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Nutter's periodic IP news update and practical tips
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Legal Update

The Supreme Court Speaks on Diagnostic Patents—*Mayo v. Prometheus* and *Myriad*

The Supreme Court issued two long-awaited decisions that are likely to have broad-reaching effects on diagnostic method patents, as well as personalized medicine patents. On March 20, 2012, the Court unanimously reversed the Federal Circuit in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, holding that Prometheus' claim, which had been twice upheld by the Federal Circuit, was an unpatentable law of nature. Shortly thereafter, the Court sent *Association for Molecular Pathology v. Myriad Genetics*—another hotly contested biotech case—back down to the Federal Circuit for further consideration in accordance with the decision in *Mayo*. Applied broadly, the Court's decisions may affect many pending and issued diagnostic method and personalized medicine patent claims and patenting strategies. Both *Mayo* and *Myriad* will likely have long-term ramifications in the pharmaceutical and biotechnology industries. The Federal Circuit's treatment of the *Myriad* claims on remand may provide better guidance on how to ensure that biotechnology patent claims survive future patentability challenges. For now, as an initial step, patent applicants, owners, and licensees should review their patents and applications on a claim-by-claim basis with the assistance of counsel to see how the Court's decisions might affect their claims.

To read more about the Supreme Court's recent rulings regarding diagnostic patents, **click here**.

The Federal Circuit Clarifies Law on Broadening Reissue Claims

In the recent decision of *In re Staats*, the Federal Circuit confirmed that patentees can seek broadened reissue claims more than two years after a patent issues so long as they first sought a broader claim within the two year period. The case arose in the context of a continuation application that was based on a reissue application. The holding rejected the reasoning employed by the Board of Patent Appeals and Interferences that required any broadened claims filed after two years to relate in some way to the reissue claims filed before the two year bar date. *In re Staats* provides a useful reminder to consider the use of broadening reissue applications, but in most cases filing a continuing application during the pendency of an original application is preferable if broader claims are desired.

To read more about the use of broadening reissue applications, **click here**.

An Overview of Expedited Prosecution Options for Patent Applicants

In our November 2010 and January 2010 issues, we reported on the Patent Office's (PTO) then-new Green Technology Pilot Program (GTPP), which was one of several programs that allow an applicant to receive expedited prosecution of their application. The GTPP in particular allows an applicant to petition for his or her application to be examined more quickly if it pertains to the development of a renewable energy source, energy conservation, or the reduction of green house gas emissions. Earlier this year, the PTO officially closed the opportunity to file petitions under the GTPP because the number of granted petitions and pending applications reached the limit of 3,500 applications being accorded special status under the pilot program. Many applicants are now faced with the question of what to do to speed up prosecution of their applications, whether they are directed to "green tech" or not. Despite the termination of the GTPP, a number of options remain available to applicants, including filing petitions to make special, the patent prosecution highway, accelerated examination, and prioritized examination.

For practical tips on quickly prosecuting “green tech” and other U.S. patent applications, **click here**.

What’s In a Name?

What’s in a name, inquired the Immortal Bard, speaking through Ms. Capulet. Well, for one thing, sometimes, a very valuable trademark, whether its intended use be to sell merchandise, BLUE IVY for cosmetics, clothing, toys, etc., or to advance a cause, JUSTICE FOR TRAYVON, or to offer a service, DEAR ABBY, or to invest in and await the judgment of history, OJ SIMPSON. While the right to use your own name in your business is sacrosanct, there are instances in which you may be precluded from doing so. Because trademark rights are tied to identifying the source of goods or services, celebrities typically have an advantage in demonstrating their right to use their names with goods and services, even if the celebrity is selling only herself (as opposed to merchandise). But fame can be fleeting. Just ask those who have attempted to trademark the term LINSANITY, as Jeremy Lin’s breakthrough in the NBA is already yesterday’s news.

To read more about issues associated with trademarking an individual’s name, **click here**.

New Evidence Permitted In Section 145 District Court Actions

The Supreme Court issued a ruling in *Kappos v. Hyatt* on April 18, 2012, that clarifies the rules regarding the introduction of new evidence in a district court action challenging a rejection of a patent application by the Board of Patent Appeals and Interferences under 35 U.S.C. § 145. The Court affirmed a prior *en banc* Federal Circuit decision, holding there are no limitations on a patent applicant’s ability to introduce new evidence in a Section 145 proceeding beyond those present in the Federal Rules of Evidence and the Federal Rules of Civil Procedure. In so holding, the Court rejected the Patent Office’s (PTO) contention that new evidence should be admissible *only* if the applicants had no reasonable opportunity to present the evidence during prosecution. The Court was also not persuaded that the Administrative Procedure Act or any other precedent precluded the introduction of new evidence or required the use of a deferential standard of review. Instead, the Court held that any new evidence introduced is evaluated under a *de novo* standard of review, though the district court does have discretion to consider the findings of the PTO when evaluating the new evidence.

To read the Supreme Court’s opinion in Kappos v. Hyatt, **click here**.

Should You Throw Away Your Lab Notebook?

On March 16, 2013, the Patent Office (PTO) will change from a first-to-invent to a first-to-file system. The Board of Patent Appeals and Interferences will be replaced by the Patent Trial and Appeal Board and interference practice will go by the way-side. Newly defined Derivation Proceedings will also begin at this time. For cases where an invention is independently conceived by two or more parties, the earliest filing date determines who receives a patent. Derivation proceedings are directed to situations in which an invention is not independently conceived, and can be used to show that an applicant derived an invention from another. The question for many in the scientific world is: does a well-kept laboratory notebook matter in the new race to the Patent Office, or in a derivation proceeding? The short answer is that laboratory notebooks may not carry the same importance with respect to derivation proceedings as they did with interferences, but they remain valuable tools for documenting the development of an invention that can be relevant during the prosecution of an application.

To read more about the role of laboratory notebooks in patent prosecution and derivation proceedings, **click here**.

Compulsory Licenses in Foreign Countries—a Fluke or a Canary?

On March 9, 2012, the Indian Controller of Patents granted the first compulsory license to an Indian company to manufacture a patented drug. The decision could have wide-ranging implications for pharmaceutical companies holding patents in India, as well as in other countries throughout the world.

In reaching its decision, the Controller of Patents interpreted the compulsory license provision of the Indian Patent Act. The Indian Patent Act allows a compulsory license when the public need for the patented item is not being met

because the patentee will not offer a license on “reasonable terms,” or if the invention is not “being worked” in India. The controller held that the reasonableness of the price for a drug primarily depends on whether members of the Indian public can afford to buy it, and not on the price needed to recoup research and development costs. The Controller also found that the drug was not “being worked” in India because Bayer was not manufacturing it in India despite having plants within the country. It is not known if this is a one-off occurrence or if it may be the beginning of a trend in India and elsewhere in the world. The decision may force pharmaceutical manufacturers to license patents covering certain drugs at lower prices so as to avoid a compulsory license, and may give manufacturers pause when considering the establishment of manufacturing facilities within a country.

To read the full opinion of the Indian Controller of Patents, **click here**.

Nutter's IP Bulletin is a bi-monthly publication of the Intellectual Property Practice at Nutter McClennen & Fish LLP in Boston. This edition of the bulletin was edited by Derek P. Roller. Assistance in the preparation of this issue was provided by Peter Nils Baylor, Padma Choudry, Kevin C. McGrath, Lydia G. Olson and Christina Sperry. For further information, please contact your Nutter attorney at 617-439-2000.

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