

Section 102: A Dead Letter For Qualifying Claims

Law360, New York (June 25, 2012, 1:17 PM ET) -- It has been three months since the U.S. Supreme Court's decision in *Prometheus* and, with the recent grant-vacate-remand of *Ultramercial* to the Federal Circuit, the patent bar is left to speculate on the application of this holding both within and outside of medical diagnostics.

This article investigates the court's conflation of the novelty inquiry under 35 USC § 102 with the patent-eligibility inquiry under § 101. We conclude that the court's desire to avoid rendering as a dead letter the "law of nature" exception to § 101 patentability has, apparently unwittingly, rendered § 102 a dead letter for certain types of claims. Left open and unresolved is the question of whether the expanded scope of § 101 also implicates the inquiry for obviousness under § 103.

The Principles of *Prometheus*

The claims at issue in *Prometheus* were drawn from the field of medical diagnostics and therapeutics. *Mayo Medical Laboratories v. Prometheus Laboratories*, 566 U.S. ____ (2012). However, the principles set forth in the decision have far-reaching implications, well beyond these specific technologies. The overarching concern of the *Prometheus* court was to deny patent eligibility to claims that simply describe a law of nature without encompassing patent-eligible subject matter that applies that natural law.

The principle and analysis may be easily applied to other types of patent-ineligible subject matter, including abstract ideas (e.g., algorithms and equations), that are frequently found in the computer and high-technology arts. Thus, it is critical for the patent practitioner to be able to identify claims that may be subject to a *Prometheus*-style challenge and devise a claiming strategy to ensure patent-eligibility.

Excepted Subject Matter: Embodying Versus Reciting

The basic rule for patent-eligibility under § 101 is that "anything under the sun that is made by man" is patent-eligible. *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), quoting S. Rep. No. 1979, 82d Cong., 2d Sess., 5 (1952); H.R. Rep. No. 1979, 82d Cong., 2d Sess., 6 (1952). However, the Supreme Court has long recognized certain exceptions to this broad rule, including claims directed to laws of nature, natural phenomena, and abstract ideas ("excepted subject matter"). *Diehr* at 185. The *Prometheus* court did nothing to alter this rule or its exceptions but articulated an analysis for determining whether claims which recite active and transformative steps do nothing more than claim those exceptions.

The court carefully noted that all inventions, at some level, embody or otherwise rest upon some law of nature (or other excepted subject matter) and this fact alone is not sufficient to deny patent eligibility. *Prometheus* at slip op. 2. It is only claims that explicitly recite excepted subject matter that are suspect. Thus, any analysis of patent-eligibility under § 101 must begin with the determination of whether the claim recites excepted subject matter or merely relies on its principles; the former generally requiring further analysis, while the latter are generally patent-eligible.

To qualify for a *Prometheus*-style analysis, the excepted subject matter in the claims must be identified and defined. The definition of excepted subject matter is best exemplified by considering the claims at issue in the precedential Supreme Court cases themselves. The *Prometheus* court defined the claimed law of nature as the "relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm." *Prometheus*, slip op. at 8.

In *Benson*, *Flook* and *Diehr*, the excepted subject matter was identified to be an algorithm or formula, at least the critical elements of which were explicitly recited in the claims. In each case, it was this explicit recitation of at least the critical elements of the excepted subject matter that induced a further analysis of patent eligibility. Taken together, the Supreme Court appears to define excepted subject matter with explicit or implicit claim language but does not include details related to the specific implementation of the excepted subject matter.

For example, the *Prometheus* court referenced thiopurine drugs but not the specific efficacy and toxicity levels. Likewise, the *Benson* court referenced the algorithm with respect to digital computers for the conversion of decimal numbers into binary numbers and the *Flook* court referenced the algorithm in monitoring a catalytic process, each without reference to the specific formulae or calculations.

