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## Contact Us:

www.gbpatent.com

gbpatent@gbpatent.com

703-716-1191 (phone)
703-716-1180 (fax)


# District Court Denies Sanofi's Motion For Preliminary Injunction Against FDA In Lovenox® Case

The U.S. District Court for the District of Columbia recently denied a request by Sanofi-Aventis LLC US ("Sanofi") for an injunction which would have prevented Sandoz and Momenta Pharmaceuticals (jointly "Sandoz") from marketing a generic version of Sanofi's blood thinner, Lovenox® (enoxaparin sodium). By way of background, FDA approved Sandoz' ANDA No. 77-857 seeking to market a generic version of Lovenox®, and Sanofi responded filing suit on July 26, against the FDA, requesting a preliminary injunction and declaratory judgment that FDA acted unlawfully in approving the ANDA.

Specifically, Sanofi argued that FDA: (1) exceeded its authority under the FDCA by requiring Sandoz to submit information, including studies, beyond that permitted in ANDAs; (2) departed from precedent by approving Sandoz' ANDA although Sandoz' proposed generic product had not yet been fully characterized; and (3) approved Sandoz' ANDA without sufficient evidence that Sandoz' proposed generic product had the "same" active ingredient as Lovenox®.

Sanofi has announced that it will continue fighting to keep generic Lovenox® off the market and that it believes that FDA has failed to ensure that Sandoz' proposed generic product contains the same active ingredient as Sanofi's Lovenox® product. Other companies such as Teva Pharmaceutical, Waston Pharmaceuticals, and Hospira have also announced plans to market their generic versions of the drug. (*See, e.g.*, G&B Update, July 2005, December 2007, May 2008).

# Another "False Marking" Suit Filed Against Pharmaceutical Company

In a disturbing trend for pharmaceutical companies, a niche industry is emerging, *i.e.*, one in suing pharmaceutical companies for "false marking." By way of explanation, "marking" relevant patent number(s) on a patented product is deemed constructive notice that the product is patented, under 35 U.S.C. § 287, for purposes of notice in calculating patent infringement damages. Recently, however, there have been a number of "false marking" lawsuits, alleging that the pharmaceutical companies are marking their products with patents that either: (1) do not cover that product; or (2)

covered the product at one time, but have since expired. "False marking" of a patent is prohibited by 35 U.S.C. § 292, and each instance could lead up to a $500 fine under the Statute.

An example being Promote Innovation (a special interest group that is not a pharmaceutical company) which has filed dozens "false marking" suits, including a recent suit against Watson Pharmaceuticals alleging "false marking" of an expired patent on its skin patch Androderm® (for treatment of low testosterone in men). Promote Innovation has brought at least 20 such suits this year alone, many against Bristol-Myers Squibb, Ranbaxy and Takeda.

Although a party (whether an individual or company) bringing a "false marking" suit is required to show injury, Promote Innovation has avoided this requirement by using the qui tam suit, wherein half of any recovered proceeds go to the U.S. Government.

With companies selling millions of products, the total cost related to "false marking" can quickly add up. However, a party bringing a false marking suit must prove intent to deceive the public, so it's difficult at this point to know the ultimate outcome of these cases.

## District Court Strikes Down Lilly's Strattera® Patent

In *Eli Lilly and Company v. Actavis Elizabeth LLC, et al.*, the U.S. District Court for the District of New Jersey recently held Lilly's U.S. Patent No. 5,658,590 ("the '590 patent") which is directed to a method of treatment for attention deficit/hyperactivity disorder with Strattera® (atomoxetine HCI), both invalid and unenforceable for inequitable conduct. While noting that the ruling "appears to be a harsh result," the Court observed that Lilly did not receive the positive test data relating to efficacy of treatment with Strattera® until months after Lilly had filed the '590 patent application with the PTO, and that permitting those late results to be applied would set a negative precedent. The Court further observed that "the fact that, in this case, clinical test results became available shortly after the filing date does not change this court's view of the law," and that under a different ruling, drugmakers "would be permitted to obtain a priority date as of the initial filing of a patent application while conceivably providing test results years down the road." The '590 patent and subsequent pediatric exclusivity were not set to expire until May 2017.

Lilly has announced that it intends to appeal the Court's ruling stating that "we continue to believe that our Strattera method-of-use patent should be found valid and should be upheld by the courts," and that "the judge did not apply what we believe has been long-settled law on the legal issue of enablement. We will take every reasonable step to protect our intellectual property rights." Lilly, however, conceded that it anticipates "near-term entry" to the market of generic versions of Strattera®.

The Court's ruling is also seen as a victory for several generic drug makers that have likewise filed ANDA's seeking approval to market a generic version(s) of Strattera®, including Actavis Elizabeth, Apotex, Aurobindo, Sun Pharmaceutical, Teva Pharmaceutical, Sandoz and Mylan.

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