



Prometheus – a new dawn for biotech patents

THE CASE:

Mayo Collaborative Services v Prometheus Labs.
Supreme Court
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Paul Hastings partner **Bruce Wexler** and summer associates **Max Yusem** and **Graham Cole** discuss how to successfully navigate patent eligibility after the landmark *Prometheus* decision

Pharmaceutical and biotech companies, legal academics and the media have expressed concern and uncertainty regarding the state of patent eligibility law in light of the Supreme Court's ruling in *Mayo Collaborative Services v. Prometheus Labs*.¹ Some are wary that *Prometheus* signals an end to patent eligibility for broad categories of subject matter, particularly discoveries in biotechnology. However, a careful inspection of *Prometheus* reveals the decision to be a fact-specific case reaffirming previous Supreme Court precedent concerning patent-eligible subject matter under 35 U.S.C. § 101.

We have observed that this reading of *Prometheus* is reinforced by a thoughtful dissenting opinion written some 18 years ago by the chief judge of the Court of Appeals for the Federal Circuit, which parallels the Supreme Court's reasoning². In this article, we discuss our analysis of *Prometheus*, illuminated by chief judge Archer's prior dissent, and set forth practical advice for dealing with § 101 patent-eligibility issues that arise in patent litigation or prosecution.

Recent developments in § 101 jurisprudence

In *Prometheus*, the Supreme Court reviewed two method patents directed at determining the optimal dose for a class of thiopurine drugs³. Prometheus Laboratories sued Mayo Clinic Rochester and Mayo Collaborative Services for selling a similar diagnostic test. The Federal Circuit held that the *Prometheus* patents complied with the patent law eligibility requirements, set forth in 35 USC § 101, because they satisfied a so-called "machine or transformation test" under which the subject matter was patent-eligible

so long as it was confined within definite bounds.

The Supreme Court vacated the Federal Circuit's judgment, and remanded for reconsideration (known as a GVR order) in light of *Bilski v. Kappos*⁴, which found a method of hedging losses in the energy industry patent ineligible. On remand in *Prometheus*, the Federal Circuit reaffirmed its previous holding of validity, forcing the Supreme Court to address the eligibility issue on the merits. The Supreme Court reversed, finding that the patents-in-suit claimed an underlying natural law inherent in the patented method.

The Supreme Court has since issued two GVR orders in light of *Prometheus* – in *Association for Molecular Pathology v. Myriad Genetics*⁵, involving a patent directed at isolated human genes, and *WildTangent v. Ultramercial*⁶, involving a patent on a method for monetising and distributing copyrighted material. The Federal Circuit had based the *Ultramercial* ruling in part on its 1994 *en banc* majority opinion in *Alappat*, which in turn involved a patent for manipulating data for display with a computer. The reasoning in *Alappat* was simple – a computer performing an algorithm was a machine and machines are patent eligible. In *Alappat*, however, chief judge Archer authored a detailed dissenting opinion that parallels the reasoning of the Supreme Court's recent opinion in *Prometheus*. The Supreme Court's recent GVR of *Ultramercial* thus puts *Alappat* back into play, and may bring the dissent again into focus.

The outcome of *Ultramercial*, *Myriad* and other recent Federal Circuit decisions regarding patent eligibility will be important because they could provide additional insight into the scope of *Prometheus*⁷. There is also a substantial chance of further Supreme Court review. No matter the final outcome

of these cases, *Prometheus* remains central to the analysis and we set forth in this article important perspectives for those faced with subject matter eligibility issues under § 101.

Section 101 patent eligibility as a gate to the remainder of patent law

Title 35, Section 101 of the United States Code, states in relevant part that whoever 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, subject to the conditions and requirements of this title.

While this language is seemingly broad, over 200 years of United States jurisprudence holds that patents, in general, may be awarded only for the discovery of useful applications of ideas and principles, rather than the discovery of "laws of nature, natural phenomena, and abstract ideas" themselves.⁸

Distinguishing whether a patent is for a useful application of an idea or an idea itself depends on the particular facts surrounding the subject matter at issue, and is not subject to a set of rules based simply on the area of technology. Indeed, this is a key takeaway message from *Prometheus*. While the absence of a bright line test can be unsettling, we believe that a firm understanding of patent eligibility principles and precedent, applied after a careful review of the particular subject matter in a given case, will enable strong advocacy and reasonable predictability⁹.

