United States Court of Appeals for the Federal Circuit

SANOFI-AVENTIS U.S., LLC, SANOFI MATURE IP, SANOFI,
Plaintiffs-Appellants

v.

DR. REDDY'S LABORATORIES, INC., DR. REDDY'S LABORATORIES, LTD., SANDOZ, INC.,
Defendants-Appellees

FRESENIUS KABI USA, LLC, ACCORD HEALTHCARE, INC., APOTEX CORP., APOTEX INC., ACTAVIS LLC, ACTAVIS ELIZABETH LLC, MYLAN LABORATORIES LIMITED,
Defendants-Cross-Appellants

2018-1804, 2018-1808, 2018-1809

Appeals from the United States District Court for the District of New Jersey in Nos. 3:14-cv-07869-MAS-LHG, 3:14-cv-08079-MAS-LHG, 3:14-cv-08082-MAS-LHG, 3:15-cv-00287-MAS-LHG, 3:15-cv-00290-MAS-LHG, 3:15-cv-00776-MAS-LHG, 3:15-cv-01835-MAS-LHG, 3:15-cv-02520-MAS-LHG, 3:15-cv-02522-MAS-LHG, 3:15-cv-02631-MAS-LHG, 3:15-cv-03107-MAS-LHG, 3:15-cv-03392-MAS-LHG, 3:16-cv-02259-MAS-LHG, 3:16-cv-05678-MAS-LHG, Judge Michael A. Shipp.

Decided: August 14, 2019

WILLIAM E. SOLANDER, Venable LLP, New York, NY, argued for plaintiffs-appellants. Also represented by KATHERINE ADAMS, DOMINICK A. CONDE, WHITNEY LYNN MEIER, DANIEL JOHN MINION.

EMILY L. RAPALINO, Goodwin Procter LLP, Boston, MA, argued for all defendants-cross-appellants. Defendants-cross-appellants Fresenius Kabi USA, LLC, Actavis LLC, Actavis Elizabeth LLC also represented by DARYL L. WIESEN, ERIC ROMEO; AVIV ZALCENSTEIN, New York, NY.

ANDREW M. ALUL, Taft, Stettinius & Hollister, LLP, Chicago, IL, argued for all defendants-cross-appellants. Defendants-cross-appellants Apotex Corp., Apotex Inc. also represented by ROSHAN SHRESTHA.

FRANK RODRIGUEZ, Windels Marx Lane & Mittendorf LLP, Madison, NJ, for defendants-appellees Dr. Reddy's Laboratories, Inc., Dr. Reddy's Laboratories, Ltd. Also represented by JAMES BARABAS.

LAURA A. LYDIGSEN, Brinks Gilson & Lione, Chicago, IL, for defendant-appellee Sandoz, Inc. Also represented by MARK HERBERT REMUS, JOSHUA JAMES.

IMRON T. ALY, Schiff Hardin, Chicago, IL, for defendant-cross-appellant Accord Healthcare, Inc. Also represented by HELEN H. JI.

MATTHEW R. REED, Wilson, Sonsini, Goodrich & Rosati, PC, Palo Alto, CA, for defendant-cross-appellant Mylan Laboratories Limited. Also represented by WENDY L. DEVINE, KRISTINA M. HANSON, San Francisco, CA.

Before LOURIE, MOORE, and TARANTO, *Circuit Judges*.

LOURIE, *Circuit Judge*.

Plaintiffs-Appellants (collectively, "Sanofi") appeal from the judgment of the U.S. District Court for the District of New Jersey holding, after a bench trial, claims 7, 11, 14–16, and 26 of U.S. Patent 8,927,592 (the "'592 patent") invalid as obvious. *Sanofi-Aventis U.S. LLC v. Fresenius Kabi USA, LLC*, No. 14-7869 (D.N.J. Dec. 19, 2017) ("*Decision*"). Defendants-Cross-Appellants (collectively, "Fresenius") cross-appeal from the same judgment holding claims 1 and 2 of U.S. Patent 5,847,170 (the "'170 patent") not invalid as obvious. Because there was no case or controversy with respect to claims 7, 11, 14–16, and 26 of the '592 patent when the district court issued its decision, we vacate the court's decision concerning those claims. We affirm the court's judgment that the '170 patent is not invalid as obvious.