Testing Pre- and Post-Solution Activity: The Absolute Conflation of §§ 101 and 102

Having identified the claim elements that recite the excepted subject matter, the Prometheus court isolated those elements from the remainder (pre- and post-solution activity) to determine whether or not the remainder was well-understood, routine, and conventional. In holding the Prometheus claims invalid, the court characterized the "administering" step as merely identifying a pre-existing audience, the broad "determining" step as an instruction to engage in well-understood, routine, conventional activity, and the order of steps as adding nothing that was not already present when the steps were considered separately. Failing to find any unconventional activity, the court concluded that the claims do nothing more than describe a natural law and provide an instruction to apply it. Prometheus, slip op. at 10.

Thus, the Prometheus court set forth a § 101 analysis that explicitly incorporates a novelty test for the nonexcepted subject matter. To that end, the court stated "that, in evaluating the significance of additional steps, the § 101 patent-eligibility inquiry and, say, the § 102 novelty inquiry might sometimes overlap." Prometheus, slip op. at 21.

We submit that the court understated this principle. The test for patent-eligibility subsumes and completely dominates the novelty test for claims that explicitly recite excepted subject matter (trivial additional limitations aside) because it is impossible to satisfy patent-eligibility and not also satisfy novelty. However, this § 101 construct differs and is more stringent than the traditional § 102 analysis in that the patentee is barred from relying on the excepted subject matter for novelty.

The view that the § 101 analysis dominates essentially the entirety of the § 102 analysis for qualifying claims squares with the precedential opinions relied upon by the Prometheus court. In Benson, the claims recited only an algorithm and contained no pre- or post-solution activity and therefore lacked both patent-eligibility and novelty because there was literally nothing recited other than the excepted subject matter which was isolated from consideration by the court.

In Flook, other than the algorithm, the claims were found to recite only the conventional steps of measuring process variables, determining an alarm limit but without reference to the novelty of the specific algorithm, and conventionally applying that alarm limit. In other words, all of the nonexcepted claim elements in Benson and Flook lacked novelty.

The patent-eligible claims in Diehr provide a counter example. The excepted subject matter — the Arrhenius equation — admittedly lacked novelty. However, the claims were held to be patent-eligible because they recited unconventional steps or combinations of steps. Thus, the same claim elements of Diehr imparted both novelty and patent-eligibility and these claim elements were not excepted subject matter.

The Prometheus analysis practically mandates that patent-eligibility and novelty be found in the same claim element or combination of elements. Similar to Benson and Flook, the Prometheus claims failed because their novelty lay solely in the recitation of the excepted subject matter — which cannot be the basis for patent-eligibility — whereas the potentially patent-eligible transformations of the claims were well known.

A Practical Application of the Prometheus Analysis

The principles of the Prometheus analysis may be illustrated by analyzing the following hypothetical claims:

1. A method for treating disease X comprising administering to a patient a therapeutically effective amount of drug Y.
2. A method for treating disease X comprising administering to a patient a therapeutically effective amount of drug Y, wherein drug Y inhibits enzyme Z.
3. A method for treating disease X comprising inhibiting enzyme Z in a patient.

For illustrative purposes, assume that the drug Y was previously used to treat disease X through an unknown mechanism and the patent applicant was the first to discover that mechanism; the inhibition of enzyme Z. Thus, each of these hypothetical claims embodies and/or recites a natural phenomenon which may be defined as the relationship between the inhibition of enzyme Z by drug Y and its therapeutic efficacy in the treatment of disease X.

Claim 1 does not explicitly or implicitly recite the natural phenomenon so therefore cannot merely describe that phenomenon. Claim 1 should be identified as patent-eligible (i.e., not subjected to a Prometheus-style analysis) and examined for patentability under the other statutory provisions. Patentability therefore would turn on a traditional novelty analysis under § 102.

