

Eli Lilly & Co. v. Teva Pharms. USA, Inc.

No. 09-1070, Fed. Cir. (Michel, Rader,* Prost)

21 U.S.C. § 355(j)(5)(B)(iii) grants district courts the discretion to adjust the statutory thirty-month stay of ANDAs if “either party to the action failed to reasonably cooperate in expediting the action.” Trial courts, thus, may shorten or extend the thirty-month statutory period based on the parties’ uncooperative discovery practices before the court.

On February 24, 2009, the Federal Circuit affirmed the district court's order extending the statutory thirty-month stay of 21 U.S.C. § 355(j)(5)(B)(iii) thereby preventing the U.S. Food & Drug Administration (FDA) from finally approving Teva's Abbreviated New Drug Application (ANDA) for generic version of raloxifene hydrochloride, which Lilly markets as Evista®. In response to the ANDA filing, Lilly sued Teva for infringement of U.S. Patents No. RE38,968, No. RE39,049, No. RE39,050, No. 6,906,086, No. 6,458,811, No. 6,797,719, and No. 6,894,064. The Federal Circuit stated:

When an ANDA certifies under paragraph IV, the applicant must provide the patentee a detailed basis for its belief that the patent is not infringed, that it is invalid, or that it is unenforceable. The patentee then has forty-five days to sue the ANDA applicant for patent infringement. If the patentee does not sue, the FDA may proceed to approve the ANDA. If the patentee does file suit, the FDA may not approve the ANDA until expiration of the patent, resolution of the suit, or thirty months after the patentee's receipt of notice, whichever is earlier. The court entertaining the suit has discretion under the statute to order a shorter or longer stay if “either party to the action fail[s] to reasonably cooperate in expediting the action.” . . .

Teva filed an ANDA with the FDA in early 2006, seeking approval to manufacture and market generic raloxifene. . . . Lilly sued Teva on June 29, 2006, alleging that Teva's ANDA infringed four method patents of its twelve listed Orange Book patents for using raloxifene to prevent or treat postmenopausal osteoporosis The FDA then stayed approval of Teva's ANDA for thirty months, from the date that Lilly received Teva's paragraph IV notifications, expiring on November 16, 2008.

On September 25, 2006, the district court entered a scheduling order, setting a trial date of March 9, 2009—four months after expiration of the thirty-month statutory stay. In February 2007, Lilly amended its complaint to assert that Teva infringed three additional Evista® patents covering raloxifene particle size and formulation. On July 8, 2008, Teva amended its ANDA to include a new particle-size measuring methodology for the active pharmaceutical ingredient in its proposed raloxifene tablets. Teva disclosed this amendment to Lilly on July 10, 2008, and provided it three batch samples on July 28, August 19, and September 17, 2008. The district court, however, previously set a discovery deadline of August 18, 2008. By September 5, 2008, Teva also provided Lilly with 27,000 pages of related documentation. Moreover, the district court ordered

Teva to produce additional raloxifene samples to Lilly by December 15, 2008, in response to Lilly's motion to compel discovery. . . .

On October 6, 2008, Lilly moved the district court for a temporary restraining order (TRO) and preliminary injunction to prevent Teva from launching its product on November 16, 2008, after expiration of the statutory thirty-month stay. The court granted Lilly's motion on October 29, 2008, to extend the statutory thirty-month stay until the beginning of trial on March 9, 2009. Lilly's motions for a TRO and preliminary injunction were thus denied as moot. . . .

The court relied on the evidence in the record that Teva altered its proposed generic raloxifene hydrochloride tablets late in the litigation. Specifically, Teva changed the particle size manufacturing specification of its active pharmaceutical ingredient and the method of measuring the particle size. Teva then delivered its changed samples to Lilly past the court's August 18, 2008, discovery deadline.

In making these findings, the district court acted within its discretion in this area. 21 U.S.C. § 355(j)(5)(B)(iii) grants district courts the discretion to adjust the statutory thirty-month stay of ANDAs if "either party to the action failed to reasonably cooperate in expediting the action." Trial courts, thus, may shorten or extend the thirty-month statutory period based on the parties' uncooperative discovery practices before the court.

In explaining the statutory language, the House Committee report specified, "[f]ailure by either party to cooperate in a reasonable manner may be used by the court to reduce or lengthen the time, as appropriate, before an ANDA approval becomes effective." Because Teva provided Lilly with its altered raloxifene samples just eight months before trial, the district court extended the stay "to provide Lilly with a reasonable amount of time to allow its expert to test and report on the altered raloxifene samples provided by Teva and for Lilly to assess and utilize that information and analysis in preparation for trial." . . .

[I]n this case, the district court extended the statutory thirty-month stay based on its findings of Teva's lack of cooperation in expediting the patent litigation in its court. The court's findings were not based on Teva's filing with the FDA. Moreover, as discussed, the district court's decision was supported by the record, its factual findings, and proper application of the law. Because the district court did not abuse its discretion with its discovery findings and extending the statutory thirty-month stay to March 9, 2009, this court affirms.

The previous statements are for information purposes only, and do not constitute legal advice. Questions regarding the matters discussed above, and any requests to be subscribed to the free electronic distribution of this publication, may be directed to Lawrence M. Sung, Ph.D., at +1 202.346.7850 or lsung@dl.com, or to any other Dewey & LeBoeuf LLP attorney with whom you regularly consult.

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