



PROGRESS IN THE PATENT-ELIGIBILITY OF GENES AFTER MYRIAD

The Supreme Court has been actively reviewing patent matters and the Myriad Genetics case is of particular interest to the biotech community. In Myriad, the Court held that isolated, but naturally occurring, DNA fell into one of the three general exceptions to patentability: "laws of nature, natural phenomena, and abstract ideas." The inventors in Myriad identified useful applications of the DNA, but the sequence they purified already existed in nature, and hence was a "natural phenomena." Following this reasoning, the Court held that human modified DNA, known as complementary DNA, is patent-eligible subject matter. The decision comes as no surprise in light of advancements in human genomic science such as the ease of genetic sequence isolation and the publication of the human genome. The challenge for patenting genomic sequences under the patent law already existed. The Court has, in effect, clarified what is patent-eligible subject matter, providing certainty and leaving room as to how claims should be drafted in patent applications and possibly reissue applications. This is a positive development because the ruling provides clarity to patent law in the biotech space.

ANTI-TRUST CONSIDERATIONS FOR HATCH-WAXMAN PATENT SETTLEMENTS

A recent Supreme Court decision holds that governments and private parties may bring anti-trust violation lawsuits against brand-name drug manufacturers to challenge so-called pay-for-delay settlement agreements. These agreements occur when a brand-name drug company sues a generic company for patent infringement. The companies then enter into a reverse settlement agreement, whereby the generic accepts a payment to stay out of the marketplace for a period of time in exchange for foregoing a patent validity challenge. The ruling in *FTC v. Actavis* combines antitrust and patent law in the context of Hatch-Waxman litigation. The Court held that while those reverse payments are not presumptively illegal, they are subject to anti-competitive scrutiny. As a result of this decision, settlement of Hatch-Waxman patent litigations will likely be discouraged. The U.S. Department of Justice and FTC will undoubtedly challenge more pharmaceutical patent settlements as having an anti-competitive effect on the market for pharmaceuticals in wake of this case. The Court did note that settlements which allow for early entry of a genetic product will likely be deemed procompetitive.

NEWS, MEDIA, AND UPDATES:

Susie Cheng published an [article](#) in the China Intellectual Property News, a newspaper run by China's Intellectual Property Office, stating that while isolated DNA was ruled to be unpatentable in Myriad, the ruling brings about certainty to patent-eligible subject matter related to gene patent and results in stronger patents, which will benefit the biotech and pharmaceutical industries in the long run. See the article above.

Susie Cheng is scheduled to publish an article in China Intellectual Property News discussing various ways pharmaceutical companies cope with the patent cliff, such as pay-for-delay, evergreening, acquiring companies and patent portfolios, and strengthening R&D to form a vigorous pipeline of new products.

Mel Garner served as a presiding justice at the [NYIPLA Annual Meeting in O'Reilly v. Morse](#), a mock oral argument reconsidering the patent-eligibility of Morse's invention under today's standards.



Leason Ellis is sponsoring the next Women in Licensing meeting on September 25th at the NYU Langone Medical Center. Women in Licensing is a forum for women in the field of intellectual property protection and licensing to network, share expertise and ideas, provide support and mentoring, and brainstorm on current topics of interest. *Elizabeth Barnhard* and *Susie Cheng* will be leading an interactive discussion on how to manage the extensive changes to U.S. patent practice resulting from enactment of the America Invents Act.

PLC has just published an [update](#) to its advertising law guide for the U.S. written by Peter Sloane and Rachel Weiss. The guide provides specific information concerning key legal issues that should be considered when designing an advertising campaign for the U.S.

Marty Schwimmer spoke on the new gTLD rollout for the [NYIPLA](#) as part of its Hot Topics in Trademarks, Advertising, Copyrights & Design Patents CLE Seminar on July 17th.

Peter Sloane's [article](#) about trademark investigations for non-use in China was published in the July/August edition of *Landslide*, a publication of the ABA Section of IP Law.

Peter Sloane has been [nominated](#) to The International Who's Who of Trademark Lawyers for 2013.

IAM Patent 1000 says of David Leason: "He is committed to the craft of IP law and has built a great practice with a strong pool of talent." We could not agree more!



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