Assuming that the method of claim 1 is disclosed in the prior art, the patent applicant may elect to introduce a limitation reciting the newly discovered mechanism of action in order to distinguish over the prior art. Claim 2 is an example of such a claim. Claim 2 is a qualifying claim that implicates a Prometheus analysis because the wherein clause may be viewed as explicitly reciting the natural phenomenon.

Accordingly, the "wherein" clause is isolated and the remainder of the claim is assessed for novelty (i.e., unconventional pre- and/or post-solution activity). Under Prometheus, claim 2 is not patent eligible because, absent the "wherein" clause, the claim reads on the prior art. We expect that the U.S. Patent Office will style these rejections as combined § 101/§ 102 rejections. Of course, if the prior art does not disclose the use of drug Y for the treatment of disease X, any rejections based on §§ 101 and 102, either alone or in combination, would be improper.

The analysis of claim 2 also illustrates two corollaries of the Prometheus analysis. First, for certain types of excepted subject matter such as natural phenomenon, the § 101 analysis subsumes the law of inherency which was traditionally within the purview of § 102. Second, claim amendments which only add detail to a claim may raise a § 101 issue which did not previously exist while not adequately addressing an existing § 102 issue. Alternatively, deletion of excepted subject matter may transform a § 101 rejection into a § 102 rejection which supports our expectation of combined §101/§102 challenges in the future.

Finally, hypothetical claim 3 represents a broadening of claims 1 and 2 which reads directly on the applicant's discovery. On its face, claim 3 appears to overcome the prima facie novelty problem of the earlier claims because it contains no reference to drug Y of the prior art and the prior art fails to suggest the inhibition of enzyme Z.

Here again, the explicit recitation of the natural phenomenon qualifies the claim for a Prometheus analysis. However, claim 3 lacks patent-eligibility because, like the claims in *Benson*, nothing remains in the claim once the excepted subject matter is isolated. Claim 3 further illustrates the conflation of patent-eligibility with novelty under *Prometheus*. Without the *Prometheus* analysis, this claim would be invalid for inherent anticipation if it is proven that the prior art drug X acted through the claimed mechanism.

Claim 3 also demonstrates that the patent eligibility inquiry is broader than the novelty analysis. For example, claim 3 is novel but would lack patent-eligibility if drug X is not in the prior art. Thus, not all qualifying claims lacking patent eligibility also lack novelty; however, all qualifying claims lacking novelty also lack patent eligibility. This § 101 analysis practically subsumes all elements of the § 102 novelty analysis. Thus, *Prometheus* effectively renders § 102 a dead letter for analysis of qualifying claims.

§101/§ 103 Challenges: An Open Question Under Prometheus

Prometheus leaves open the question of whether the § 101 analysis of qualifying claims also dominates the § 103 analysis for obviousness. The court did not specifically indicate the factual basis for its determination that each of the nonexcepted claim elements were routine and conventional. However, this question is moot in *Prometheus* because any single prior art reference that performed the "determining" step necessarily had previously performed the "administering" step.

This question becomes important for claims in which multiple prior art documents are required to demonstrate that each claim element is routine and conventional. Could this result in a patentee facing a combined §101/§103 challenge? And, if so, could a patentee be faced with arguing secondary indicia of nonobviousness in order to establish patent-eligibility?

Conclusions

The desire of the *Prometheus* court to avoid rendering as a dead letter the "law of nature" exception to § 101 patent-eligibility has, in fact, elevated the importance of § 101 from that of a mere gatekeeper to a rigorous requirement for patentability. In doing so, the court merges the § 102 novelty analysis into § 101, rendering § 102 a dead letter for qualifying claims. *Prometheus* raises more questions than it answers with respect to its implication of other statutory provisions.

--By Anthony C. Kuhlmann and Barry S. Wilson, Sheppard Mullin Richter & Hampton LLP

Anthony Kuhlmann and Barry Wilson are special counsel in the intellectual property practice group in Sheppard Mullin's Del Mar, Calif., office.

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