Taking a step back, we can see that § 101 issues often arise in two related situations: (1) the invention is the discovery of a new law of nature or abstract idea (without a specific application), or (2) the invention includes the discovery of an application of a law of nature or abstract idea but the patentee seeks broad exclusivity through claims directed to the law or

idea itself. Supreme Court decisions of patent ineligibility such as *Parker v Flook* (patent claiming a method for adjusting alarm limits within a particular industry)¹⁰ and *Gottschalk v. Benson* (patent claiming a method for converting numbers from binary to decimal)¹¹ provide examples of the former, while *O'Reilly v Morse* (patent claiming a method for sending signals over long distances using electrical current)¹² provides a classic example of the latter.

There are two philosophies driving the denial of patent eligibility in these situations. The first is the concept that patents should not monopolise fundamental research, which would thereby prevent others from making useful discoveries within the broadly claimed field. This concern is usually satisfied by including some form of structural limitation in the claims of the patent, without necessarily focusing heavily on the substance of that limitation. The presence of structure or physical acts in the claim allows for the argument that the claim is patent-eligible because the scope is not in fact as broad as the law of nature or abstract idea itself.

The second philosophy driving the denial of patent-eligibility, however, is not as clear cut, and is not necessarily addressed merely by adding structure to the claims. This concept is that patents should not be awarded where the invention in fact resides in the discovery of a new natural law or abstract idea without substantial useful application of that law or idea. In *Alappat*, chief judge Archer explained this concept vividly using the example of a patent claiming a compact disc wherein the structure consisted of the specific arrangement of pits in the plastic material that encodes a particular new song identified in the patent claim. The patent in such a case is not monopolising a pure idea (because the claim recites structure) and the claimed structure of the patent is novel (since the arrangements of pits defined by the song is a new combination). Yet, the invention clearly resides in the discovery of the song notwithstanding the structure present in the patent claims. Patent law is simply not appropriate for analysing the inventiveness of music. Thus, if § 101 patent-eligibility strictures were not a hurdle in this situation, the end result could be the award of a patent for the discovery of new music, an abstract concept that is not the "stuff" of patent law. A similar rationale can apply in considering patents for discoveries of new natural laws and abstract ideas. This second philosophy accordingly requires that the totality of the claimed subject matter and nature of the invention be carefully analysed on its facts, even if the claim recites

structure or physical acts. The subject matter must be sufficiently directed to an invention residing in the substantial application of a law or idea to pass through the § 101 gate. This ensures that the remaining provisions of patent law, particularly novelty and non-obviousness, may be meaningfully applied.

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A key to successful advocacy is to understand that a particular judge or patent examiner might analyse claims with both these philosophies in mind. In fact, the Supreme Court in *Prometheus* and chief judge Archer in *Alappat* tailored their opinions to address both of these concerns.

Section 101 analysis under *Prometheus*

In *Prometheus*, the Supreme Court first asks the question: What is the invention? The concept of "invention" is ethereal because all patentable inventions are born out of natural laws or abstract ideas. As eloquently stated over 100 years ago by a renowned United States patent law commentator:

[T]he whole of the act of invention ... embraces more than the new arrangement of particles of matter in new relations. The purpose of such new arrangements is to produce some new effect or result, by calling into activity some latent law, or force, or property, by means of which, in a new application, the new effect or result may be accomplished. In every form in which matter is used, in every production of the ingenuity of man [or women], he [or she] relies upon the laws of nature and the properties of matter, and seeks for new effects and results through their agency and aid.¹³

From a high level, "inventions" are (1) some arrangement of "particles" (ie, structures, materials, etc), (2) natural laws or abstract ideas that are invoked when the "particles" are arranged, and (3) useful effects achieved as a result of this arrangement¹⁴.

