NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

GALDERMA LABORATORIES, L.P., NESTLE SKIN HEALTH S.A., TCD ROYALTY SUB LLC,
Plaintiffs-Appellees

v.

AMNEAL PHARMACEUTICALS LLC, AMNEAL PHARMACEUTICALS CO. (I) PVT. LTD., NKA AMNEAL PHARMACEUTICALS PVT. LTD.,
Defendants-Appellants

2019-1021

Appeal from the United States District Court for the District of Delaware in No. 1:16-cv-00207-LPS, Chief Judge Leonard P. Stark.

Decided: March 25, 2020

GERALD J. FLATTMANN, JR., King & Spalding LLP, New York, NY, argued for plaintiffs-appellees. Also represented by EVAN D. DIAMOND, VANESSA YEN.

GEORGE C. LOMBARDI, Winston & Strawn LLP, Chicago, IL, argued for defendants-appellants. Also

represented by MAUREEN L. RURKA, KEVIN E. WARNER; EIMERIC REIG-PLESSIS, San Francisco, CA.

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

MOORE, *Circuit Judge*.

Appellees Galderma Laboratories, L.P., Nestle Skin Health S.A., and TCD Royalty Sub LLC (collectively, Galderma) sued Amneal Pharmaceuticals, LLC and Amneal Pharmaceuticals Co. (I) Pvt. Ltd. (n/k/a Amneal Pharmaceuticals Pvt. Ltd.) (collectively, Amneal) for infringement of U.S. Patent Nos. 8,206,740, 8,394,405, and 8,470,364 (collectively, the Chang Patents) and U.S. Patent Nos. 8,603,506 and 9,241,946 (collectively, the Ashley II Patents). The Chang and Ashley II Patents relate to low-dose doxycycline formulations to treat, among other diseases, acne or rosacea. Following a bench trial, the district court found that Amneal's product infringes the asserted claims under the doctrine of equivalents. Amneal appeals. We have jurisdiction under 28 U.S.C. § 1295(a)(1). For the reasons discussed below, we affirm the district court's judgment as to infringement of the Chang Patents and reverse the district court's judgment as to infringement of the Ashley II Patents.

DISCUSSION

Following a bench trial, we review a district court's conclusions of law de novo and factual findings for clear error. *Senju Pharm. Co., v. Lupin Ltd.*, 780 F.3d 1337, 1341 (Fed. Cir. 2015). Prosecution history estoppel and claim vitiation are issues of law we review de novo. *Trading Techs. Int'l v. Open E Cry, LLC*, 728 F.3d 1309, 1318 (Fed. Cir. 2013); *Cadence Pharm. Inc. v. Exela Pharmsci Inc.*, 780 F.3d 1364, 1368 (Fed. Cir. 2015). Prosecution history estoppel "may be subject to underlying facts," which we review for clear error. *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1324 (Fed. Cir. 2009). We review

infringement under the doctrine of equivalents for clear error. *Conoco, Inc. v. Energy & Envtl Int'l*, 460 F.3d 1349, 1357 (Fed. Cir. 2006).

I

The Chang Patents

The Chang Patents describe compositions of doxycycline with an Immediate Release (IR) component and a Delayed Release (DR) component, combined into one unit for once-daily dosing. Claim 1 of the '740 patent is illustrative:

> 1. An oral pharmaceutical composition of doxycycline, which at a once-daily dosage will give steady state blood levels of doxycycline of a minimum of 0.1 µg/ml and a maximum of 1.0 µg/ml, the composition consisting of (i) an immediate release (IR) portion comprising 30 mg doxycycline; (ii) a delayed release (DR) portion comprising 10 mg doxycycline; and optionally, (iii) one or more pharmaceutically acceptable excipients.

"Immediate release" or IR is defined by the '740 patent as "a dosage form that is intended to release substantially all of the active ingredient on administration with no enhanced, delayed or extended release effect." '740 patent at 4:5–8. "Delayed release" or DR is not expressly defined.

