NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

BRAINTREE LABORATORIES, INC.,
Plaintiff-Appellant

v.

BRECKENRIDGE PHARMACEUTICAL, INC.,
Defendant-Appellee

2016-1731

Appeal from the United States District Court for the Southern District of New York in No. 1:12-cv-06851-AJN, Judge Alison J. Nathan.

Decided: May 5, 2017

MARK CHRISTOPHER FLEMING, Wilmer Cutler Pickering Hale and Dorr LLP, Boston, MA, argued for plaintiff-appellant. Also represented by JOHN JOSEPH REGAN, JR., MICHAEL ADAM GREENE, ANNA E. LUMELSKY; CHRISTOPHER R. NOYES, New York, NY.

STEVEN M. LIEBERMAN, Rothwell, Figg, Ernst & Manbeck, P.C., Washington, DC, argued for defendant-appellee. Also represented by JENNIFER NOCK, LISA N.

PHILLIPS; ROBERT VROOM, Breckenridge Pharmaceutical, Inc., New York, NY.

Before NEWMAN, MOORE, and WALLACH, *Circuit Judges.*

MOORE, *Circuit Judge.*

Braintree Laboratories, Inc. ("Braintree") appeals from the Southern District of New York's summary judgment that Breckenridge Pharmaceutical, Inc. ("Breckenridge") does not directly infringe or induce infringement of the asserted claims of U.S. Patent No. 6,946,149 ("the '149 patent"). For the reasons discussed below, we *reverse* and *remand*.

BACKGROUND

The '149 patent is directed to compositions and methods for purging a patient's colon, as is routinely performed prior to a colonoscopy. Braintree markets a bowel prep kit named SUPREP, which is listed in the Food and Drug Administration's ("FDA") Approved Drug Products with Therapeutic Equivalence Evaluations as covered by one or more claims of the '149 patent. SUPREP is sold as a kit consisting of two six-ounce bottles of an aqueous hypertonic solution of potassium sulfate, magnesium sulfate, and sodium sulfate. Its FDA-approved label instructs patients to fill each bottle with water to the sixteen-ounce line (473 mL) prior to consumption and directs that the first bottle be taken the evening before and the second bottle the morning of the colonoscopy. According to SUPREP's label, "[t]he dose for colon cleansing requires administration of two bottles of SUPREP." J.A. 2028.

On March 15, 2012, Breckenridge submitted an Abbreviated New Drug Application ("ANDA") to the FDA, seeking approval to market a generic version of SUPREP. After Breckenridge sent Braintree a Paragraph IV letter asserting that the '149 patent was invalid or not infringed

by its proposed product, Braintree filed the instant action accusing Breckenridge of infringement. Braintree asserts that Breckenridge's proposed product infringes composition claims 15 and 18 and method claims 19, 20, and 23. Each of the asserted method claims recite, *inter alia*, methods for "inducing colonic purgation" through oral administration of the claimed compositions. For purposes of this appeal, claim 15 is representative:

> 15. A composition for inducing purgation of the colon of a patient, the composition comprising from about 100 ml to about 500 ml of an aqueous hypertonic solution comprising an effective amount of Na_2SO_4, an effective amount of $MgSO_4$, and an effective amount of K_2SO_4, wherein the composition does not produce any clinically significant electrolyte shifts and does not include phosphate.

The parties' dispute centers on the relationship between the "purgation" and "from about 100 ml to about 500 ml" limitations.

We previously construed the "purgation" limitation of the '149 patent in *Braintree Laboratories, Inc. v. Novel Laboratories, Inc.*, 749 F.3d 1349 (Fed. Cir. 2014). In that appeal, Novel—another ANDA applicant for a generic version of SUPREP—argued the district court erred in construing "purgation" to encompass something less than full colon cleansing. Novel argued "purgation" must mean full cleansing of the colon sufficient for a colonoscopy. Under Novel's noninfringement theory, one bottle of its generic version of SUPREP could not satisfy the "purgation" limitation because full cleansing only occurs after ingestion of two bottles. But two bottles could not satisfy the volume limitation "from about 100 ml to about 500 ml" because two bottles contain 946 mL of solution.

We rejected Novel's argument and affirmed the district court's construction of "purgation" to mean "an evacuation of a copious amount of stool from the bowels

after oral administration of the solution." *Id.* at 1354–55. We reasoned the claims only require "*inducing* purgation." *Id.* We stated Braintree's "one bottle" theory of infringement—in which one bottle of Novel's proposed product both induces "purgation" and satisfies the volume limitation—"can prevail" under the district court's construction. *Id.* at 1354.

The dissent stated that Braintree's "one bottle" infringement theory is erroneous as a matter of law because under 35 U.S.C. § 271(e), Braintree can only assert infringement over the product as described in Novel's ANDA, which discloses 946 mL in volume. *Id.* at 1361–63. The dissent added that apart from the § 271(e) issue, Braintree's "one bottle" theory rests on an incorrect claim construction because "from about 100 ml to about 500 ml" must refer to the total volume of consumed solution. *Id.* at 1363–65.