The court's analysis in *Prometheus* focuses

on determining whether the claimed invention simply embodies the underlying natural law or if the patentee has incorporated this otherwise un-patentable subject matter into an inventive application. Analytically, this requires identifying the laws or ideas that the claimed invention encompasses. In *Prometheus*, the natural law underlying the patent, embodied by the "determining step" was the "relationship... between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm".

Next, the Court determined "whether the claims do significantly more than simply describe these natural relations". In *Alappat*, chief judge Archer advocated for a similar step because, if the court "look[ed] only to whether the claim reads on structure and *ignore[d]* the claimed invention, [it would] result in the awarding of patents for discoveries well beyond the scope of the patent law". This effectively requires a limited dissection of the claim language.

This limited dissection in *Prometheus* began with the "administering" step. According to the court, the patent claim defined a subset of patients that existed before the discovery of the natural law because thiopurine drugs were in use long before the patent was filed. Furthermore, the court reasoned that the relationship between the class of drugs and its metabolites necessarily exists in a patient population that has taken the drug. Thus, the recitation of a step that is inherent in the confines of the natural law will not create patentable subject matter under § 101.

The court then found that the step of instructing doctors to determine metabolite concentrations by standard lab techniques was "purely conventional or obvious". This language has sparked concern with commentators that the court conflated analyses under §§ 102 (novelty) and 103 (non-obviousness) with § 101 (patent eligibility). However, a review of the cases cited by the Supreme Court demonstrates that, in its opinion, the court did not look externally from the patent text to analyse the prior art and its relationship to the invention, as in a typical novelty or obviousness analysis. The court instead took the patent at face value and focused on the patent specification when analysing what the invention purported to be. Hopefully, district courts implementing *Prometheus* will use this kind of high level analysis, rather than parse through extrinsic evidence of novelty and obviousness.

Finally, the Court considered all of the steps together and determined that they

"add[ed] nothing to the laws of nature that [were] not already present when the steps [were] considered separately". Even taken as a whole, the Prometheus invention was said to amount to claiming the natural relationship itself, making it ineligible for a patent. This "whole greater than the sum of the parts" reasoning has also led to significant concern that the court has added another aspect to §101 that challengers can use to invalidate patents. But, as chief judge Archer's dissent in *Alappat* explained, the Supreme Court's prior *Diehr* decision was also based on the totality of subject matter. In *Diehr*, the Court found patent eligibility because the invention as a whole involved a novel application of a natural law. By incorporating this final step in *Prometheus*, the Supreme Court was both following precedent and leaving the door open for new technologies.

Practice tips and strategy going forward

After *Prometheus*, it is still the case that "it is impossible to generalise with bright line rules the dividing line between what is in substance the invention or discovery of a useful application within §101 versus merely the discovery of an abstract idea or law of nature or principle outside §101." The Supreme Court in *Prometheus* did not minimise §101 in favour of other sections of the Patent Act, or accept a bright line rule for determining subject matter eligibility. Instead, the court performed a fact-based analysis of the claimed invention to determine exactly what the patentee alleged to have invented and whether it was eligible subject matter.

When considering §101 eligibility issues, one should read a patent fully to understand what the patentee purports to have invented. Thinking back to the basic concept of invention, consider aspects relating to the arrangements of "particles" (ie, arrangements of structure, materials, substances, etc), how the natural laws or abstract ideas operate on those "particles", and the operational effects achieved. Within each of these considerations, look for subject matter to emphasise as significant beyond the natural laws or abstract ideas themselves. Finally, consider the subject matter as a whole. Of course the claim defines the metes and bounds of the invention, but one should anticipate that the patent specification will be fully read in determining what that claim means. Alternatively, in the drafting stage, the patent application should not only tout the natural law itself, but also the totality of its useful application through the arrangements of structure and operational effects.

It is important to understand the natural laws or abstract ideas present in the claimed

invention. In this regard consider the spectrum of Supreme Court precedent from *Flook* and *Benson* to *Diehr*. In *Flook*, the claims simply instructed one to apply a formula for calculating alarm limits to any relevant alarm setting within a defined industry. Such application was insufficient for patent eligibility, as it was in *Benson*, because the patent effectively claimed the underlying natural law or idea. *Diehr* provides an opposing bookend because the patent-in-suit claimed a method to provide superior rubber products, rather than just the underlying natural law.