In June 2013, Amneal filed a petition for *inter partes* review of the Chang '740 and '405 patents, which the Board instituted in December 2013. During the *inter partes* review, Patent Owner[1] sought to distinguish the claimed DR portion from the prior-art secondary loading portion of

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[1] The *inter partes* review proceedings were between Amneal Pharmaceuticals, LLC and Supernus Pharmaceuticals, Inc., the previous assignee of the Chang patents. The proceedings as to the '740 and '405 patents were consolidated. We refer to the '740 proceeding throughout.

slow-release pellets that begin dissolving in the stomach as disclosed in U.S. Patent No. 5,348,748 (Sheth). It argued that "'a DR portion' as claimed in the Chang '740 patent requires ***no substantial release*** from the portion until some time other than promptly after administration – and in particular, until after the DR portion passes through the acidic stomach and sections of the GI tract below pH 4.5." J.A. 2560 (emphasis in original); *see also* J.A. 16958–61, J.A. 2749. It further argued that Sheth's "secondary loading" portion was "intentionally designed to be 'leaky' in the stomach," but that "the Chang '740 patent expressly states that for the 'DR portion' described and claimed therein, 'there is ***no substantial release*** of doxycycline in the acidic stomach environment of approximately below pH 4.5.'" J.A. 16957–58 (emphasis in original). Patent Owner argued that "the approach taught by Sheth is substantially different from the claimed IR/DR formulations of the Chang '740 patent, and in fact would ***teach away*** from the claimed formulations of the Chang '740 patent." J.A. 16953 ¶ 170 (emphasis in original); J.A. 2189 at 53:22–24 (Sheth "shows a substantial portion is dissolving in the acidic environment of the stomach. The point is that's not delayed release.").

The Board rejected Patent Owner's argument and instead agreed with Amneal "that the broadest reasonable construction of 'delayed release,' in light of the specification of the '740 patent, is not limited to formulations requiring that there be no substantial release in the stomach." J.A. 17023. It stated that "[t]he portion of the '740 patent specification upon which [Patent Owner] relies to support its narrower construction addresses properties of 'enteric coated pellets,' not a delayed-release component." *Id.* Because the '740 patent discloses formats other than enteric coated pellets as being delayed-release components, the Board would "not read the limitations of an embodiment, even a preferred embodiment, into the construction of a

claim term that is plainly used elsewhere in the specification more broadly." *Id.* (citing *In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004)). After reviewing "other evidence of how the term is understood and used by persons of ordinary skill in the art," the Board construed "delayed release" to mean "release of a drug at a time other than immediately following oral administration." J.A. 17024. The Board ultimately found that Sheth did not disclose a "delayed release" format under the proper construction. J.A. 17029.

Galderma sued Amneal in March 2016, alleging, inter alia, infringement of the Chang Patents. Like the Board, the district court construed "delayed release" or "DR" as "release of a drug at a time other than immediately following oral administration." Based on this construction, the district court found, after a bench trial, that Amneal's product contained the equivalent of the claimed 10 mg DR portion and entered judgment of infringement against Amneal. Amneal appeals this judgment, arguing that Galderma is precluded from asserting infringement under the doctrine of equivalents due to argument-based estoppel, amendment-based estoppel, and claim vitiation. Alternatively, it argues its product does not infringe the Chang Patents under the doctrine of equivalents. We first address the parties' arguments with respect to argument-based estoppel. We conclude that the district court did not err in concluding that Galderma "did not disclaim particular DR formulations." J.A. 70.

Amneal argues that Patent Owner's arguments during the '740 *inter partes* review proceedings clearly and unmistakably surrendered subject matter and therefore preclude a finding that Amneal's products infringe the Chang patents under the doctrine of equivalents. Based on Patent Owner's statements, Amneal argues that competitors would interpret a DR portion as not encompassing a drug that begins dissolving or "leaking" in the stomach. Galderma argues that Amneal has not shown any statements

that, when considered within the context of the complete *inter partes* review record, amount to a "clear and unmistakable surrender."

We have held that "statements made by a patent owner during an IPR proceeding can be considered during claim construction and relied upon to support a finding of prosecution disclaimer" so long as the statements are "both clear and unmistakable." *Aylus Networks, Inc. v. Apple Inc.*, 856 F.3d 1353, 1361–62 (Fed. Cir. 2017). Prosecution disclaimer "promotes the public notice function of the intrinsic evidence and protects the public's reliance on definitive statements made during prosecution." *Id.* at 1360 (citing *Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1324 (Fed. Cir. 2003)). The doctrine is rooted in the understanding that "[c]ompetitors are entitled to rely on those representations when determining a course of lawful conduct, such as launching a new product or designing-around a patented invention." *Id.* (citing *Biogen Idec, Inc. v. GlaxoSmithKline LLC*, 713 F.3d 1090, 1095 (Fed. Cir. 2013)).

