



Biotechnology and Pharmaceutical Litigation

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Prometheus Labs. v. Mayo Update

This case [Appeal No. 2008-1403] is one of the pending Federal Circuit cases that are questioning whether medical diagnostic and treatment methods are the proper subject matter for patent protection under 35 U.S.C. §101. Other cases include *Classen Immunotherapies Inc. v. Biogen Idec* (method of determining an immunization schedule) and *Association for Molecular Pathology v. Myriad Genetics* (gene patents).

In the District Court the claims were held to be invalid as lacking patentable subject matter under Section 101. On appeal, the Federal Circuit reversed holding that the steps of administering the drug and determining the level of drug were both sufficiently transformative of a particular article into a different state or thing.

The Supreme Court had granted *certiorari*. However, following the Court's *Bilski* decision, the Court vacated the Federal Circuit's *Prometheus* decision and remanded for a new opinion. Mayo had requested that the Federal Circuit hear the case en banc.

On September 1, 2010, the Federal Circuit issued an order that apparently denied Mayo's en banc request and instructed the parties to each file 20-page briefs addressing the effect of the Supreme Court's *Bilski* decision on the disposition, no later than October 1, 2010. The order further stated that no additional briefing or oral argument is contemplated at this time. A review of PACER shows that both parties filed their briefs on October 1, 2010.

These cases will be monitored for future columns.

Written Description Standard Applied in Patent Interference

On September 7, 2010, in *Goeddel v. Sugano* [Appeal No. 2009-1156], the Federal Circuit reversed an interference decision from the US Patent and Trademark Office (USPTO) and found that the Sugano patent application was not entitled to priority in the proceeding based on the filing date of Sugano's earlier Japanese application.

The Sugano and Goeddel applications both claimed a recombinant DNA process for directly producing mature human interferon beta, known to have therapeutic value against pathogens and tumors, but the Japanese application did not describe mature interferon beta or the DNA encoding it, unaccompanied by the naturally-occurring pre-sequence.

According to the Federal Circuit, the USPTO had incorrectly found that priority was properly established if a skilled artisan could "envision" the invention of the interference counts.

The Federal Circuit instead applied the written description standard of *Ariad v. Eli Lilly & Co.* Under that standard, the proper inquiry is whether the application conveyed that the inventor *had possession* of the subject matter of the count, as of the filing date, which the Japanese application failed to accomplish.

PTO Issues New Section 103 Guidelines

On September 1, 2010, the USPTO published updated examination

guidelines for examination of patent claims for obviousness under 35 U.S.C. § 103. The 18 page guidelines do not have the force of law, but will impact how examiners judge obviousness in practice. Litigators may want to consider these obviousness guidelines for their use as well.

These guidelines are an update of the 2007 *KSR* Guidelines for PTO personnel to use when applying the law of obviousness under Section 103. The purpose of the 2007 Guidelines was to give PTO personnel practical guidance on how to evaluate obviousness issues under Section 103 in accordance with the Supreme Court's decision in *KSR International Co. v. Teleflex Inc.* [550 U.S. 398 (2007)].

The purpose of the 2010 Update is to provide additional Federal Circuit examples of the law of obviousness. Given the body of caselaw that has developed since the 2007 Guidelines, the boundaries between obviousness and nonobviousness are perhaps better defined.

The 2010 Guideline provides specific teaching points for each of the Federal Circuit cases discussed therein. Case teaching points are summarized at Federal Register, Vol. 75, No. 169 at 53659-53660. Federal Circuit cases outlined in the 2010 Guidelines include the following teaching points:

1. Combining Prior Art Elements
2. Substituting One Known Element for Another
3. The Obvious to Try Rationale
4. Consideration of Evidence

False Marking Case Updates

On August 31, 2010, the Federal Circuit reversed the district court's dismissal of a patent false marking (*qui tam*) action for lack of standing in *Stauffer v. Brooks Brothers, Inc.* [Appeal No. 2009-1428].

Mr. Stauffer is a patent attorney, and his *qui tam* complaint alleged that Brooks Brothers had falsely

marked its bowties with long-expired patents. Brooks Brothers was successful in having the case dismissed at the District Court for lack of standing on the part of Mr. Stauffer.

Judge Stein of the Southern District of New York had ruled that Mr. Stauffer lacked standing because he did not identify an actual injury to a competitor, the market for the product or the US economy. The Federal Circuit reversed and remanded the case, finding that 35 U.S.C. § 292(b), which provides that “[a]ny person may sue for the penalty” of false marking and apportioning the penalty between the claimant and the government, gave Mr. Stauffer standing to sue.

However, as part of the remand, the Federal Circuit took note of Brooks Brothers’ motion to dismiss for failure to state a claim because the complaint did not allege intent to deceive with sufficient specificity under the pleading standard of FRCP Rule 9(b), in which complaints must sufficiently allege that defendants had an “intent to deceive,” a critical element of the false marking statute.

Twombly Update

Defense counsel beware. The 2007 decision from the Supreme Court in *Bell Atlantic Corp. v. Twombly* [550 U.S. 544 (2007)] clarified the standards for deciding motions to dismiss for a plaintiff’s failure to state enough facts to show that the claim is plausible, not merely conceivable.