While the *Novel* appeal was pending, Breckenridge stipulated that the district court's *Novel* construction of "purgation" would apply in this case. Breckenridge further stipulated to "be bound by a final decision in the Novel Case . . . on any issues having to do with patent invalidity . . . and non-infringement" other than the "from about 100 ml to about 500 ml" limitation. J.A. 296–27 ¶¶ 3, 8. Breckenridge subsequently moved for summary judgment of noninfringement based on this limitation, arguing its proposed generic does not infringe the claims of the '149 patent "because it is administered as 946 ml of aqueous solution, and thus falls outside the recited volume range." J.A. 1228. It argued that based both on the claim construction of the term and the infringement inquiry under § 271(e), "from about 100 ml to about 500 ml" must refer to the total volume of solution administered. It argued its proposed label could not induce infringement of method claims 19, 20, and 23 under § 271(e) because its ANDA label instructs patients to consume the "entire amount" of solution (946 mL) for the

sole indication of "preparation for colonoscopy"—not only one bottle to "induce colonic purgation."

The district court granted Breckenridge's motion for summary judgment of noninfringement. It held that *Novel* did not preclude Breckenridge's noninfringement theory because that opinion did not address the separate volume limitation. It construed "from about 100 ml to about 500 ml" to mean "the entire volume of solution administered to a patient over a treatment period rather than the volume of a single bottle, or half-dose." J.A. 13–14. Because every asserted claim requires "from about 100 ml to about 500 ml," the district court found that Breckenridge's proposed product, with a total volume of 946 mL, does not infringe any of the asserted claims. The district court also agreed that Breckenridge's ANDA label could not induce infringement under § 271(e), finding inducing purgation without "achieving a fully cleansed colon" is not an FDA-approved use of Breckenridge's product. For method claim 23, it found no induced infringement because the effective amount that is administered in two or more doses must be in the range of from about 100 ml to about 500 ml. Braintree appeals. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

DISCUSSION

A. Claim Construction

The parties dispute *Novel's* preclusive effect on the district court's construction of "from about 100 ml to about 500 ml." Breckenridge argues that *Novel* is irrelevant because the construction of "from about 100 ml to about 500 ml" was not at issue in *Novel*. We disagree.

The meaning of the term "from about 100 ml to about 500 ml" was necessarily connected to our construction of "purgation." Novel intertwined the volume and purgation limitations throughout its briefing to argue noninfringement under its construction of "purgation." *See, e.g.*,

J.A. 1598–99. We rejected Novel's construction of "purgation" and held that "while cleansing is the goal specifically articulated in the specification, it is not a claim requirement." *Novel*, 749 F.3d at 1355. We concurrently interpreted "from about 100 ml to about 500 ml" as what is necessary to induce purgation. Our construction stemmed from the arguments presented and the claim language, which linked the "purgation" and "from about 100 ml to about 500 ml" limitations. The parties do not dispute that the preamble, "[a] composition for inducing purgation," is limiting. The claim's recitation of "the composition comprising from about 100 ml to about 500 ml" derives antecedent basis from the preamble. The same composition for "inducing purgation" must be "from about 100 ml to about 500 ml." In *Novel*, this court construed "from about 100 ml to about 500 ml" to be the amount of the composition that induces "purgation," which is less than full cleansing. 749 F.3d at 1354. We further explained,

> Each of those half-dose sixteen ounce solutions has a total volume of 473 mL, which is within the range found in the asserted claims of the '149 patent, but Braintree concedes that neither dose accomplishes a full cleansing. Thus, Braintree's "one bottle" infringement theory asserts that one (half-dose) bottle of SUPREP, diluted with water to become a sixteen ounce solution, falls within the asserted claims. This infringement theory can prevail if purgation means the "evacuation of a copious amount of stool from the bowels after oral administration of the solution," which is something less than a full cleansing.

Id.

We are mindful of the due process implications of binding Breckenridge to a claim construction decision in which it was neither a party nor in privity with one. *See, e.g.*, *Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402

U.S. 313, 329 (1971) ("Due process prohibits estopping [litigants who never appeared in a prior action] despite one or more existing adjudications of the identical issue which stand squarely against their position."). However, Breckenridge expressly stipulated that "the claim construction of 'purgation' adopted by the District Court in the Novel Case will apply." J.A. 296 ¶ 5. Breckenridge further agreed "to be bound by a final decision in the Novel Case" on "any issues" related to patent invalidity and noninfringement. J.A. 297 ¶ 8. Whether or not the construction Breckenridge advocates has merit, in light of its stipulations, *Novel* foreclosed the district court's construction of "from about 100 ml to about 500 ml."

B. Noninfringement Under 35 U.S.C. § 271(e)

Breckenridge argues the district court's summary judgment of noninfringement should be affirmed notwithstanding its construction of the volume limitation because Braintree's infringement theory is contrary to 35 U.S.C. § 271(e). We disagree.