Statements by the patent owner are not considered in a vacuum; rather, the skilled artisan would look at the record as a whole in assessing claim scope. *See Wang Labs., Inc. v. Toshiba Corp.*, 993 F.2d 858, 867 (Fed. Cir. 1993) ("The prosecution history must be examined as a whole in determining whether estoppel applies."). There is no doubt that the Board rejected the Patent Owner's attempt to limit the meaning of delayed release. *See* J.A. 17023 ("[W]e agree with Amneal that the broadest reasonable construction of 'delayed release,' in light of the specification of the '740 patent, is not limited to formulations requiring that there be no substantial release in the stomach."). Because the Board rejected the Patent Owner's arguments regarding the meaning of delayed release, the record before the Patent Office clearly put the public on notice that the meaning of delayed release with respect to the Chang Patents is not limited to formulations requiring that there be

no substantial release in the stomach. While clear and limiting statements made by the patent owner can give rise to disclaimer, they do not in this case where those statements were clearly and expressly rejected by the Patent Office. Because the record makes clear to a skilled artisan that Patent Owner's arguments were rejected, those arguments do not impact claim scope. Accordingly, we see no error in the district court's conclusion that Galderma was not precluded by these statements from asserting the doctrine of equivalents.[2] J.A. 70.[3]

Contrary to Amneal's assertion, our decision in *American Piledriving* does not compel a different result. In that case, we held that a patentee was bound by arguments that it made to an examiner to distinguish prior art. *Am. Piledriving Equip., Inc. v. Geoquip, Inc.*, 637 F.3d 1324, 1336 (Fed. Cir. 2011). We explained that the patentee had

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[2] Amneal further argues that Patent Owner disavowed compositions that exhibit a "substantially constant rate" of release by arguing that their dissolution profiles "cannot be achieved with an IR/DR-only formulation as claimed in the Chang '740 patent." *See* J.A. 2552; J.A. 2545–46, 2553–54, 2562, 16910–12. We agree with Galderma that Amneal did not raise this estoppel argument before the district court. While Amneal did compare its product's dissolution profile to that of Sheth, it did not argue that Galderma disavowed products exhibiting a "substantially constant rate." *See* J.A. 5393–94 (arguing that its later-releasing portion "[a]chieves a different *result* than DR") (emphasis in original). The argument is therefore waived.

[3] Amneal also argues that the district court erred in determining that Galderma's doctrine of equivalents argument was not precluded due to the doctrines of amendment-based estoppel and claim vitiation. We see no error in the district court's decisions as to these doctrines.

"unambiguously argued" a particular construction during reexamination and, "regardless of whether the examiner agreed with American Piledriving's arguments concerning [the claim term], its statements still inform the proper construction." *Id.* *American Piledriving* is distinguishable for multiple reasons including that the statements were not made during *inter partes* review, the statements were used to inform claim construction not prosecution history disclaimer and our court did not find that the examiner had clearly and expressly rejected the patentee's proposed construction.

A prosecution history statement may inform the proper construction of a term without rising to the level of a clear and unmistakable disclaimer. *See, e.g.*, *Shire Dev., LLC v. Watson Pharm., Inc.*, 787 F.3d 1359, 1366 (Fed. Cir. 2015) ("Although the prosecution history statements do not rise to the level of unmistakable disavowal, they do inform the claim construction."). In *American Piledriving*, the claim language and specification compelled a particular construction and the statements made during prosecution merely served as additional support that "remove[d] all doubt" about the correct construction. *See* 637 F.3d at 1334–36. Here, in contrast, the claim construction is undisputed and the only question is whether a clear and unmistakable disclaimer bars a finding of infringement under the doctrine of equivalents. A person of ordinary skill in the art would not read the prosecution history in this case and conclude that the patent owner's claim construction that the Board expressly rejected was a clear and unmistakable surrender.

Having determined that the district court did not err in considering Galderma's doctrine of equivalents arguments, we now turn to the merits of the court's infringement finding. Amneal argues that Patent Owner's arguments during *inter partes* review preclude a finding of infringement as its theory contradicts every "substantial" difference it

identified during *inter partes* review. For example, Patent Owner argued that (1) release of the drug in the stomach from "leaky" SR portions was "substantially different" from the claimed DR portion, and (2) "substantially constant release" from SR-containing formulations was "significantly different" from the two-pulse dissolution of the claimed "IR/DR only" formulations. Amneal argues that its product has both. Galderma argues that Amneal's product is at least equivalent to the claimed invention under the district court's construction of DR as "release of a drug at a time other than immediately following oral administration." It argues that Amneal's product contains a portion of doxycycline that performs substantially the same function, in substantially the same way, to achieve substantially the same result as the DR portion claimed.

