United States Court of Appeals for the Federal Circuit

EAGLE PHARMACEUTICALS INC.,
Plaintiff-Appellant

v.

SLAYBACK PHARMA LLC,
Defendant-Appellee

2019-1924

Appeal from the United States District Court for the District of Delaware in No. 1:18-cv-01953-CFC, United States District Judge Colm F. Connolly.

Decided: May 8, 2020

DANIEL BROWN, Latham & Watkins LLP, New York, NY, argued for plaintiff-appellant. Also represented by KENNETH G. SCHULER, MARC NATHAN ZUBICK, Chicago, IL; GREGORY SOBOLSKI, San Francisco, CA; GABRIEL BELL, Washington, DC.

CONSTANCE HUTTNER, Budd Larner, P.C., Short Hills, NJ, argued for defendant-appellee. Also represented by JAMES BARABAS, BETH C. FINKELSTEIN, ANDREW J. MILLER, Windels Marx Lane & Mittendorf LLP, Madison, NJ.

Before O'MALLEY, REYNA, and CHEN, *Circuit Judges*.

REYNA, *Circuit Judge.*

Eagle Pharmaceuticals appeals a district court judgment of non-infringement on the pleadings. Eagle sued Slayback Pharma LLC for infringing four patents covering Eagle's brand name bendamustine pharmaceutical product. Eagle argues that the district court committed two errors when it concluded that the dedication-disclosure doctrine barred Eagle's claim of infringement under the doctrine of equivalents. First, Eagle contends that the district court erred when it concluded that the asserted patents disclose, but do not claim, ethanol—and therefore dedicated ethanol to the public. Second, Eagle contends that the district court improperly applied the dedication-disclosure doctrine at the pleadings stage, in the presence of factual disputes and without drawing all inferences in Eagle's favor. Because we find no error in the district court's judgment on the pleadings, we affirm.

BACKGROUND

Eagle Pharmaceuticals Inc. ("Eagle") filed suit in the U.S. District Court for the District of Delaware accusing Slayback Pharma LLC ("Slayback") of infringing four patents under the doctrine of equivalents.[1] Eagle's infringement claims stem from Slayback's new drug application ("NDA") for a generic version of Eagle's branded bendamustine product, BELRAPZO®. J.A. 105. Bendamustine is used to treat chronic lymphocytic leukemia and indolent B-cell non-Hodgkin lymphoma.

For purposes of this appeal, Eagle's four asserted patents share essentially the same written description and all independent claims recite essentially the same limitations.

---

[1] Eagle asserted U.S. Patent Nos. 9,265,831; 9,572,796; 9,572,797; and 10,010,533.

The parties agree that Claim 1 of U.S. Patent No. 9,572,796 ("the '796 patent"), shown below in relevant part, is representative.[2]

> 1. A non-aqueous liquid composition comprising:
>
> bendamustine, or a pharmaceutically acceptable salt thereof;
>
> a ***pharmaceutically acceptable fluid*** comprising a mixture of polyethylene glycol and propylene glycol, wherein the ratio of polyethylene glycol to propylene glycol in the pharmaceutically acceptable fluid is from about 95:5 to about 50:50; and
>
> a stabilizing amount of an antioxidant;
>
> . . . .

'796 patent at col. 13 ll. 22–35 (emphasis added).

Slayback conceded that its generic product literally infringes all claim limitations except for the "pharmaceutically acceptable fluid" limitation. Eagle asserted that Slayback's product infringes the "pharmaceutically acceptable fluid" limitation under the doctrine of equivalents. Specifically, Eagle asserted that the ethanol in Slayback's product is insubstantially different from the propylene glycol ("PG") in the claimed composition.

On January 4, 2019, Slayback moved for a judgment of non-infringement on the pleadings under Federal Rule of Civil Procedure 12(c). Slayback argued that the disclosure-dedication doctrine barred Eagle's claim of infringement under the doctrine of equivalents because the asserted patents disclose, but do not claim, ethanol as an alternative solvent to PG.

---

[2] All citations are to U.S. Patent No. 9,572,796.

The specification expressly and repeatedly identifies "ethanol" as an alternative "pharmaceutically acceptable fluid" to PG. '796 patent at col. 1 ll. 60–64, col. 4 ll. 34–42, 43–48, col. 5 ll. 25–35, 38–50, col. 6 ll. 3–14, 31–65, col. 7 ll. 1–8. For example, the Summary of the Invention discloses that:

> In other aspects of the invention, the bendamustine-containing compositions include a) a ***pharmaceutically acceptable fluid*** which contains one or more of propylene glycol, ***ethanol***, polyethylene glycol, benzyl alcohol and glycofurol, and b) a stabilizing amount of a chloride salt.