The district court held Breckenridge's ANDA label could not induce infringement of method claims 19 and 20 because inducing purgation is not an FDA-approved use of Breckenridge's proposed product. J.A. 18.[1] It reasoned

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[1] The district court further held that Breckenridge does not infringe method claim 23, which provides "the effective amount of the composition is administered in two or more doses within a treatment period," by construing this limitation to mean *dividing* the total composition (of "from about 100 ml to about 500 ml) into separate dosages, as compared to repeating administration of the composition. J.A. 19–20. We agree with Braintree that the district court's noninfringement decision based on this limitation contradicts the parties' stipulation to limit summary judgment. Appellee's Br. 52 (citing J.A. 296

that because our *Novel* decision distinguished "purgation" from full colon cleansing, purgation is a distinct treatment, rather than merely a mechanism to achieve the goal of full colon cleansing. J.A. 17–18. We do not agree.

This case is distinguishable from the cases in which we have held an ANDA applicant's proposed label would not induce infringement. In *Warner-Lambert Co v. Apotex Corp.*, 316 F.3d 1348 (Fed. Cir. 2003), we held that an ANDA applicant's labeled indication for partial seizures would not induce infringement of a "method for treating neurodegenerative diseases." We noted that the two indications were entirely distinct because partial seizure is not a neurodegenerative disease. *Id.* at 1353. We explained that to gain approval for the neurodegenerative disease indication, which was not an approved indication for the brand product, the ANDA applicant would have had to submit safety and efficacy data to the FDA. *Id.* at 1360, 1361 n.6. Similarly, in *Allergan, Inc. v. Alcon Labs., Inc.*, 324 F.3d 1322 (Fed. Cir. 2003), we held that an ANDA applicant's labeled indication for reducing intraocular pressure would not induce infringement of methods of "protecting the optic nerve and retina" and "providing neural protection." Because the claimed uses were not approved by the FDA, the ANDA applicant could not be held liable for infringement "even though [the proposed drug] necessarily had those protective effects in patients who took the drug for the approved purpose." *Bayer Schering Pharma AG v. Lupin, Ltd.*, 676 F.3d 1316, 1321 (Fed. Cir. 2012) (citing *Allergan*, 324 F.3d at 1324). In *Bayer*, we addressed induced infringement of method claims for "simultaneously achieving, during premenopause or menopause, a contraceptive effect, an antiandrogenic effect, and an antialdosterone effect" based on

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¶ 3). We thus reverse this portion of the district court's decision.

an ANDA label with the indication "for oral contraception." 676 F.3d at 1319–20. We explained that while the ANDA label mentioned the potential for the claimed effects, "it does not do so in any way that recommends or suggests to physicians that the drug is safe and effective for administration to patients for the purposes of inducing these effects." *Id.* at 1322. We therefore held the ANDA applicant could not be held liable for inducing a physician to infringe the method claims. *Id.* at 1326.

In contrast, inducing purgation is not a distinct use of Breckenridge's proposed product; inducing purgation is the *means* by which the approved indication achieves its result. Breckenridge concedes that its proposed product "cleanses the colon of a patient *by inducing purgation*" when taken as directed by its label. J.A. 1780–81 ¶¶ 25, 37–38 (emphasis added). Its stipulations make clear that inducing purgation is not supplemental or ancillary to its proposed indication of colon cleansing—it is plainly within the scope of Breckenridge's proposed indication.

We hold that Breckenridge's labeled indication for colon cleansing "recommends or suggests to physicians that the drug is safe and effective for administration to patients for the purposes of inducing [purgation]." *Bayer*, 676 F.3d at 1322. There can be no dispute that, given SUPREP's sole approved use, the FDA has approved SUPREP as safe and effective for the indication of colon cleansing. Because Breckenridge's labeled indication of colon cleansing requires performing the claimed steps in order to achieve colon cleansing, it follows that a physician would understand Breckenridge's ANDA label to recommend or suggest that "inducing purgation" is safe and effective. To hold otherwise would lead to the absurd result that a physician would understand Breckenridge's proposed product to be safe and effective for fully cleansing the colon, but not safe and effective at accomplishing a partial colon cleansing. Because Breckenridge's ANDA label "instruct[s] how to engage in an infringing use, [it]

show[s] an affirmative intent that the product be used to infringe." *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1059 (Fed. Cir. 2010) (citation omitted).

Breckenridge stipulated that its proposed product infringes claims 15, 18, 19, 20, and 23 of the '149 patent if its motion for summary judgment of noninfringement is denied. J.A. 296 ¶ 3. It further agreed not to raise any defenses or counterclaims other than the noninfringement defense articulated in its motion for summary judgment. *Id.* ¶¶ 4, 6. We thus *reverse* the district court's grant of summary judgment and *remand* with an instruction to enter judgment for Braintree.

CONCLUSION

We have considered all of Breckenridge's arguments on appeal and find them to be without merit. For the foregoing reasons, we *reverse* the district court's grant of summary judgment of noninfringement and *remand* for entry of judgment for Braintree.

REVERSED AND REMANDED

COSTS

Costs to Braintree.