We review the district court's fact findings for clear error, and are not free to make a different finding on appeal.[4] *See Rolls-Royce Ltd. v. GTE Valeron Corp.*, 800 F.2d 1101, 1110 (Fed. Cir. 1986) ("This court does not sit to reweigh the evidence presented to the district court, nor will it draw its own inferences, nor make its own fact findings. It will not reverse unless the inferences drawn and facts found by the trial court are on the full record so unsupported as to have been the result of clear error."). The district court found that Amneal's product contains a DR portion of doxycycline and a separate portion of doxycycline that is not available for release until a time "other than

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[4] The district court considered the importance of the application of the correct burden of proof by the factfinder and concluded that "Galderma has proven infringement by a preponderance of the evidence." J.A. 75–76 n.8 ("[T]he Court, when sitting as factfinder, is called upon to make a determination based on the evidence presented, applying the appropriate burden of proof, even when there is strong evidence on both sides of the dispute.").

immediately following oral administration." J.A. 78. The district court found that these portions together satisfy the DR limitation. *Id.* Because the record evidence supports the district court's finding, we conclude that the district court did not clearly err in finding infringement under the doctrine of equivalents. Amneal's product is manufactured by layering doxycycline such that doxycycline releases at various intervals. *See* J.A. 5619–20 at B-61:1-B-64:5; J.A. 5621 at B-67:7–19; J.A. 5625 at B-83:21–84:11; J.A. 5627 at B-92:8–93:2; J.A. 5642 at B-153–54; J.A. 14524, 14531. Because a portion is prevented from releasing immediately, such later-releasing portion of doxycycline occurs "at a time other than immediately following oral administration." *See* J.A. 76 (citing J.A. 41 ¶ 85); *see also* J.A. 5658–59 at B-218:6–219:4. Therefore, this later-releasing portion, "in combination with [the DR portion of doxycycline], is insubstantially different from the 10 mg DR portion claimed in Chang." J.A. 78; *see also* J.A. 80–81 (concluding that Amneal's product's combination "performs the same function in the same way to achieve the same result as the 10 mg DR portion claimed in Chang."). In view of the evidence, we hold that the district court did not clearly err in finding infringement under the doctrine of equivalents with respect to the Chang Patents.

II

The Ashley II Patents

The district court further concluded that Amneal's product infringes the asserted claims of the Ashley II Patents under the doctrine of equivalents. Following argument in this court, Galderma filed a letter pursuant to Federal Rule of Appellate Procedure 28(j) alleging that this court lacks jurisdiction as to the Ashley II Patents based on actions taken by Amneal regarding its ANDA after filing its Notice of Appeal. We instructed the parties to submit supplemental briefing limited to this issue. Galderma alleges that this court should dismiss the appeal because

Amneal's actions divested this court of jurisdiction over the Ashley II Patents. Amneal argues that there remains a justiciable controversy between Galderma and Amneal concerning infringement of the Ashley II Patents.

A

We hold that Amneal's actions did not divest this court of subject matter jurisdiction. There is no dispute that the district court had subject matter jurisdiction when the action was filed. There is also no dispute that Amneal's appeal is from a "final decision of a district court . . . in a[] civil action arising under . . . an[] Act of Congress relating to patents . . ." and therefore that this court had jurisdiction at the time the Notice of Appeal was filed. 28 U.S.C. § 1295(a)(1). As the Supreme Court stated in *Caraco Pharmaceutical Laboratories, Ltd. v. Novo Nordisk, A/S*, "[t]he want of an infringing act is a merits problem, not a jurisdictional one." 566 U.S. 399, 412 n.5 (2012) (concluding that jurisdiction existed because the suit "'ar[ose] under a[n] Act of Congress relating to patents.' 28 U.S.C. § 1338(a)."). As such, this court retains jurisdiction over the judgment with respect to the Ashley II patents.

We further conclude that there remains a justiciable controversy between the parties such that the action is not moot. An action is moot when "events have eradicated the effects of a defendant's act or omission, and there is no reasonable expectation that the alleged violation will recur." *Ferring B.V. v. Watson Labs, Inc.-Fla.*, 764 F.3d 1382, 1391 (Fed. Cir. 2014). "In cases where a defendant voluntarily ceases the challenged practice, it is necessary for the court to determine whether 'there is no reasonable expectation that the wrong will be repeated.'" *Id.* (quoting *United States v. W.T. Grant Co.,* 345 U.S. 629, 633 (1953)). We have reviewed the parties' supplemental briefing and the current status of Amneal's ANDA. Because there is no question that the allegedly infringing conduct could

"reasonably be expected to recur," we have not been divested of jurisdiction and the action is not moot. *See Friends of the Earth, Inc. v. Laidlaw Envtl. Servs., Inc.*, 528 U.S. 167, 189 (2000). We therefore consider the issue of infringement under the doctrine of equivalents.

