12-9-2022

Takeda Pharmaceutical Co Ltd v. Zydus Pharmaceuticals (USA) In

NOT PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 21-2608

TAKEDA PHARMACEUTICAL CO LTD; TAKEDA PHARMACEUTICALS USA INC; TAKEDA PHARMACEUTICALS AMERICA INC

v.

ZYDUS PHARMACEUTICALS (USA) INC; CADILA HEALTHCARE LTD,
Appellants

On Appeal from the United States District Court
for the District of New Jersey
(No. 3-18-cv-01994)
U.S. District Judge: Honorable Freda L. Wolfson

Submitted Under Third Circuit L.A.R. 34.1(a)
December 9, 2022

Before: SHWARTZ, MATEY, and FUENTES Circuit Judges.

(Filed: December 9, 2022)

OPINION*

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* This disposition is not an opinion of the full court and pursuant to I.O.P. 5.7 does not constitute binding precedent.

SHWARTZ, Circuit Judge.

Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Ltd. ("Zydus") appeal the District Court's order granting summary judgment to Takeda Pharmaceutical Co. Ltd., Takeda Pharmaceuticals USA Inc., and Takeda Pharmaceuticals America Inc. ("Takeda") on Zydus's antitrust counterclaims. Because Takeda had an objective basis for bringing its patent infringement claims, those claims cannot provide a basis for antitrust liability. We will therefore affirm.

I

A

Takeda manufactures Prevacid SoluTab ("Prevacid"), which is used to treat gastroesophageal reflux disease. Prevacid dissolves in the patient's mouth leaving fine granules that obviate the need for the patient to swallow. Takeda holds four patents related to Prevacid, including Patent No. 6,328,994 ("'994 patent").

In 2009, Zydus filed an Abbreviated New Drug Application ("ANDA") seeking Food and Drug Administration ("FDA") approval to market a generic version of Prevacid. Pursuant to the Hatch-Waxman Act, Zydus served Takeda with a "Paragraph IV Certification" asserting that their generic version did not infringe Takeda's patents. Within forty-five days of receiving the certification, Takeda sued Zydus for infringement, triggering the Hatch-Waxman Act's automatic thirty-month stay on the FDA's ability to approve Zydus's generic version of Prevacid. 21 U.S.C. § 355(j)(5)(B)(iii).

During the ensuing litigation, the District Court construed language in the '994 patent stating that Prevacid's fine granules "hav[e] an average particle diameter of 400

μm or less," App. 261, 1092. It found that the language established a particle diameter 400 μm plus or minus ten percent, such that granules measuring up to 440 μm were captured by the patent's language. The Court then held a bench trial at which Zydus's expert found the generic drug's granules averaged between 443 μm and 457 μm because they had become "agglomerate[d]" or stuck together during the manufacturing process, App. 98. Takeda's expert measured the generic drug's granules when deagglomerated (i.e. separated) and found that they measured 420 μm. The Court concluded that the patent required deagglomeration and held that Zydus's product literally infringed the patent.

The United States Court of Appeals for the Federal Circuit reversed the District Court's claim construction ruling and finding of infringement. Takeda Pharm. Co. v. Zydus Pharms. USA, Inc., 743 F.3d 1359 (Fed. Cir. 2014). The Federal Circuit interpreted the patent's language to require "an average . . . diameter of precisely 400 μm or less" rather than the ten percent variance imposed by the District Court. Id. at 1363-65. Because Zydus's granules were larger than 400 μm, its product did not infringe the patent. Id. at 1365-66. Judgment was ultimately entered for Zydus. Takeda Pharm. Co. v. Zydus Pharms. USA, Inc., No. 10-CV-01723, 2014 WL 12629965, at *2 (D.N.J. Oct. 16, 2014).

B

Despite the favorable judgment, Zydus did not immediately obtain FDA approval to market a generic of Prevacid. Instead, Zydus amended its ANDA with a new formulation of the product, which addressed the FDA's concerns regarding a risk of

clogging when the drug was delivered via oral or nasogastric tubes by "incorporating new excipients at the extra-granular manufacturing stage," App. 1776. It did not make any changes "to the ingredients or manufacturing of the [granules that] . . . were the focus of the prior litigation." App. 1776.

