NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

ELI LILLY AND COMPANY,
Plaintiff-Appellee

v.

APOTEX, INC.,
Defendant-Appellant

2020-1328

Appeal from the United States District Court for the Southern District of Indiana in No. 1:17-cv-02865-TWP-MPB, Judge Tanya Walton Pratt.

Decided: December 21, 2020

ADAM LAWRENCE PERLMAN, Latham & Watkins LLP, Washington, DC, argued for plaintiff-appellee. Also represented by JAMES PATRICK LEEDS, Eli Lilly and Company, Indianapolis, IN; DOV PHILIP GROSSMAN, DAVID M. KRINSKY, ANDREW P. LEMENS, XUN LIU, CHARLES MCCLOUD, Williams & Connolly LLP, Washington, DC.

WILLIAM A. RAKOCZY, Rakoczy Molino Mazzochi Siwik LLP, Chicago, IL, argued for defendant-appellant. Also

represented by XIAOMEI CAI, JOSEPH THOMAS JAROS, CYNTHIA H. SUN, RACHEL WALDRON.

Before PROST, *Chief Judge*, BRYSON and STOLL, *Circuit Judges*.

STOLL, *Circuit Judge*.

Apotex, Inc. appeals from the judgment of the district court in a patent-infringement suit brought by Eli Lilly & Company under the Hatch-Waxman Act, 21 U.S.C. § 355. The district court granted Lilly's motion for summary judgment of infringement, holding that prosecution history estoppel does not bar Lilly from asserting infringement of certain claims of U.S. Patent No. 7,772,209 under the doctrine of equivalents. Because we discern no error in the district court's decision, we affirm.

BACKGROUND

I

The '209 patent relates to "a method of administering an antifolate to a mammal in need thereof, comprising administering an effective amount of said antifolate in combination with a methylmalonic acid lowering agent." '209 patent col. 2 ll. 55–58. Antifolates block the function of certain enzymes in the folic acid pathway and, thus, impede the growth of cancer cells. Antifolates can also affect normal cells, however, leading to severe toxicities in patients receiving antifolate chemotherapy. The '209 patent inventors discovered that administering an antifolate following pretreatment with a methylmalonic acid lowering agent, such as vitamin B12, reduces the toxicities associated with antifolates "without adversely affecting therapeutic efficacy." *Id.* at col. 2 ll. 32–37. The specification identifies "Pemetrexed Disodium (ALIMTA), as manufactured by Eli Lilly & Co." as the "most preferred" antifolate encompassed by the claims. *Id.* at col. 4 ll. 42–43.

Independent claims 1 and 12 are illustrative of the '209 patent claims:

> 1. A method for administering pemetrexed disodium to a patient in need thereof comprising administering an effective amount of folic acid and an effective amount of a methylmalonic acid lowering agent followed by administering an effective amount of pemetrexed disodium, wherein
>
> the methylmalonic acid lowering agent is selected from the group consisting of vitamin B12, hydroxycobalamin, cyano-10-chlorocobalamin, aquocobalamin perchlorate, aquo-10-cobalamin perchlorate, azidocobalamin, cobalamin, cyanocobalamin, or chlorocobalamin.
>
> . . .
>
> 12. An improved method for administering pemetrexed disodium to a patient in need of chemotherapeutic treatment, wherein the improvement comprises:
>
> a) administration of between about 350 µg and about 1000 µg of folic acid prior to the first administration of pemetrexed disodium;
>
> b) administration of about 500 µg to about 1500 µg of vitamin B12, prior to the first administration of pemetrexed disodium; and
>
> c) administration of pemetrexed disodium.

Id. at col. 10 ll. 56–65, col. 11 l. 25–col. 12 l. 4.

The '209 patent claims cover the use of Lilly's pharmaceutical product ALIMTA®, which is indicated for the treatment of mesothelioma and certain types of lung cancer. ALIMTA® contains pemetrexed disodium, i.e., the disodium salt form of the compound pemetrexed. Though ALIMTA® is distributed as a solid powder formulation of

pemetrexed disodium, it is dissolved in solution before being intravenously injected into a patient. When pemetrexed disodium dissolves, the pemetrexed and sodium ions dissociate from each other, and the dissociated pemetrexed anion exerts a chemotherapeutic effect in the patient.

The '209 patent claims priority from U.S. Patent Application No. 10/297,821, in which Lilly originally sought independent claims directed to methods of administering "an antifolate" in combination with a methylmalonic acid lowering agent. Lilly also sought dependent claims limiting the antifolate to "ALIMTA." For example, dependent claim 9 recited "[a] method of any one of claims 1–8 wherein the antifolate is ALIMTA." J.A. 6214.