B

The Ashley II Patents are related to methods of treating acne or rosacea by oral administration of a low-dose doxycycline. Galderma asserted infringement of claims 3, 4, 5, 15, and 16 of the '506 patent and claims 13, 14, 15, and 16 of the '946 patent. Claim 15 of the '506 patent is illustrative:

> 15. A method for treating papules and pustules of rosacea in a human in need thereof, the method comprising administering orally to said human doxycycline, or a pharmaceutically acceptable salt thereof, in an amount of 40 mg per day, wherein the amount results in no reduction of skin microflora during a six-month treatment, without administering a bisphosphonate compound.

The district court construed "wherein the amount results in no reduction of skin microflora during a six-month treatment" as "wherein the amount results in no reduction of skin microflora vis-à-vis a placebo control during a six-month treatment, with microbiological sampling at baseline and month six." It found that Amneal's product infringes the asserted claims of the Ashley II Patents under the doctrine of equivalents and entered a judgment of infringement against Amneal.

Amneal appeals this judgment, arguing that Galderma presented no argument or evidence regarding the doctrine of equivalents as to the Ashley II Patents. It argues that allegations of infringement under the doctrine of equivalents require "particularized testimony and linking argument as to the 'insubstantiality of the differences' between

the claimed invention and the accused . . . process, or with respect to the function, way, result test . . . evidence must be presented on a limitation-by-limitation basis." Appellants' Br. 57 (citing *Texas Instruments Inc. v. Cypress Semiconductor Corp.*, 90 F.3d 1558, 1567 (Fed. Cir. 1996)). Galderma argues that it asserted infringement under the doctrine of equivalents in the pretrial order. It further argues that it presented evidence on why Amneal's product would not reduce skin microflora, and "particularized testimony and argument under the 'function-way-result' test as to why the 'sub-antibacterial amount' terms . . . were infringed under the doctrine of equivalents," which "applied equally to the overlapping subject matter of the 'skin microflora' terms." Appellees' Br. 54. Amneal responds that any argument was related to the "sub-antibacterial amount" limitation of the Ashley I patents[5] and the record does not support an assertion that Galderma's case on the "sub-antibacterial amount" limitations of other patents "applie[s] equally to the overlapping subject matter of the 'skin microflora' terms" here. Appellants' Reply Br. 23.

Galderma did not present particularized testimony and linking argument as to the reduction in skin microflora term. *See* J.A. 5477 (219:10–220:9, e.g., Q: So do you have an opinion as to whether Amneal's ANDA product has substantially the same function as a sub-antibacterial amount? A: Yes, it does . . . [b]ecause it functions the same way. It's not inhibiting organisms, not selecting flora resistance, not affecting the flora."). Rather, it presented testimony with respect to the "sub-antibacterial amount" limitation of the Ashley I patents and, now attempting to find support for the district court's finding, it alleges that

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[5] The Ashley I Patents are related patents. Although they were asserted in the district court below, they are not presently on appeal.

such testimony provides the necessary particularized testimony for the skin microflora terms as well. Because the record wholly lacked the requisite particularized testimony required to find infringement under the doctrine of equivalents, we reverse the district court's judgment.[6]

CONCLUSION

We have considered the parties' remaining arguments and find them unpersuasive. For the foregoing reasons, we affirm the district court's judgment as to infringement of the Chang Patents and reverse the district court's judgment as to infringement of the Ashley II Patents.

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[6] Alternatively, Galderma argues that in view of the substantial evidence and court's factual findings, we can affirm the district court's judgment because Amneal's product literally infringes. It argues, for example, that the asserted claims and specification (including the results of Example 38 from which the "no reduction of skin microflora" term was derived) expressly identify a 40 mg/day doxycycline dosage as an amount meeting the limitation. It further argues that Skidmore and Example 38 is "the strongest intrinsic evidence of what the patentee intended to convey with the skin microflora limitation." Amneal argues that Skidmore reports clinical results of a different twice-daily 20 mg formulation, not Amneal's once-daily product, and was limited to the forehead, while the "skin microflora" limitation requires no reduction on the skin generally. We see no clear error in the district court's finding that "it may be impossible to prove that absolutely no microflora in any part of the body is inhibited by administration of 40 mg doxycycline once daily," but "Skidmore, which reports on one area of the body . . . is insufficient to prove 'no reduction of skin microflora vis-à-vis a placebo' in all parts of the body and, thus, does not prove literal infringement." J.A. 89.

AFFIRMED-IN-PART AND REVERSED-IN-PART

COSTS

Each party shall bear its own costs.