Zydus sent Takeda a new Paragraph IV Certification, explaining that the amended ANDA "still requires that its fine granules . . . [measure] not less than 440 μm," App. 453–54. Takeda nonetheless sued Zydus for infringement of the same patents, which again triggered Hatch-Waxman's thirty-month stay period. Zydus counterclaimed, alleging Takeda's suit was a sham meant to foreclose Zydus's entrance into the market in violation of the Sherman Act and New Jersey's antitrust laws.

After testing Zydus's product and concluding that it did not infringe its patents, Takeda dismissed its infringement claims. Zydus did not, however, dismiss its antitrust counterclaims and the parties eventually both moved for summary judgment on those claims. The District Court granted Takeda's motion, and denied Zydus's cross-motion, because it concluded that Takeda was immune from antitrust liability under the Noerr-Pennington, explaining that (1) Takeda had an objective basis for believing that Zydus's reformulated drug directly infringed its patents based on the parties' prior litigation, Zydus's course of dealing with the FDA, and Takeda's experience with other manufacturers' attempts to create a generic version of Prevacid, Takeda Pharm. Co. v. Zydus Pharms. (USA) Inc., No. 18-CV-01994, 2021 WL 3144897, at *12–14 (D.N.J. July 26, 2021); (2) even if it had none of this information, Takeda still had a valid infringement claim under the doctrine of equivalents, id. at *15; and (3) Takeda had a

subjective basis for the claim based primarily on a pre-filing letter from its outside counsel which "recite[d] several legitimate grounds for" bringing suit, id. at *17–19.

Zydus appeals.

II[1]

Under the Noerr-Pennington doctrine, "[a] party who petitions the government for redress generally is immune from antitrust liability." Cheminor Drugs, Ltd. v. Ethyl Corp., 168 F.3d 119, 122 (3d Cir. 1999) (citations omitted). This immunity extends to those who petition the courts by initiating litigation. Cal. Motor Transp. Co. v. Trucking Unlimited, 404 U.S. 508, 510–11 (1972). It does not apply, however, where a lawsuit is a "mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor." E. R.R. Presidents Conf. v. Noerr Motor Freight, Inc., 365 U.S. 127, 144 (1961).

To determine whether a lawsuit is a "sham," courts apply a two-part test. Pro. Real Est. Invs., Inc. v. Columbia Pictures Indus., Inc., 508 U.S. 49, 60 (1993). "First, the lawsuit must be objectively baseless in the sense that no reasonable litigant could

[1] The District Court had jurisdiction under 28 U.S.C. §§ 1331, 1337, 1338(a), and 1367. We have appellate jurisdiction under 28 U.S.C. § 1291 because Takeda dismissed its patent infringement claims, leaving only antitrust counterclaims that do not involve a substantial question of patent law. FTC v. AbbVie Inc, 976 F.3d 327, 346–50 (3d Cir. 2020) (concluding that the Federal Circuit did not have exclusive jurisdiction over an antitrust suit that was based in part on a sham-litigation theory of anti-competitive conduct).

Our review "of a grant of summary judgment is plenary." Watson v. Eastman Kodak Co., 235 F.3d 851, 854 (3d Cir. 2000) (citation omitted). Summary judgment is appropriate where "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a).

realistically expect success on the merits."[2] Id. Second, "[o]nly if [the] challenged litigation is objectively meritless may a court examine the litigant's subjective motivation" to determine "whether the baseless lawsuit conceals an attempt to interfere . . . with . . . a competitor."[3] Id. at 60–61 (citations and quotation marks omitted).

Here, we need only evaluate the first prong because Takeda had two objectively valid bases for bringing its second patent infringement suit against Zydus: (1) literal infringement and (2) the doctrine of equivalents.[4]

A

At the time it filed its second infringement suit, Takeda had a reasonable basis for its literal infringement claim. See FilmTec Corp. v. Hydranautics, 67 F.3d 931, 938 (Fed. Cir. 1995) (explaining that the objective baselessness prong "requires an inquiry into the reasonableness of the" litigation when it was filed). Indeed, even though Zydus certified its product did not infringe Takeda's patents in its Paragraph IV Certification, Zydus's ANDA submission is, "by statutory definition, an infringing act." In re Wellbutrin XL

[2] Where, as here, there is no dispute over the predicate facts underlying the legal proceeding, the reasonableness of the suit is a question of law. Pro. Real Estate, 508 U.S. at 63; see also In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class, 868 F.3d 132, 151 (3d Cir. 2017).

