported inventions that the U.S. Supreme Court has found to be unpatentable. To be patentable, there must be something more – there must be a human invention that produces a result beyond what the law of nature or product of nature produces itself.

This something more has been required by the U.S. Supreme Court in its cases. In fact, State Street itself cites the U.S. Supreme Court precedents indicating a mere useful, practical application of a law of nature or product of nature is not enough – the application must be *new*. The law or product must be used in some way *beyond* the way it functions in nature:

Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130, 68 S.Ct. 440, 92 L.Ed. 588 (1948) (“He who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes. If there is to be an invention from such a discovery, it must come from the application of the law to a *new* and useful end.”); *Mackay Radio & Tel. Co. v. Radio Corp. of Am.*, 306 U.S. 86, 94, 59 S.Ct. 427, 83 L.Ed. 506 (1939) (“While a scientific truth, or the mathematical expression of it, is not a patentable invention, a *novel* and useful structure created with the aid of knowledge of scientific truth may be.”).

State Street, 149 F.3d at 1374 (emphasis added).

The dissenting justices in Metabolite, 548 U.S. ___, 2006 WL 1699360, at *13-14 cast serious doubt on the use of the overly-broad State Street test, saying

That case [*State Street*] does say that a process is patentable if it produces a “useful, concrete, and tangible result.” 149 F.3d at 1373. But this Court has never made such a statement and, if taken literally, the statement would cover instances where this Court has held the contrary. The Court, for example, has invalidated a claim to the use of electromagnetic current for transmitting messages over long distances even though it produces a

result that seems “useful, concrete, and tangible.” *Morse, supra*, at 116, 56 U.S. 62, 14 L. Ed. 601. Similarly the Court has invalidated a patent setting forth a system for triggering alarm limits in connection with catalytic conversion despite a similar utility, concreteness, and tangibility. *Flook, supra*. And the Court has invalidated a patent setting forth a process that transforms, for computer-programming purposes, decimal figures into binary figures -- even though the result would seem useful, concrete, and at least arguably (within the computer's wiring system) tangible. *Gottschalk, supra*....

The flaw in the Interim Guidelines created by the reliance on State Street is not resolved by implying that a patent is permissible so long as it does not preempt all uses of the patented invention. Yes, it is improper to grant a patent over all uses of a law of nature. But it is also improper to grant a patent on even just one use of such a law of nature if there is no major human invention involved -- because such patents would cover pre-existing processes and not inventions. Several U.S. Supreme Court cases make this point. The patent in Funk Bros. did not involve all uses of the bacteria, just a particular one employing six bacteria, but it was still unpatentable. The patent claim at issue in O'Reilly v. Morse, 56 U.S. (15 How.) 62, 113 (1853) did not involve all uses of electromagnetic waves, just use of electromagnetic waves to write at a distance, but it was held invalid under the patent law.

The Court in Morse was concerned that granting Morse broad rights beyond his particular invention would overcompensate him by giving him rights to subsequent inventions that he did not himself create. The justices were also concerned that such a large grant of rights would deter other inventions. Finally, they were concerned that the public would lose out. The Court in the Morse case denied Morse's broad patent claim, saying:

If this claim can be maintained, it matters not by what process or machinery the result is accomplished. For aught that we now know some

future inventor, in the onward march of science, may discover a mode of writing or printing at a distance by means of the electric or galvanic current, without using any part of the process or combination set forth in the plaintiff's specification. His invention may be less complicated -- less liable to get out of order -- less expensive in construction, and in its operation. But yet if it is covered by this patent the inventor could not use it, nor the public have the benefit of it without the permission of this patentee.

Morse, 56 U.S. (15 How.) at 113.

This overcompensation was one of the concerns in the Metabolite case. At oral argument, Justice Breyer (Tr. 26), Justice Souter (Tr. 9), and Justice Stevens (Tr. 36) in particular expressed concern that the “test-plus-correlation” patent would allow the patent holder to assert rights to a later test that another person invented. That, in fact, was the point made by LabCorp in its challenge to the patent: that the patent prevented doctors from using a more efficient test because, when they read the test results they would then apply the correlation and infringe the test-plus-correlation patent. Brief for Petitioner, Laboratory Corporation of America Holdings v. Metabolite Laboratories, Inc., 2005 WL 35433099, at *25-26, *44-45. Justice Breyer pointed out in oral argument how a patent that sweeps in future inventions is contrary to the purpose of the patent law: “You have millions of doctors and scientists and computer people who are working extremely hard to think of useful ideas and if you don’t give them an incentive, they may think of less.” (Tr. 38.)