Now a number of Federal District Courts have extended the *Twombly* pleading requirements for complaints to the pleading of affirmative defenses presented in a defendant’s answer. This means that, in many courts, affirmative defenses under Rule 8(c) must meet the notice-pleading standards of Rule 8(a) as interpreted by the Supreme Court in *Twombly*.

Relevant quotes from District Courts include the following (citations omitted):

- The court is inclined to think that a defendant has the same Rule 8 obligations with respect to notice pleading as does a plaintiff.
- The pleading requirements for affirmative defenses are the same as for claims of relief.
- The affirmative defense, as pled, must offer enough facts to show the defense is plausible on its face.
- The court can see no reason why the same principles applied to pleading claims should not apply to the pleading of affirmative defenses, which also are governed by Rule 8.
- A defendant must plead an affirmative defense with enough specificity or factual particularity to give the plaintiff fair notice of the defense that is being advanced.
- Affirmative defenses must be based on factual allegations that give rise to the relief requested.
- Machine or transformation is particular.
- Machine or transformation meaningfully limits the execution of the steps.
- Machine implements the claimed steps.
- The article being transformed is particular.
- The article undergoes a change in state or thing (e.g., objectively different function or use).
- The article being transformed is an object or substance.
- The claim is directed toward applying a law of nature.
- Law of nature is practically applied.
- The application of the law of nature meaningfully limits the execution of the steps.
- The claim is more than a mere statement of a concept.
- The claim describes a particular solution to a problem to be solved.
- The claim implements a concept in some tangible way.
- The performance of the steps is observable and verifiable.

So, check your local court to see if they are following this expanding list of courts regarding this enhanced affirmative defense pleading standard.

USPTO Bilski Update

The USPTO published a notice in the July 27, 2010, *Federal Register* titled “Interim Guidance for Determining Subject Matter Eligibility for Process Claims in view of the Supreme Court’s decision in *Bilski*.”

The notice provides interim guidelines for USPTO examiners. It lists and explains several factors to be considered in determining whether method claims are drawn to abstract ideas. As above regarding the obviousness guidelines, litigators may find these *Bilski* guidelines useful.

Factors Weighing Toward Section 101 Eligible Subject Matter

- Recitation of a machine or transformation (either expressly or inherently).
- No recitation of a machine or transformation (either express or inherent).
- Insufficient recitation of a machine or transformation.
- Involvement of machine or transformation with the steps is merely nominally, insignificantly, or tangentially related to the performance of the steps, e.g., data gathering, or merely recites a field in which the method is intended to be applied.
- Machine is generically recited such that it covers any machine capable of performing the claimed step(s).
- Machine is merely an object on which the method operates.

- Transformation involves only a change in position or location of article.
- The claimed “article” is merely a general concept.
- The claim is not directed to an application of a law of nature.
- The claim would monopolize a natural force or patent a scientific fact; *e.g.*, by claiming every mode of producing an effect of that law of nature.
- A “law of nature” is applied in a merely subjective determination.
- A “law of nature” is merely nominally, insignificantly, or tangentially related to the performance of the steps.
- The claim is a mere statement of a general concept.
- Use of the concept, as expressed in the method, would effectively grant a monopoly over the concept.
- Both known and unknown uses of the concept are covered, and can be performed through any existing or future-devised machinery, or even without any apparatus.
- The claim only states a problem to be solved.
- The general concept is disembodied.
- The mechanism(s) by which the steps are implemented is subjective or imperceptible.

Patent Term Adjustment Update

On July 20, 2010, the USPTO announced on its Web site that letters from patent applicants and patentees objecting to PTO patent term adjustment determinations will simply be placed in the file of the applicant or patent owner without further review. Certificates of Correction will not be granted for errors in patent term adjustment calculations.

If an applicant or patentee wants the PTO to reconsider that determination, it must do so under 37 C.F.R. §1.705, or by filing a terminal disclaimer at any time disclaiming any period considered in excess of the appropriate patent term adjustment. Here is another item for litigators to check. Should a terminal disclaimer have been filed to correct a PTO mistake in the PTA calculation?

Patent Reform Legislation Update

Senate Bill S. 515, the 2010 Patent Reform Act, remains alive and kicking. On September 15, 2010, 25 senators signed a letter that was sent to Majority Leader Harry Reid, asking him to bring patent reform legislation to the Senate floor for a vote “as soon as possible.” Arguments in support of the request included the following:

- “Strengthening our patent system and spurring innovation and investment is an action we should take now to stimulate our economy.”
- This legislation would “speed the patent application process...”
- This legislation “would also allow the public to bring forward relevant information to the USPTO during the patent examination process and after the patent has been granted, improving the clarity and quality of patents...”
- This legislation would “also move the US Patent system into greater harmony with the rest of the world...”
- This legislation will “improve the economy and create jobs without adding to the deficit.”

Patent reform is usually not a hot topic—but maybe this time. Or maybe not.

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