Thus, it is critical that the limitations of the claims, taken as a whole, bring forth an *application* that is of substance, rather than adding trivial gloss to a patent actually seeking to protect a natural law or abstract idea itself. The more the patent is on the spectrum closer to *Diehr*, rather than *Flook*, *Benson*, or *Prometheus*, the better, in terms of eligibility.

Conclusion

It will be interesting to watch how §101 issues are litigated under *Prometheus* and how District Courts and the Federal Circuit apply the decision. Hopefully, future cases will recognise that *Prometheus* did not broadly hold that certain categories of technology are patent-ineligible. Instead, the court sought to reaffirm earlier precedent holding that, while patent law does not protect natural laws or abstract ideas, inventive applications of those laws and ideas are patentable. While this principle does not create black-and-white demarcations that can be generalised for a given area of technology, we believe well-constructed and fact-specific arguments for patent eligibility can be formulated by having a thorough understanding of the patented invention, the principles underlying §101 and relevant Supreme Court precedent¹⁵.

Footnotes

1. 132 S.Ct. 1289 (2012). See, 'Brent Kendall, Top Court Decision Stirs Alarm in Biotech', WALL ST J, 21 March 2012; Greg Stohr, 'Diagnostic Medical-Test Patents Limited by US High Court', BLOOMBERG, 20 March 2012; Barry Wilson, *Applying Prometheus To Myriad: Possible Outcomes*, LAW360, 21 May 2012, available at <http://www.law360.com/articles/336262/print?section=ip>.
2. See *In re Alappat*, 33 F.3d 1526, 1551–69 (Fed. Cir. 1994).
3. US patent No. 6,355,623 and 6,680,302 embodied findings that concentrations of thiopurine metabolites beyond certain thresholds correlated with positive and negative treatment outcomes in patients with Crohn's disease or ulcerative colitis.

4. 130 S. Ct. 3218 (2010) (holding that the machine or transformation test, while informative, is not dispositive of § 101 eligibility).
5. 132 S.Ct. 1794 (2012).
6. 132 S.Ct. 2431 (2012).
7. See, eg, *CLS Bank International v Alice Corp.*, 2011-1301, 2012 WL 2708400 at * 13 (Fed. Cir. 9 July 2012) (holding, over vigorous dissent, that a patent covering a computerised trading platform was patent eligible because it covered the "practical application of a business concept ...which requires computer implemented steps").
8. *Prometheus*, 132 S.Ct. at 1292 (citing *Diehr*, 450 U.S. at 185, 187); see also *Alappat*, 33 F.3d at 1551-52 (Archer, CJ, dissenting).
9. This kind of situation exists in other areas of intellectual property law. For example, copyright law allows protection of the expression of an idea, but prohibits exclusive rights in the idea itself. "Although [courts] find the task of distinguishing between idea and expression difficult and somewhat imprecise they nevertheless continue to make those important distinctions." *Alappat*, 33 F.3d at 1554 n. 15 (Archer, C.J., dissenting).
10. 437 US 584, 595-96 (1978).
11. 490 US 63, 64, 71-73 (1972).
12. 56 US 62 (1853).
13. *Alappat*, 33 F.3d at 1551-52 (Archer, CJ, dissenting) (quoting G. Curtis, *A Treatise on the Law of Patents for Useful Inventions* at xxiii-xxv (4th ed. 1873)).
14. A unifying theme with other aspects of patent law exists: consider, for example, the doctrine of equivalents which looks to the "way" (arrangement of particles), "function" (principles of operation), and "result" (effects achieved) of a claimed invention to judge whether changes in these aspects render the subject matter substantially different from the invention as claimed. See *Hilton Davis Chemical Co v Warner-Jenkinson Co*, 114 F.3d 1161, 1164 (Fed. Cir. 1997) (*en banc*).
15. *Alappat*, 33 F.3d at 1554 (Archer, CJ, dissenting).
16. Chief Judge Archer's thought-exercises in *Alappat* may also be useful for this purpose.

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