[3] Zydus had the burden of proving that Takeda is not entitled to Noerr-Pennington immunity, In re Wellbutrin, 868 F.3d at 148 n.18, but "[b]ecause our decision in this case does not hinge on the standard of proof," we need not determine whether Zydus was required to make its showing by a preponderance of the evidence or by clear and convincing evidence, id.

[4] For the same reason, we need not analyze the substance of Zydus's antitrust claims.

Antitrust Litig. Indirect Purchaser Class, 868 F.3d 132, 149 (3d Cir. 2017); see also 35 U.S.C. § 271(e)(2)(A) ("It shall be an act of infringement to submit . . . [an ANDA] for a drug claimed in a patent . . . ."). Thus, Takeda's literal infringement claim "could only be objectively baseless if no reasonable person could disagree with [Zydus's] assertion[] of noninfringement . . . in [its revised Paragraph IV] [C]ertification." In re Wellbutrin, 868 F.3d at 149.

It was reasonable for Takeda to disagree with Zydus's assertion of noninfringement. Zydus's Paragraph IV Certification stated that it amended the formulation of its generic product. Takeda reasonably inferred the new formulation addressed clogging risks, which other generic manufacturers had experienced by including smaller granules that could fall within Takeda's patents. Thus, Takeda had a basis to perceive a reasonable chance of success in its patent infringement claim. See id. at 150 (explaining patentee need only have evidence to suggest "the non-infringement theory . . . was, or at least could be, infirm").

Zydus argues its amended ANDA renders Takeda's suit unreasonable because it specified that Zydus's granules would measure 440 μm or more and Takeda's patents, as construed by the Federal Circuit, only capture granules measuring 400 μm or less. This argument fails for two reasons. First, the language in Zydus's ANDA does not control the infringement inquiry, which is instead "focused on [the product] likely to be sold following FDA approval." Glaxo, Inc. v. Novopharm, Ltd., 110 F.3d 1562, 1568 (Fed. Cir. 1997); see also Tyco Healthcare Grp. LP v. Mut. Pharm. Co., 762 F.3d 1338, 1344 (Fed. Cir. 2014) ("[I]t is not unreasonable for a patent owner to allege infringement . . . if

the patent owner has evidence that the as-marketed commercial ANDA product will infringe, even though the hypothetical product specified in the ANDA could not infringe."); Abbott Labs v. TorPharm, Inc., 300 F.3d 1367, 1373 (Fed. Cir. 2002) ("It is also possible, at least in theory, that other evidence may directly contradict the clear representations of the ANDA and create a dispute of material fact regarding the identity of the compound that is likely to be sold following FDA approval.").

Second, Takeda reasonably discounted Zydus's description of its own product based on the events in the first infringement case. In that case, Zydus asserted in its ANDA that its granules measured at least 450 μm but its own expert found that some of its granules measured less than 450 μm. This history gave Takeda reason to be skeptical of the revised ANDA's statement that the granules were now no smaller than 440 μm, and Takeda reasonably acted on this skepticism by seeking to test Zydus's product.[5] See

[5] To the extent Zydus faults Takeda for failing to test Zydus's product prior to the litigation, its argument is unavailing because Takeda's actions were consistent with the Hatch-Waxman Act. Nothing in the Act requires a brand name manufacturer to conduct a pre-suit investigation that includes testing the drug. Rather, the Act's "design and intent" is to "incentivize[] brand-name drug manufacturers to promptly file patent infringement suits by rewarding them with a stay of up to 30 months if they do so." In re Wellbutrin, 868 F.3d at 157–58. This "file-now, discover-details-later policy" contemplates that the brand name manufacturer cannot know every detail about the generic drug before it files suit. Id. at 151 n.22. Litigation provides a forum for learning these details, and for the prompt resolution of the infringement claims, before the generic goes to market. FTC v. AbbVie Inc., 976 F.3d at 339. Takeda followed the Act's intent here—in only five months, Takeda brought suit, used the discovery process to obtain Zydus's product, tested the product, and then dismissed its claims after its testing indicated that the product did not infringe. See In re Terazosin Hydrochloride Antitrust Litig., 335 F. Supp. 2d 1336, 1357–58 (S.D. Fla. 2004) (explaining that a brand manufacturer's suit was not objectively baseless where it sued to "obtain additional information about the proposed generic products" and then dismissed the suit "[a]fter