Id. at col. 1 ll. 60–64 (emphasis added). Likewise, the specification teaches that:

> Preferred ***pharmaceutically acceptable fluids*** include PG, PEG or ***ethanol*** in this embodiment of the invention.

Id. at col. 4 ll. 44–46 (emphasis added).

Eagle opposed Slayback's motion, arguing that the asserted patents do not disclose ethanol as an alternative to PG for the *claimed* embodiment that contains an antioxidant. J.A. 238. Eagle asserted that the specification only discloses ethanol when discussing *unclaimed* embodiments that contain chloride salt. *Id.* According to Eagle, a skilled artisan would thus "not understand the specification to teach ethanol as an alternative to propylene glycol in the claimed formulations." J.A. 234.

In support of its opposition, Eagle submitted an expert declaration from Dr. Mansoor Amiji. Dr. Amiji opined that a skilled artisan would understand the specification to disclose three distinct categories of formulations that each contain different ingredients and work in different ways. Dr. Amiji opined that a skilled artisan "would not view the specific ethanol-containing formulations including chloride

salts as a disclosure that ethanol was specifically identified as an alternative to the claim limitation at issue in the asserted claims." J.A. 260 ¶ 45. Slayback did not submit evidence to rebut Dr. Amiji's testimony.

On May 9, 2019, the district court granted Slayback's motion for judgment of non-infringement on the pleadings. The court determined that "[t]he parties have not identified a claim construction dispute, and the written description of the asserted patents unambiguously and repeatedly identifies [ethanol] as an alternative to propylene glycol." *Eagle Pharm., Inc. v. Slayback Pharma LLC*, 382 F. Supp. 3d 341, 346 (D. Del. 2019). The court rejected Eagle's attempt to "manufacture a factual dispute" and declined to consider the expert declaration of Dr. Amiji. *Id.* at 346, 346 n.2. The court concluded that it had "sufficient context to decide a question of law—i.e., that the disclosure-dedication doctrine applies to bar Eagle's claims for infringement under the doctrine of equivalents." *Id.* at 346.

Eagle timely appealed. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

ANALYSIS

We review the district court's judgment on the pleadings under the law of the regional circuit, which in this case is the Third Circuit. *Data Engine Techs. LLC v. Google LLC*, 906 F.3d 999, 1007 (Fed. Cir. 2018). The Third Circuit reviews the grant of judgment on the pleadings de novo, "accept[ing] all of the allegations in the pleadings of the party against whom the motion is addressed as true and draw[ing] all reasonable inferences in favor of the non-moving party." *Id.* (quoting *Allstate Prop. & Cas. Ins. Co. v. Squires*, 667 F.3d 388, 390 (3d Cir. 2012)). In doing so, we "disregard rote recitals of the elements of a cause of action, legal conclusions, and mere conclusory statements." *James v. City of Wilkes-Barre*, 700 F.3d 675, 679 (3d Cir. 2012). Rule 12(c) judgment is appropriate when the moving party clearly establishes that there are "no material

issues of fact, and that he or she is entitled to judgment as a matter of law." *DiCarlo v. St. Mary Hospital*, 530 F.3d 255, 259 (3d Cir. 2008); *see* FED. R. CIV. P. 12(c).

Under the doctrine of equivalents, "a product or process that does not literally infringe upon the express terms of a patent claim may nonetheless be found to infringe if there is 'equivalence' between the elements of the accused product or process and the claimed elements of the patented invention." *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 21, 29 (1997). The doctrine of equivalents prevents "the unscrupulous copyist [from] mak[ing] unimportant and insubstantial changes and substitutions in the patent which, though adding nothing, would be enough to take the copied matter outside the claim, and hence outside the reach of law." *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 607 (1950). The central question for infringement under the doctrine of equivalents is whether "the accused product or process contain[s] elements identical or equivalent to each claimed element of the patented invention." *Warner-Jenkinson*, 520 U.S. at 40.

The disclosure-dedication doctrine bars application of the doctrine of equivalents. *Johnson & Johnston Assoc. v. R.E. Servs.*, 285 F.3d 1046, 1054 (Fed. Cir. 2002) (en banc). It states that "when a patent drafter discloses but declines to claim subject matter, . . . this action dedicates the unclaimed subject matter to the public." *Id.* By preventing a patentee from recapturing unclaimed subject matter, the disclosure-dedication doctrine reinforces "the primacy of the claims in defining the scope of the patentee's exclusive right." *Id.* To determine whether the disclosure-dedication doctrine applies in a given case, we ask whether the specification discloses unclaimed subject matter with "such specificity that one of ordinary skill in the art could identify the subject matter that had been disclosed and not claimed." *PSC Comput. Prods., Inc. v. Foxconn Int'l, Inc.*, 355 F.3d 1353, 1360 (Fed. Cir. 2004). If the court concludes

that the inventor dedicated an alleged equivalent to the public, the patent owner cannot prevail on its doctrine of equivalents infringement claim based on that equivalent. *Maxwell v. J. Baker, Inc.*, 86 F.3d 1098, 1108 (Fed. Cir. 1996).

