

UNITED STATES DISTRICT COURT FOR THE
NORTHERN DISTRICT OF ILLINOIS,
EASTERN DIVISION

ABBOTT LABORATORIES,)
)
 Plaintiff,)
) No. 97 C 7515
) Richard A. Posner,
) Circuit Judge,
) sitting by designation
 v.)
)
)
 APOTEX, INC.)
 and APOTEX CORPORATION,)
)
 Defendants.)

ORDER

Abbott has patented a chemical called divalproex sodium, but its claims are limited to an oligomer consisting of about four to six units of the chemical. After a bench trial in 2004, I found that an Apotex divalproex sodium product was an oligomer and thus was infringing. *Abbott Laboratories v. Tor-Pharm, Inc.*, 309 F. Supp. 2d 1043 (N.D. Ill. 2004). I issued an injunction, No. 97 C 7515 (N.D. Ill. Mar. 31, 2004), which the Federal Circuit summarily affirmed, 122 Fed. Appx. 511 (Fed. Cir. 2005) (per curiam).

In March 2005, Nu-Pharm, Inc., a tiny (six employees) company formerly owned by Apotex, filed an ANDA for a divalproex sodium product that had been developed by and was owned by Apotex, but was produced by one or the other of two processes different from the process by which the infringing

No. 97 C 7515

2

product had been created. Abbott requested a ruling that Apotex was violating the injunction. After conducting an evidentiary hearing, I ruled that the “new” Apotex product was identical to both Abbott’s product and Apotex’s original product and was indeed an oligomer and thus was within the scope of the patent claims. No. 97 C 7515, 2006 U.S. Dist. LEXIS 76971 (N.D. Ill. Oct. 6, 2006). I issued a new injunction extending the previous injunction to encompass the new Apotex product. Apotex has appealed and now asks me to stay the injunction pending appeal. *Standard Havens Products, Inc. v. Gencor Industries, Inc.*, 897 F.2d 511, 512 (Fed. Cir. 1990).

Apotex’s prospects for prevailing on appeal are exceedingly dim. The evidence that its “new” product is an oligomer is overwhelming. 2006 U.S. Dist. LEXIS 76971, at *22. Multiple tests conducted or reviewed by Abbott’s expert, the eminent supramolecular chemist Jerry Atwood, showed this conclusively, while the evidence presented by Apotex’s experts had serious flaws and some of it actually supported Abbott.

The best Apotex has been able to do in its motion for a stay is dispute my conclusion that the model for the structure of Apotex’s product that one of its experts, Peter Stephens, generated by modifying the model that another one of Apotex’s experts, Michael Hursthouse, had developed from a single crystal X-ray diffraction experiment was unreliable. Atwood showed that Stephens’s model did not agree well with Hursthouse’s data on which it was based as judged by “R value,” a measure of the discrepancy between the hypothesized model and the data used to test it. Atwood determined that the R value for the Stephens model was 41.51%, whereas the R value of a reliable model is generally not significantly in excess of 5 to 10 percent. Jack D. Dunitz, *X-Ray Analysis and the Structure of Organic Molecules* 184 (1995). Apotex now argues that the R value of the Stephens model was actually 4.1%. The argument overlooks the questionable way in which Stephens constructed his model—manipulating the model Hursthouse had created from his single crystal X-ray diffraction study to fit Stephens’s own data from a different test, powder X-ray diffraction analysis, which provides less information than a single crystal experi-

No. 97 C 7515

3

ment. The 4.1% R value is a measure merely of the agreement of Stephens's model with the data that he altered Hursthouse's model to fit. If you change a model to fit given data, it will fit the data. Atwood's 41.51% R value measures the agreement of Stephens's model with *Hursthouse's* data, whereas Apotex's approach yields no information on the agreement of the model with the data collected from the crystal that the model purports to represent; it shows merely that Stephens's efforts to manipulate Hursthouse's model to fit his own data were successful.

Apotex also argues that I improperly concluded that Stephens's manipulation of the Hursthouse model resulted in a "break" every seven units in a divalproex sodium chain, which suggests an oligomer. But Atwood testified convincingly that Stephens's model revealed "a lengthening of sodium-oxygen distances" indicative of a "clear break in the strength of the sodium-oxygen interaction," and thus that the Stephens model suggested that Apotex's new divalproex sodium product was in fact an oligomer.