In September 2004, the Examiner rejected the claims reciting "ALIMTA" under 35 U.S.C. § 112. Under the heading "Vague and Indefinite Language Rejections," the Examiner explained:

> Claims 9, 29, 30, and 33 (as depending from claim 9) are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant claims refer to the trade name "ALIMTA." It is improper claim language to use a trademark or trade name in a claim to identify or describe a material or product. This not only renders a claim indefinite, but also constitutes an improper use of the trademark or trade name ([Manual of Patent Examining Procedure (MPEP)] § 2173.05(u)).

J.A. 6222.

In January 2005, Lilly canceled its dependent claims reciting "ALIMTA" in response to the Examiner's § 112 rejection. Lilly simultaneously amended its independent

claims to replace "an antifolate" with "pemetrexed disodium" to overcome certain anticipation and obviousness rejections. Thereafter, the Examiner withdrew the § 112 rejection in view of the cancellation of the claims that had recited "ALIMTA."

In July 2007, Lilly filed U.S. Patent Application No. 11/776,329, which ultimately issued as the '209 patent. In its Preliminary Amendment, Lilly canceled claims reciting "ALIMTA" and instead prosecuted only claims reciting "pemetrexed disodium."

II

Apotex submitted a New Drug Application with the U.S. Food and Drug Administration seeking approval to market and sell its own pemetrexed product prior to the expiration of the '209 patent. Apotex's proposed product contains pemetrexed dipotassium, a different salt form of pemetrexed from pemetrexed disodium. Lilly then sued Apotex for patent infringement, alleging that the use of Apotex's proposed product would infringe claims 9, 10, 12–15, 18, 19, 21, and 22 of the '209 patent.

Lilly and Apotex filed cross-motions for summary judgment on Lilly's infringement claims. While the motions were pending, this court issued its decision in *Eli Lilly & Co. v. Hospira, Inc.*, 933 F.3d 1320 (Fed. Cir. 2019), *cert. denied*, 207 L. Ed. 2d 1052 (June 15, 2020). In *Hospira*, this court affirmed the district court's judgments of infringement of the '209 patent claims against Hospira, Inc., Dr. Reddy's Laboratories, Ltd., and Dr. Reddy's Laboratories, Inc., which had sought FDA approval to market and sell pemetrexed ditromethamine products. *Id.* at 1324, 1326. This court agreed with the district court's conclusion that Lilly's amendment narrowing the '821 application's claims from the administration of "an antifolate" to "pemetrexed disodium" did not give rise to prosecution history estoppel and, thus, that Lilly was not barred from pursuing infringement under the doctrine of equivalents. *Id.*

at 1327, 1330–34. This court held that "Lilly's amendment was merely tangential to pemetrexed ditromethamine because the prosecution history, in view of the '209 patent itself, strongly indicates that the reason for the amendment was not to cede other, functionally identical, pemetrexed salts." *Id.* at 1331.

In its summary judgment decision in this case, the district court considered whether Lilly's amendment replacing "ALIMTA" with "pemetrexed disodium" gives rise to prosecution history estoppel and whether any exceptions to estoppel apply. *Eli Lilly & Co. v. Apotex, Inc.*, 430 F. Supp. 3d 560, 565 (S.D. Ind. 2019) (*Decision*). The district court noted that in Lilly's opening brief, Lilly argued that Apotex's only defense to infringement under the doctrine of equivalents was prosecution history estoppel, and that if the court rejected that defense, Lilly is entitled to summary judgment that Apotex will induce and contribute to the infringement of the asserted claims because Apotex conceded that the use of its proposed product will infringe. *Id.* Because Apotex did not respond to Lilly's assertions, the district court concluded that Apotex "conceded the merits of doctrine-of-equivalents infringement and that it will induce and contribute to infringement of the" asserted claims. *Id.*

Next, the district court rejected Apotex's argument that because the term "ALIMTA" in the original claims would have been understood to mean "pemetrexed," Lilly's amendment to replace "ALIMTA" with "pemetrexed disodium" was a narrowing amendment and Lilly surrendered all other salt forms of pemetrexed. *Id.* at 566–68. Based on its review of the intrinsic evidence, the district court determined that Lilly's amendment was not a narrowing amendment and, thus, prosecution history estoppel does not apply to bar Lilly from asserting infringement based on the doctrine of equivalents. *Id.* at 567–68. Therefore, the district court granted Lilly's motion and denied Apotex's cross-motion. The district court entered final judgment in

favor of Lilly, prohibiting FDA approval of Apotex's proposed product until the expiration of the '209 patent pursuant to 35 U.S.C. § 271(e)(4)(A).

