United States Court of Appeals for the Federal Circuit

ASTRAZENECA AB, aka ASTRA ZENICA AB, AKTIEBOLAGET HASSLE, KBI-E INC., KBI INC., ASTRAZENECA LP,
Plaintiffs-Appellees

v.

APOTEX CORP., APOTEX INC., TORPHARM INC.,
Defendants-Appellants

2014-1221

Appeal from the United States District Court for the Southern District of New York in No. 1:01-cv-09351-DLC, Senior Judge Denise Cote.

Decided: April 7, 2015

CONSTANTINE L. TRELA, JR., Sidley Austin, LLP, Chicago, IL, argued for plaintiffs-appellees. Also represented by JOHN W. TREECE, DAVID C. GIARDINA; JOSHUA EUGENE ANDERSON, Los Angeles, CA; PAUL ZEGGER, Washington, DC.

JAMES F. HURST, Winston & Strawn LLP, Chicago, IL, argued for defendants-appellants. Also represented by

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STEFFEN NATHANAEL JOHNSON, EIMERIC REIG-PLESSIS, CHRISTOPHER ERNEST MILLS, Washington, DC.

Before O'MALLEY, CLEVENGER, and BRYSON, *Circuit Judges.*

BRYSON, *Circuit Judge.*

Apotex Corp., Apotex Inc., and TorPharm Inc., (collectively, "Apotex") appeal from a final judgment entered against them by the United States District Court for the Southern District of New York. We previously affirmed the district court's decision in an earlier phase of the same litigation holding that Apotex had infringed certain patents held by AstraZeneca AB and related parties (collectively, "Astra"). *In re Omeprazole Patent Litig.*, 536 F.3d 1361 (Fed. Cir. 2008). In the portion of the proceeding now under review, the district court awarded damages to Astra on a reasonable royalty theory of recovery. We affirm in part, reverse in part, and remand.

I

A

The patents at issue in this case are U.S. Patent No. 4,786,505 ("the '505 patent") and U.S. Patent No. 4,853,230 ("the '230 patent"). The two patents relate to pharmaceutical formulations containing omeprazole, the active ingredient in Astra's highly successful prescription drug, Prilosec.

Omeprazole is a "proton pump inhibitor" ("PPI"). It inhibits gastric acid secretion and for that reason is effective in treating acid-related gastrointestinal disorders. However, the omeprazole molecule can be unstable in certain environments. In particular, it is susceptible to degradation in acidic and neutral media. Its stability is also affected by moisture and organic solvents.

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To protect the omeprazole in a pharmaceutical dosage from gastric acid in the stomach, formulators have tried covering the omeprazole with an enteric coating. Enteric coatings, however, contain acidic compounds, which can cause the omeprazole in the drug core to decompose while the dosage is in storage, resulting in discoloration and decreasing omeprazole content in the dosage over time. To enhance the storage stability of a pharmaceutical dosage, alkaline reacting compounds ("ARCs") must be added to the drug core. The addition of ARCs, however, can compromise a conventional enteric coating. Ordinarily, an enteric coating allows for some diffusion of water from gastric juices into the drug core. But when water enters the drug core, it dissolves parts of the core and produces an alkaline solution near the enteric coating. The alkaline solution in turn can cause the enteric coating to dissolve.

The inventors of the '505 and '230 patents solved that problem by adding a water-soluble, inert subcoating that separates the drug core, and thus the alkaline material, from the enteric coating. The resulting formulation, consisting of an active ingredient core with ARCs, a water-soluble subcoating, and an enteric coating, provides a dosage form of omeprazole that has both good storage stability and sufficient gastric acid resistance to prevent the active ingredient from degrading in the stomach. Once the dosage reaches the small intestine, where the drug can be effectively absorbed, the solubility of the subcoating allows for rapid release of the omeprazole in the drug core.

Astra held patents on both the active ingredient, omeprazole, and the formulation for delivering it. The active ingredient patents expired in 2001, but several patents covering the formulation, including the patents at issue in this case, did not expire until April 20, 2007.

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Starting in 1997, anticipating the expiration of the active ingredient patents, eight generic drug manufacturers, including Apotex, filed Abbreviated New Drug Applications ("ANDAs") with the Food and Drug Administration ("FDA"), seeking permission to manufacture and sell omeprazole. Those applications were accompanied by what are known as "Paragraph IV certifications," in which the generic drug manufacturers asserted that their formulations did not infringe the '505 and '230 patents and that the patents were invalid. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Astra subsequently sued all eight generic drug companies in the same district court. The lawsuits were divided into two groups, each involving four defendants.

In the "first wave" litigation, the district court found that the '505 and '230 patents were not invalid and that three of the first wave defendants—all except Kremers Urban Development Co. and Schwarz Pharma, Inc. (collectively, "KUDCo")—infringed the patents. We affirmed the district court's decision in *In re Omeprazole Patent Litig.*, 84 F. App'x 76 (Fed. Cir. 2003) ("*Omeprazole I*"), and *In re Omeprazole Patent Litig.*, 483 F.3d 1364 (Fed. Cir. 2007) ("*Omeprazole II*").

On May 31, 2007, during the "second wave" litigation, the district court issued an opinion holding that the generic version of omeprazole manufactured by Mylan Laboratories, Inc., and Mylan Pharmaceuticals, Inc., (collectively, "Mylan") did not infringe the patents. The district court also held that the generic version of omeprazole manufactured by Lek Pharmaceutical and Chemical Company D.D. and Lek USA, Inc., (collectively, "Lek") did not infringe Astra's patents. The court, however, entered judgment of infringement against Apotex. We affirmed the judgment in favor of Mylan in *In re Omeprazole Patent Litig.*, 281 F. App'x 974 (Fed. Cir. 2008) ("*Omeprazole III*"). We affirmed the judgment of infringement

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against Apotex in *In re Omeprazole Patent Litig.*, 536 F.3d 1361 (Fed. Cir. 2008) ("*Omeprazole IV*").

Apotex started selling its generic omeprazole product in November 2003, during the pendency of the second wave litigation. It continued selling its generic product until 2007, when the district court held that Apotex's formulation infringed Astra's patents. After we affirmed the district court's judgment of liability against Apotex, the district court held a bench trial to determine Astra's damages.

B

Upon a finding of infringement, the patentee is entitled to "damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer." 35 U.S.C. § 284. The two "alternative categories of infringement compensation" under section 284 are "the patentee's lost profits and the reasonable royalty he would have received through arms-length bargaining." *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1324 (Fed. Cir. 2009).

The parties in this case agreed that damages were to be assessed based on a reasonable royalty theory. The district court sought to determine the reasonable royalty by analyzing the royalty that would have been reached through a hypothetical negotiation between the parties in November 2003, when Apotex began to infringe. Following the bench trial, the court held that Astra was entitled to 50 percent of Apotex's gross margin from its sales of omeprazole between 2003 and 2007.

In the course of its analysis, the court made detailed findings of fact. In summary, the court's findings were as follows:

Three generic companies launched their generic omeprazole products after the district court's first wave

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