Apotex denies that it committed any act of infringement. But the submission of an ANDA that erroneously certifies that the commercial manufacture, use, or sale of the new drug would not infringe a patent is an act of infringement. 35 U.S.C. § 271(e)(2); *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 677–78 (1990); *Allergan, Inc. v. Alcon Laboratories, Inc.*, 324 F.3d 1322, 1330 (Fed. Cir. 2003) (per curiam); *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1567–69 (Fed Cir. 1997). Apotex's use of Nu-Pharm as a stalking horse for filing the ANDA for a drug that Apotex, not Nu-Pharm, owned and manufactured, 2006 U.S. Dist. LEXIS 76971, at *8–9, does not relieve it of liability for infringement. *Pellegrini v. Analog Devices, Inc.*, 375 F.3d 1113, 1118 (Fed Cir. 2004); *Crowell v. Baker Oil Tools, Inc.*, 143 F.2d 1003, 1004 (9th Cir. 1944) ("one may infringe a patent if he employs an agent for that purpose."). Otherwise, generic manufacturers would be able to evade the Hatch-Waxman provision that filing an ANDA for a drug that infringes a patent is itself an act of infringement simply by recruiting others to file the ANDA. Apotex's principal, Bernard Sherman, admitted that his primary reason for selecting Nu-

No. 97 C 7515

4

Pharm to file the ANDA for Apotex's product was the concern that Apotex if it did it itself might violate the injunction I issued in 2004. Indeed it would.

Apotex is further liable for induced infringement under 35 U.S.C. § 271(b), for aiding and abetting Nu-Pharm's direct act of infringement (the filing of the ANDA). *Water Technologies Corp. v. Calco, Ltd.*, 850 F.2d 660, 668 (Fed. Cir. 1988). (Apotex drafted the ANDA.) Section 271(e)(2) defines the filing of an ANDA for an infringing drug as an act of infringement, and section 271(b) extends liability for induced infringement to "whoever actively induces infringement." Nothing in the language or legislative history of the Hatch-Waxman Act indicates that a party cannot be held liable for inducing the filing of an ANDA for an infringing drug.

Not only are Apotex's chances of prevailing on appeal remote, but the balance of equities strongly favors Abbott. Apotex has failed to demonstrate that either itself or its puppet Nu-Pharm would suffer harm as a result of the injunction's remaining in effect pending appeal. I did not enjoin Apotex from taking any steps in the ANDA approval process prior to final approval. Apotex has not yet obtained preliminary approval from the FDA, and the 30-month statutory stay of approval that was triggered by Abbott's infringement suit against Nu-Pharm, which is currently pending before another judge, *Abbott Laboratories v. Nu-Pharm, Inc.*, No. 05 C. 3714, (N.D. Ill. June 24, 2005), would prevent final approval at any time before November 2007. Apotex contends that Nu-Pharm is harmed because proceedings in the Nu-Pharm litigation have been stayed in response to my injunction, thus averting the possibility that Apotex might obtain a favorable judgment in that litigation, which would dissolve the 30-month stay and pave the way for final approval. In other words, Apotex hopes that it might obtain from another judge a judgment inconsistent with the injunction—a frank acknowledgment of forum shopping hardly worthy of legal protection. Staying the injunction might result in the resumption of the other litigation, which would require Abbott to incur further costs of litigation as a consequence of Apo-

No. 97 C 7515

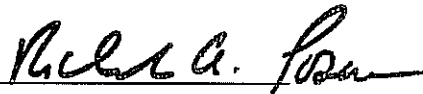
5

tex's attempt to obtain conflicting judgments before its appeal is decided.

Apotex's contention that a failure to stay the injunction will "chill" the development of generic alternatives to patented drugs is frivolous. The only activity that will be "chilled"—and rightly so—by the injunction is the filing of subsequent ANDAs by adjudged infringers who tweak the process by which their infringing products are made without conducting any scientific testing to demonstrate that the new product is different from the infringing one. The public interest in the conservation of scarce judicial resources argues against a stay, as the stay might lead to duplicative proceedings while the appeal in this case is pending. The only reason for the other lawsuit, which Apotex would like to pursue in the hope of generating a conflict between district court judgments, is Apotex's use of a cat's paw to file the ANDA, which induced Abbott to sue Nu-Pharm rather than merely ask me to rule that the injunction was being violated.

For all these reasons, the motion for a stay is

DENIED.


Richard A. Posner
Circuit Judge

Dated: November 27, 2006