

DECEMBER 8, 2006

Sanofi-Synthelabo v. Apotex, Inc.

No. 06-1613, Federal Circuit (*Lourie*, Clevenger, Bryson)

[M]erely because a patentee is able to identify a monetary amount that it deems sufficient to avoid or end litigation does not necessarily mean that it automatically foregoes its right to seek a preliminary injunction or that any potential irreparable injury ceases to exist if infringement resumes.

On December 8, 2006, the Federal Circuit affirmed the district court's preliminary injunction against Apotex from infringing U.S. Patent 4,847,265, which related to clopidogrel bisulfate, marketed by Sanofi as Plavix®. The Federal Circuit stated:

Sanofi, as the moving party, may be entitled to a preliminary injunction if it establishes four factors: "(1) a reasonable likelihood of its success on the merits; (2) irreparable harm if an injunction is not granted; (3) a balance of hardships tipping in its favor; and (4) the injunction's . . . impact on the public interest." . . .

The district court applied a presumption of irreparable harm in light of its conclusion that Sanofi established a likelihood of success on the merits. The court also found that Sanofi proffered substantial evidence establishing other forms of irreparable harm, including irreversible price erosion, loss of good will, potential lay-offs of Sanofi employees, and the discontinuance of clinical trials that are devoted to other medical uses for Plavix®.

Apotex argues that the district court clearly erred in concluding that Sanofi would suffer irreparable harm in the absence of an injunction. According to Apotex, the settlement agreement entered into by Sanofi and Apotex negated any finding of irreparable harm. Apotex contends that Sanofi quantified in the May agreement the measure of harm it would suffer in the event Apotex marketed a generic product—specifically, 40%-50% of Apotex's net sales. . . .



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[T]he district court did not clearly err in finding that Sanofi satisfied this factor. We are not persuaded by Apotex’s assertion that Sanofi contracted away its right to prove irreparable harm by entering into the May agreement, which includes a provision that capped damages for infringement by Apotex. [T]he parties contemplated the possibility of a preliminary injunction in the event of regulatory denial. . . . Moreover, merely because a patentee is able to identify a monetary amount that it deems sufficient to avoid or end litigation does not necessarily mean that it automatically foregoes its right to seek a preliminary injunction or that any potential irreparable injury ceases to exist if infringement resumes. . . .

[T]he district court [also did not abuse] its discretion in concluding that Sanofi would suffer irreversible price erosion if an injunction were not entered. Based on the evidence Sanofi adduced, including the testimony of its economics expert, Professor Hausman, and a declaration from a Sanofi executive, Hugh O’Neill, the court found that Sanofi would suffer irreversible price erosion in light of a complex pricing scheme that is directly affected by the presence of the generic product in the market. In particular, the court found that since Apotex’s generic product entered the market, Sanofi has been forced to offer discounted rates and price concessions to third-party payors, such as health maintenance organizations, in order to keep Plavix® on a favorable pricing tier, which governs what consumers pay for that drug. The court found that the availability of a generic product encourages third party payors to place Plavix® on a less favorable tier, thereby requiring consumers to pay a higher co-pay, and perhaps deterring them from purchasing Plavix®. The court identified additional consequences of unfavorable tier placement, including a decrease in demand for Plavix®. According to Sanofi, it is nearly impossible to restore Plavix® to its pre-launch price since the generic product entered the market.

Apotex does not argue that price erosion is not a valid ground for finding irreparable harm, but rather challenges the district court’s findings as to price erosion. We conclude that the district court did not clearly err in its evaluation of the evidence relating to price erosion. While Apotex asserts that price erosion had already occurred, and thus an injunction is not necessary because it cannot ameliorate Sanofi’s position, Apotex fails to identify clear errors in the district court’s analysis, and fails to proffer evidence of its own sufficient to rebut the court’s findings. Apotex also fails to demonstrate that the court clearly erred in its findings with respect to the additional factors that established irreparable harm, including loss of good will, the potential reduction in work force, and the discontinuation of clinical trials. Accordingly, [the] district court did not clearly err in finding irreparable harm.

For more information on these issues or other intellectual property law matters, please contact **Lawrence M. Sung, Ph.D.** at lsung@nixonpeabody.com or (202) 585-8221.

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