This appeal centers on Eagle's challenge to the merits and procedural aspects of the district court's application of the disclosure-dedication doctrine.

A.

Eagle first challenges the merits of the district court's determination that the disclosure-dedication doctrine bars Eagle's infringement claims under the doctrine of equivalents. Eagle contends, as it did below, that the disclosure-dedication doctrine does not apply because the asserted patents do not disclose ethanol as an alternative to PG for the *claimed* embodiment containing an antioxidant.

Eagle contends that the asserted patents disclose three distinct "categories" of bendamustine formulations: (i) chloride salt formulations; (ii) antioxidant formulations; and (iii) dimethyl sulfoxide ("DMSO") formulations. Appellant Br. 20. According to Eagle, a skilled artisan would recognize that the three separate categories "have separate ingredients[] and work in different ways." *Id.* Eagle asserts that the specification only discloses ethanol as an alternative to PG when discussing the *unclaimed* chloride salt formulations; it never discloses ethanol as an alternative to PG when discussing the *claimed* antioxidant formulations. *Id.* at 4. As a result, Eagle concludes, a "skilled artisan would not understand that ethanol . . . is an alternative to PG in the separate, claimed 'PEG/PG/antioxidant' category of formulations." *Id.* at 20. We disagree.

The disclosure-dedication doctrine does not require the specification to disclose the allegedly dedicated subject matter in an embodiment that exactly matches the claimed embodiment. *Johnson*, 285 F.3d at 1052. In *Johnson*, we

rejected this embodiment-level approach to the disclosure-dedication doctrine and denied the patentee's attempt to avoid dedication by claiming that the disclosure occurred in an "alternative [embodiment] distinct from the claimed invention." *Id.* Instead, we have held that the disclosure-dedication doctrine requires only that the specification disclose the unclaimed matter "as an alternative to the relevant claim limitation." *Pfizer, Inc. v. Teva Pharm. USA, Inc.*, 429 F.3d 1364, 1378 (Fed. Cir. 2005).

We conclude that the asserted patents disclose ethanol as an alternative to PG in the "pharmaceutically acceptable fluid" claim limitation. The specification repeatedly identifies—without qualification—ethanol as an alternative pharmaceutically acceptable fluid. '796 patent at col. 1 ll. 60–64, col. 4 ll. 34–42, 43–48, col. 5 ll. 25–35, 38–50, col. 6 ll. 3–14, 31–65, col. 7 ll. 1–8. Aside from the description of certain exemplary embodiments, nothing in the specification suggests that these repeated disclosures of ethanol are limited to certain formulations, or that they do not extend to the claimed formulation.

Eagle asserts that, in *Pfizer*, we declined to apply the dedication-disclosure doctrine because the alleged alternative disclosed in the specification (microcrystalline cellulose) did not serve the same purpose (preventing hydrolysis) as the claimed "saccharide." 429 F.3d at 1379 (concluding that the disclosed microcrystalline cellulose "does not appear to relate to the claimed invention"). Eagle contends that the chloride salt category of formulations in the present case likewise "work[] by a different mechanism" than the claimed antioxidant formulations, and thus a skilled artisan would understand that ethanol does not relate to the claimed invention. Appellant Br. 30. We are not persuaded.

In *Pfizer*, the claim limitation-at-issue recited a specific purpose: "a suitable amount of a saccharide *to inhibit hydrolysis*." 429 F.3d at 1373, 1378 (emphasis added). The

asserted alternative, microcrystalline cellulose, was disclosed in the specification without any relation to hydrolysis. *Id.* As a result, we were "not convinced that one of ordinary skill in the art would come to the conclusion that the inventors have identified microcrystalline cellulose in that formulation as an alternative to a 'saccharide' that prevents hydrolysis." *Id.*

In this case, the claim limitation-at-issue has only one stated purpose: that the fluid be "pharmaceutically acceptable." Unlike in *Pfizer*, the specification here repeatedly discloses ethanol as serving that purpose, i.e., the specification expressly discloses ethanol as a "pharmaceutically acceptable fluid." *E.g.*, '796 patent at col. 1 ll. 60–64, col. ll. 34–42, 43–48. We therefore hold that the asserted patents dedicated ethanol to the public by disclosing, but not claiming, ethanol as an alternative to PG in the "pharmaceutically acceptable solvent" claim limitation. As a result, we affirm the district court on this point.