Apotex appeals. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

DISCUSSION

We review a district court's grant of summary judgment according to the law of the regional circuit, here, the Seventh Circuit. *Hospira*, 933 F.3d at 1327 (citing *Kaneka Corp. v. Xiamen Kingdomway Grp. Co.*, 790 F.3d 1298, 1303 (Fed. Cir. 2015)). In the Seventh Circuit, summary judgment is reviewed de novo, construing all facts and drawing all inferences in favor of the non-movant. *Id.* at 1327–28 (citing *Wis. Alumni Rsch. Found. v. Apple Inc.*, 905 F.3d 1341, 1352 (Fed. Cir. 2018)). Whether prosecution history estoppel applies to bar a doctrine of equivalents claim is a question of law, reviewed de novo. *Id.* at 1330 (citing *Regents of Univ. of Cal. v. Dakocytomation Cal., Inc.*, 517 F.3d 1364, 1371 (Fed. Cir. 2008)).

The district court correctly concluded that prosecution history estoppel does not bar Lilly from asserting infringement by equivalents. The intrinsic record demonstrates that Lilly did not narrow the scope of its claims when it amended the claims reciting the administration of "ALIMTA" to instead recite the administration of "pemetrexed disodium." A narrowing amendment is required to invoke estoppel. *See id.* ("Prosecution history estoppel arises when a patent applicant narrows the scope of his claims during prosecution for a reason 'substantial[ly] relating to patentability.'" (alteration in original) (quoting *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359, 1366–67 (Fed. Cir. 2003) (en banc))).

Lilly's patent applications from which the '209 patent claims priority equate "ALIMTA" with "pemetrexed disodium." *See, e.g.*, J.A. 6198 ('821 application stating

"pemetrexed disodium (Alimta®, Eli Lilly and Company, Indianapolis, IN)"); J.A. 7016 (PCT application No. PCT/US01/14860 stating "pemetrexed disodium (Alimta®, Eli Lilly and Company, Indianapolis, IN)"). This definitional language from the earlier applications was also included in the '209 patent specification. The specification refers to "pemetrexed disodium" twice, both times in association with ALIMTA. '209 patent col. 1 ll. 58–59 (stating "pemetrexed disodium (Alimta®, Eli Lilly and Company, Indianapolis, Ind.)"); *id.* at col. 4 ll. 42–43 (stating that the "most preferred" antifolate of the patent is "Pemetrexed Disodium (ALIMTA), as manufactured by Eli Lilly & Co."). Indeed, the specification indicates that "ALIMTA" is Lilly's trade name for that compound by expressly equating "ALIMTA" with pemetrexed disodium "as manufactured by Eli Lilly & Co." *Id.* at col. 4 ll. 42–43. Similar to the earlier applications, the specification does not use "ALIMTA" to refer to pemetrexed alone or to any other salt form of pemetrexed. Thus, the intrinsic evidence supports the district court's construction of "ALIMTA" to be synonymous with "pemetrexed disodium."

Moreover, the prosecution history confirms that the inventors used "ALIMTA" in the original claims—and the Examiner understood the term—as Lilly's trade name for pemetrexed disodium. Specifically, the Examiner rejected the claims of the '821 application on the ground that the improper use of a trade name in the claims renders the claims indefinite. In doing so, the Examiner cited MPEP § 2173.05(u), which, as of the date of the rejection, provided that "[i]f the trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph." MPEP § 2173.05(u) (2004). The provision further provides that the "claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product," and that the "value of a trademark would be lost

to the extent that it became descriptive of a product, rather than used as an identification of a source or origin of a product." *Id.* For these reasons, the MPEP instructs examiners that "the use of a trademark or trade name in a claim to identify or describe a material or product would not only render a claim indefinite, but would also constitute an improper use of the trademark or trade name." *Id.*

Following Patent Office procedure, the Examiner in this case rejected the claims of the '821 application as indefinite because they improperly used the trade name "ALIMTA." In response to the rejection, Lilly canceled its claims reciting the trade name and pursued claims using the generic name for the same substance, which mooted the rejection. Additionally, as the district court observed, the Examiner "explicitly noted that pemetrexed disodium was 'also known by the trade name ALIMTA'" in the contemporaneous obviousness rejection. *Decision*, 430 F. Supp. 3d at 567 (quoting J.A. 6223). The Examiner also characterized claims 9, 29, 30, and 33, the dependent claims reciting "ALIMTA," as "specifically cit[ing] pemetrexed disodium." J.A. 6224–25.