The way for examiners to assure that they do not improperly grant patents on laws of nature is to assure that the patent involves something that was actually invented by man, in addition to the law of nature. Justice Scalia made this point in the Metabolite oral argument by asking, “What was made by man here?... [W]hat [claim] 13 involves is simply discovery of the natural principle that when one, when there is the presence of one

substance in a human being, there is a deficiency of two other ones. That's just a natural principle. What's made by man about that?" (Tr. 40.)

3. Examiners should assure that a patent will not remove knowledge from the public domain.

The U.S. Supreme Court spoke on the motivation for the creation of a patent system in Graham v. John Deere Co. of Kansas City, 383 U.S. 1 (1966). After an extensive examination of constitutional history, the Court wrote:

Congress may not authorize the issuance of patents whose effects are to remove existent knowledge from the public domain, or to restrict free access to materials already available. Innovation, advancement, and things which add to the sum of useful knowledge are inherent requisites in a patent system which by constitutional command must 'promote the Progress of...useful Arts.' This is the *standard* expressed in the Constitution and it may not be ignored.

383 U.S. at 6 (emphasis in opinion).

Laws of nature and products of nature are part of the prior public domain. One of the problems that the dissenting justices saw with the patent at issue in Metabolite was that it allowed the patent holder rights to tests for homocysteine that had previously been part of the public domain, as well as rights to tests that would be discovered by others in the future – if the person employing the test then applied the law of nature (high homocysteine equals vitamin deficiency).

Related to the products of nature doctrine is the doctrine of inherency under the novelty requirement of patent law. A 2002 Federal Circuit case, for example, held that a patent cannot be granted to an applicant who has found previously unknown qualities in a natural product. In re Cruciferous Sprout Litigation, 301 F.3d 1343 (Fed. Cir. 2002). In that case the Federal Circuit stated, “[T]he glucosinolate and Phase 2 enzyme-including

potential of sprouts necessarily have existed as long as sprouts themselves, which is certainly more than one year before the date of application” 301 F.3d at 1350.

Conclusion

In conclusion, ISLAT has focused on Questions 2, 3, and 4 posed by the USPTO in its request for comments. As to Question 2 and 3, the USPTO Guidelines are too broad and would allow patents on laws of nature or products of nature that would be prohibited by the Patent Clause of the Constitution, the Patent Act, and U.S. Supreme Court precedent. The solution is to add material to the Interim Guidelines to emphasize that there must be a human innovation that is new and novel beyond the law of nature itself and that the law of nature must be used in a way that goes beyond how it functions in nature.

As to Question 4, if the patent would preempt all uses of the laws of nature, the patent should not be granted. But, even if it preempts only a single use, the patent should not be granted without human innovation that goes beyond the law of nature.

The Interim Guidelines should also note that the prohibitions on patents on laws of nature and products of nature are not just judicially-created exceptions. Those prohibitions are inherent in the Patent Clause of the Constitution and the Patent Act since patents are to be issued for *inventions* and things *made by man*, not pre-existing phenomenon.

It is vital that the USPTO establish a clear procedure for patent examination regarding subject matter patentability, particularly related to statutory subject matter. Accordingly, ISLAT commends the USPTO’s initiative in drafting the Interim Guidelines, and appreciates the opportunity to provide recommendations.

The Interim Guidelines provide patent examiners with a procedure by which they can attempt to distinguish between patents which improperly claim abstract ideas, laws of nature, or natural phenomena cleverly disguised in misleading language, and those which legitimately propose an inventive process, manufacture, machine, or composition of matter. ISLAT has provided the above recommendations in an attempt to further clarify the patent examination process. Given the USPTO's mission of encouraging technology and innovation, directives such as the Interim Guidelines can help examiners avoid the grant of broad monopolies which inevitably overcompensate patentees and stymie creation of the useful arts.

Sincerely,

Lori Andrews, J.D.