B.

Eagle also challenges the district court's judgment on procedural grounds. Eagle asserts that, at the time the district court entered judgment of non-infringement on the pleadings, a factual dispute existed: whether a skilled artisan would understand the specification to disclose ethanol as an alternative to PG in the claimed invention. Eagle argues that the district court erred by resolving that factual dispute at the pleadings stage without drawing all reasonable inferences in Eagle's favor. Appellant Br. 46 (citing *Nalco Co. v. Chem-Mod, LLC*, 883 F.3d 1337, 1349 (Fed. Cir. 2018)). Specifically, Eagle argues that the district court was required to infer that a "skilled artisan would not have understood that ethanol was an alternative to PG in the claimed 'PEG/PG/Antioxidant' category of formulations." *Id.* at 44. Eagle explains that the district court erred by improperly ignoring Dr. Amiji's declaration, which

was "the best (and *only*) evidence of a skilled artisan's understanding of [the] disclosure." *Id.* at 45.

As a preliminary matter, when ruling on a Rule 12(c) motion, district courts have discretion to consider evidence outside the complaint for purposes of deciding whether to accept that evidence and convert the motion into one for summary judgment. *Kulwicki v. Dawson*, 969 F.2d 1454, 1462 (3d Cir. 1992); *see also* 5C WRIGHT & MILLER, FED. PRAC. & PROC. CIV. § 1371 (3d ed.) ("As is true of practice under Rule 12(b)(6), it is well-settled that it is within the district court's discretion whether to accept extra-pleading matter on a motion for judgment on the pleadings and treat it as one for summary judgment or to reject it and maintain the character of the motion as one under Rule 12(c)."). We conclude that the district court did not abuse its discretion when it set aside Dr. Amiji's declaration. The district court reviewed Dr. Amiji's declaration and determined that it was merely an "attempt[] to manufacture a factual dispute." *Eagle*, 382 F. Supp. 3d at 346. The district court also found that the patents themselves provided "sufficient context to decide" the legal issue at hand. *Id.* Eagle has not persuaded us otherwise. In opposing Slayback's motion to dismiss, Eagle conceded that the district court's "reliance on expert testimony would be improper at this preliminary [pleadings] stage." J.A. 233.

We find no error in the district court's decision to grant judgment of non-infringement on the pleadings. The application of the disclosure-dedication doctrine is a question of law. *Pfizer*, 429 F.3d at 1378. Here the district court concluded that the patents themselves provided "sufficient context to decide a question of law, i.e., that the disclosure-dedication doctrine applies to bar Eagle's claims for infringement under the doctrine of equivalents." *Eagle*, 382 F. Supp. 3d at 346.

Expert testimony is not always required for a district court to determine how a skilled artisan would understand

a patent's disclosure and claimed invention. *Union Carbide Corp. v. Am. Can Co.*, 724 F.2d 1567, 1573 (Fed. Cir. 1984) (stating that a patent's disclosure may be "easily understandable without the need for expert explanatory testimony"). For example, in *Amgen Inc. v. Coherus BioSciences Inc.*, we held that expert testimony was not necessary to understand whether a patent owner "clearly and unmistakably surrendered unclaimed [disclosure] during prosecution." 931 F.3d 1154, 1160 (Fed. Cir. 2019) (affirming judgment of non-infringement on the pleadings because prosecution history precluded Amgen's infringement allegations based on the doctrine of equivalents). We explained that "Amgen's statements during prosecution," on their face, showed that "a competitor would reasonably believe that Amgen surrendered unclaimed salt combinations" as a matter of law. *Id.* (internal quotations omitted).

Here, we conclude that the only reasonable inference that can be made from the patent disclosures is that a skilled artisan would understand the patents to disclose ethanol as an alternative to the claimed PG. Nothing in the record permits us to infer that a skilled artisan "would have understood that the patent specification describes distinct categories of formulations that contain different ingredients and work in different ways." Appellant Br. 44. As a result, even when viewing the pleadings in the light most favorable to Eagle, we conclude there is no material issue of fact to resolve and Slayback is entitled to judgment in its favor as a matter of law.

CONCLUSION

We have considered Eagle's other arguments and find them unpersuasive. We affirm the district court's judgment of non-infringement on the pleadings.

AFFIRMED

COSTS

No costs.