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Federal Circuit Affirms Invalidity of Lilly's Gemzar® Patent

In *Sun Pharmaceutical Industries, Ltd. v. Eli Lilly & Co.*, the Court of Appeals for the Federal Circuit ("Federal Circuit") affirmed the Southern District of Indiana District Court's ruling that Lilly's method of use patent for the cancer drug Gemzar® (gemcitabine HCl) was invalid under the doctrine of obviousness-type double patenting. Sun filed an Abbreviated New Drug Application ("ANDA") with a Paragraph IV certification seeking approval to market a generic version of Gemzar® in the United States. Thereafter, Sun field suit against Lilly seeking an Order declaring Lilly's U.S. Patent No. 5,464,826 ("the '826 patent") (method of use patent for the treatment of cancer with Gemzar®) invalid and not infringed. Lilly counterclaimed for infringement of the '826 patent and infringement of U.S. Patent No. 4,808,614 ("the '614 patent"), which covers the compound for gemcitabine.

The Federal Circuit, based upon its rulings in *Geneva v. GlaxoSmithKline* and *Pfizer v. Teva*, held that the claims of the later filed '826 method patent were not patentably distinct from the claims of the '614 patent. Specifically, the Federal Circuit held that the disclosure in the specification of the '614 patent that gemcitabine could be used as a method for treating cancer, rendered the later method claims of the '826 patent invalid for double patenting. The Federal Circuit reiterated its position that in determining whether there is obviousness-type double patenting, it is proper for a court to examine the specification of an earlier patent to ascertain the scope of the claims of that patent. The Federal Circuit further reasoned that, since the specification of the '614 patent disclosed a method for treating cancer, then the scope of the compound claim of the '614 patent also covered the method of treatment; and that, accordingly, any such later filed method claim would be invalid under obviousness-type double patenting. The Federal Circuit's decision paves the way for Sun to market its generic version of Gemzar® in November 2010, when the '614 patent expires.

Lilly has commented that it disagrees with the Federal Circuit's holding and likely will request a rehearing *en banc*.

DC District Court Orders FTC to Answer Questions Regarding Potentially Improper Actions in Connection with the FTC's Review of Alleged Watson-Apotex Pay for Delay Scheme

The DC District Court has ordered the FTC to answer questions regarding its allegedly improper behavior while investigating a pay-for-delay settlement agreement between Watson Pharmaceuticals ("Watson") and Apotex Corp. ("Apotex") in the Provigil® infringement litigation. The current suit centers around the FTC's investigation of the Watson-Apotex settlement where it is alleged that the FTC, in seeking to broker a different deal between Watson and Apotex, disclosed proprietary Watson information to Apotex. In response to a Watson motion, the DC District Court found that there was a "strong possibility that the FTC [shared] confidential information with [Apotex]," and ordered the FTC to answer questions posed by Watson's Motion. By way of example, Watson asserted that, during conversations with Watson's counsel, the assistant director of the FTC, Markus Meier, brought up an idea that would involve Watson licensing, relinquishing, or sharing its 180-day marketing exclusivity. The FTC has responded that, after this conversation, it did not play any further role in the negotiations, although, it is alleged that the FTC pressured Watson into making a deal.

On a related issue, the FTC has announced that it has recently seen a rise in the number of pay-for-delay settlements, which the FTC asserts delay the availability of generic drugs by an average of 17 months. While the number of pay-for-delay settlements is on the rise, the FTC also noted that they still only account for about 75 percent of patent settlements so far in 2010.

Genzyme Files Suit Against Impax for Generic Renvela® ANDA

Genzyme Corporation ("Genzyme") has filed a patent infringement lawsuit against Impax Laboratories ("Impax") in response to Impax' filing of an ANDA with a Paragraph IV certification seeking approval to market a generic version of Genzyme's kidney disease drug Renvela® (sevelamer carbonate). Specifically, Impax' ANDA is seeking to market generic Renvela® powder in 2.4- and 0.8- gram packets, and asserts that Genzyme's U.S. Patent No. 5,667,775 ("the '775 patent") is invalid and would not be infringed by the generic drug. Thereafter, Genzyme filed suit on July 1 in the Maryland District Court asking the Court to issue an injunction prohibiting Impax from manufacturing or selling generic Renvela® before the '775 patent expires in September 2014. Genzyme is also seeking unspecified monetary damages.

The FDA approved Renvela® in 2007 and the European Medicines Agency approved the drug last year. Renvela®, along with Genzyme's other phosphate binder, Renagel® (sevelamer HCl), had worldwide sales of about $707 million in 2009.

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