Tyco, 762 F.3d at 1344 (explaining patentee may have "a reasonable expectation of a favorable outcome even though the generic manufacturer's ANDA application describes a generic drug with characteristics that [could] take it outside the patent's claims" in situations where "the ANDA is based on faulty testing or screening procedures"); see also Takeda, 743 F.3d at 1367 n.3 (recognizing, in the previous litigation between these parties, that "there is the potential for inconsistent results" when measuring the product's granules). Thus, Takeda had an objective basis to sue Zydus for literal infringement.

B

Takeda also had an objective basis for bringing suit under the doctrine of equivalents. Unlike a literal infringement claim, which requires a plaintiff to show that the accused product contains every component of the asserted claims, Presidio Components, Inc. v. Am. Tech. Ceramics Corp., 702 F.3d 1351, 1358 (Fed. Cir. 2012), under the doctrine of equivalents, "a product . . . infringe[s] if there is 'equivalence' between the elements of the accused product . . . and the claimed elements of the patented invention," Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 21 (1997) (quoting Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 609 (1950)). Put differently, the doctrine states that a product not captured by the patent's language may still infringe "if it performs substantially the same overall function or work, in substantially the same way, to produce substantially the same overall result as the

receiving that information"). Imposing antitrust liability on Takeda in this situation would "punish behavior that Congress sought to encourage." In re Wellbutrin, 868 F.3d at 158 (citation omitted).

claimed invention." Dolly, Inc. v. Spalding & Evenflo Cos., 16 F.3d 394, 397 (Fed Cir. 1994). In the previous litigation, Takeda's expert testified that a deviation in granule size of up to ten percent was "universally accepted," which could reasonably indicate that granules measuring as low as 440 μm are "insubstantially different" from Takeda's product.

Zydus argues Takeda's doctrine of equivalents theory was objectively baseless because of two related limitations on the doctrine: (1) prosecution history estoppel and (2) specification disavowal. Relevant here, these limitations bar a patent holder from using equivalency to capture product elements or specifications it had previously disavowed, or which are explicitly excluded by the language in its patent. See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 733–34 (2002) (discussing prosecution history estoppel); Dolly, 16 F.3d at 400 (discussing specification disavowal). For each of these limitations, Zydus relies on the Federal Circuit case. Zydus argues that, in the previous litigation, the Federal Circuit recognized that Takeda's patents create a "clear dividing line between the 'fine' granules of 400 μm or less (which avoid a feeling of roughness in the mouth) and 'conventional' granules of 400 μm or more (which do not)." Takeda, 743 F.3d at 1364. According to Zydus, the Federal Circuit's reasoning means it was unreasonable for Takeda to now argue that granules greater than 400 μm were equivalent to Prevacid.

Contrary to Zydus's view, the Federal Circuit's ruling does not render Takeda's doctrine of equivalents claim unreasonable. First, the Federal Circuit evaluated an earlier formulation of the product and its reasoning there does not make the present suit based

upon a different formulation objectively unreasonable. Second, the Federal Circuit provided no opinion about whether Zydus infringed under the doctrine of equivalents. Thus, while the patent's language and the Federal Circuit's reasoning may have limited Takeda's success on its infringement claim, there was still a reasonable chance that it would succeed. See Pro. Real Estate, 508 U.S. at 62-63. As a result, Takeda's suit against Zydus was not objectively baseless.

III

For the foregoing reasons, Takeda is entitled to immunity from antitrust liability under Noerr-Pennington and so we will affirm the order of the District Court.