Furthermore, in its January 2005 response to the rejection, Lilly corrected a typographical error in the specification by replacing "Pemetrexed Sodium (ALIMTA)" with "Pemetrexed *Di*sodium (ALIMTA)." J.A. 6230 (emphasis added); J.A. 6233 (same). Lilly explained that the "compound was appropriately named and referenced at least on page 2, lines 6–7," J.A. 6233, which stated "pemetrexed disodium (Alimta®, Eli Lilly and Company, Indianapolis, IN)," J.A. 6198. Nothing in the prosecution history suggests that Lilly's amendment narrowed the claims, that the Examiner understood Lilly to be narrowing the claims, or that either Lilly or the Examiner understood "ALIMTA" to mean anything other than pemetrexed disodium.

On appeal, Apotex contends that the district court "erred by concluding that the 'indefinite' claim term

'ALIMTA' meant only 'pemetrexed disodium.'" Appellant's Br. 47. In Apotex's view, the Examiner concluded that "ALIMTA" was indefinite because it had at least two possible meanings: "pemetrexed" and "pemetrexed disodium." *Id.* at 48. Apotex further argues that because "pemetrexed" is indisputably broader than "pemetrexed disodium," Lilly's "amendment was a narrowing amendment that triggered prosecution history estoppel." *Id.*

Apotex misreads the prosecution history. In particular, it erroneously interprets the Examiner's § 112 rejection as two separate rejections: indefiniteness and improper use of a trade name. The Examiner did not, however, reject the original claims as "indefinite" because there was ambiguity about whether "ALIMTA" has multiple meanings. Instead, in accordance with Patent Office procedure, the Examiner rejected the claims reciting "ALIMTA" as indefinite *because* ALIMTA is a trade name. Trade names are not anchored to a single specific meaning and thus can introduce potential vagueness into patent claims.

Apotex also contends that, in prosecuting European Patent Application No. 01948214.0, the European counterpart to the '209 patent, Lilly amended claims originally reciting "ALIMTA" to instead recite "pemetrexed." Apotex argues that in response to a European Patent Office rejection "finding the claim term 'ALIMTA' 'unclear,' Lilly 'refocused' its claims on 'the antifolate compound pemetrexed,' and added dependent claims to 'pemetrexed disodium.'" Reply Br. 26 (citations omitted).

Apotex's reliance on Lilly's prosecution of the European application is misplaced. As an initial matter, we have cautioned against relying on the prosecution of foreign applications in interpreting claim terms of U.S. patents and patent applications. *See AIA Eng'g Ltd. v. Magotteaux Int'l S/A*, 657 F.3d 1264, 1279 (Fed. Cir. 2011). Moreover, we agree with Lilly that this evidence in fact supports the district court's conclusion that "ALIMTA" means "pemetrexed

disodium." Contrary to Apotex's assertion, Lilly did not equate "ALIMTA" with "pemetrexed" during prosecution of its European application. Rather, after Lilly attempted to pursue new claims directed to the use of "pemetrexed" instead of "an antifolate," the Examiner rejected the claims because Lilly only disclosed pemetrexed disodium in its specification. J.A. 7468–69. Thereafter, Lilly informed the EPO examiner that it was amending its claims "to refer to the preferred embodiment, the use of pemetrexed disodium (ALIMTA®) as manufactured by Eli Lilly and Company, as the antifolate drug." J.A. 7490. Lilly also stated that "all references to ALIMTA in pages 10 *et seq* have been replaced by pemetrexed disodium with the registered trademark ALIMTA being retained in parenthesis." J.A. 7491. In light of the European prosecution history as a whole, we do not read Lilly's statement that it was "refocus[ing]" the claims in its application to suggest that Lilly equated "ALIMTA" with "pemetrexed."

We have considered Apotex's other arguments, but we do not find them persuasive. The district court properly concluded that prosecution history estoppel does not bar Lilly's infringement claims under the doctrine of equivalents. Because we agree with the district court that the amendment at issue did not narrow the claims, we need not reach the alternative tangentiality argument raised by Lilly. Accordingly, we conclude that the district court did not err in granting summary judgment in favor of Lilly.

CONCLUSION

For the foregoing reasons, we affirm the judgment of the district court.

AFFIRMED