BACKGROUND

Sanofi owns the '170 and '592 patents, respectively claiming the compound cabazitaxel and methods of using it. Sanofi markets cabazitaxel under the trade name Jevtana® to treat certain drug-resistant prostate cancers. Both the '170 and '592 patents are listed in the Orange Book[1] as covering cabazitaxel.

Cabazitaxel belongs to a family of compounds called taxanes and is the third and most recent taxane drug to gain approval by the Food and Drug Administration ("FDA"). The other two are paclitaxel, approved in 1992, and docetaxel, approved in 1996. The chemical structures of docetaxel and cabazitaxel are depicted below:

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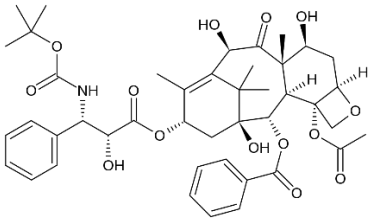
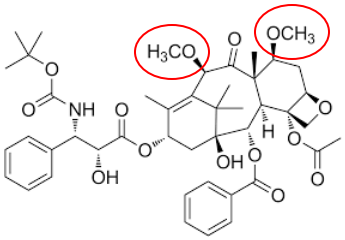
[1] This publication is formally entitled "Approved Drug Products with Therapeutic Equivalence Evaluations."



Docetaxel



Cabazitaxel

As annotated above, cabazitaxel differs from docetaxel in the substitution of two methoxy groups for hydroxyl groups. The carbon atoms to which the right and left methoxy groups are bound are referred to as C7 and C10, respectively. A fully numbered cabazitaxel is depicted in Appendix A, and the carbon positions are numbered in the same way in docetaxel.[2]

Cabazitaxel was the product of a multi-year research program aimed at identifying taxane analogs with better activity than docetaxel in resistant tumors. By making substitutions at multiple positions on docetaxel with various functional groups, Sanofi scientists synthesized several hundred compounds and tested their activities. Of this group, cabazitaxel was one of two compounds that entered into human studies. It obtained FDA approval in 2010.

Fresenius and the other defendants-appellees[3] (collectively, "Defendants") filed Abbreviated New Drug Applications ("ANDAs") to market generic versions of cabazitaxel prior to the expiration of the '592 and '170 patents, prompting Sanofi to sue the Defendants for infringement in the District of New Jersey. Defendants counterclaimed for a

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[2] In contrast to docetaxel, paclitaxel, the other FDA-approved prior art taxane, has an acetoxy group at C10 instead of a hydroxyl. It also has a different sidechain group at C3′.

[3] Three defendants have not joined Fresenius's cross-appeal.

declaratory judgment of invalidity of the '592 patent. The case ultimately proceeded to a bench trial concerning both patents.

However, while the district court case was pending, the Patent Trial and Appeal Board (the "Board") of the United States Patent and Trademark Office instituted *inter partes* review of the '592 patent. Soon after the district court trial began, the Board held claims 1–5 and 7–30 unpatentable as obvious and denied Sanofi's motion to amend its claims. Although Sanofi did appeal from the Board's denial of its motion to amend, it did not appeal from the Board's decision with respect to claims 7, 11, 14–16, and 26. And on December 8, 2017, Sanofi filed a statutory disclaimer of those claims (the "disclaimed claims") in the Patent and Trademark Office and so informed the district court. J.A. 14135–36; *see* 37 C.F.R. § 1.321(a).

Soon after the disclaimer, the district court entered a post-trial order reaching two conclusions relevant to this appeal. First, despite the statutory disclaimer of the disclaimed claims, the court concluded that a case or controversy still existed with respect to those claims and that they were invalid as obvious. *Decision*, slip op. at 45–46, 79–83. Second, the court held that the Defendants failed to prove that claims 1 and 2 of the '170 patent, claiming the cabazitaxel compound and related pharmaceutical compositions (and set forth in Appendix B), would have been obvious over the prior art. *Id.* at 42–43.[4]

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[4] Over one year after the district court's judgment, and after the parties completed briefing in this appeal, we vacated the Board's decision denying Sanofi's motion to amend and remanded the case to the Board for further proceedings. *See Sanofi Mature IP v. Mylan Labs. Ltd.*, 757 F. App'x 988, 994 (Fed. Cir. 2019). We held that the Board erroneously placed the burden on Sanofi to prove the

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