No. 2019-1021

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

Appeal from the U.S. District Court for the District of Delaware,
Case No. 1:16-cv-00207-LPS, Chief Judge Leonard P. Stark

PETITION FOR REHEARING EN BANC

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CERTIFICATE OF INTEREST

Counsel for Defendants-Appellants Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals Co. (I) Pvt. Ltd. (n/k/a Amneal Pharmaceuticals Pvt. Ltd.) (collectively, "Amneal") certifies the following:

1. Full names of parties represented by me:

Amneal Pharmaceuticals LLC

Amneal Pharmaceuticals Co. (I) Pvt. Ltd.
(n/k/a Amneal Pharmaceuticals Pvt. Ltd.)

2. Name of real party in interest (Please only include any real party in interest NOT identified in Question 3) represented by me is:

N/A

3. Parent corporations and publicly held companies that own 10% or more of stock in the parties:

Amneal Pharmaceuticals LLC has one parent corporation, Amneal Pharmaceuticals, Inc. Amneal Pharmaceuticals, Inc. is a publicly held company that owns more than 10% (ten percent) of Amneal Pharmaceuticals LLC's stock.

Amneal Pharmaceuticals Co. (I) Pvt. Ltd. (n/k/a Amneal Pharmaceuticals Pvt. Ltd.) is a wholly owned subsidiary of Amneal Pharmaceuticals LLC (see above).

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court (and who have not or will not enter an appearance in this case) are:

Young, Conaway, Stargatt & Taylor, LLP: Anne S. Gaza, Samantha Wilson

Winston & Strawn LLP: Karalena M. Guerrieri, Ryan B. Hauer (no longer with the firm), Elizabeth E. Grden

5. The title and number of any case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. *See* Fed. Cir. R. 47.4(a)(5) and 47.5(b):

Galderma Labs., L.P. et al. v. Sun Pharm. Indus. Ltd., et al., No. 20-1152 (Fed. Cir.)

Galderma Labs., L.P. et al. v. Sun Pharm. Indus. Ltd., et al., No. 18-1588-LPS (D. Del.)

Galderma Labs., L.P. et al. v. Amneal Pharms., LLC, et al., No. 19-440-LPS (D. Del.)

Dated: April 23, 2020

/s/ George C. Lombardi
GEORGE C. LOMBARDI
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CIRCUIT RULE 35(b)(2) STATEMENT

Based on my professional judgment, I believe the panel decision is contrary to the following decisions of this Court: *Amgen Inc. v. Coherus BioSciences Inc.*, 931 F.3d 1154 (Fed. Cir. 2019); *Aylus Networks, Inc. v. Apple Inc.*, 856 F.3d 1353 (Fed. Cir. 2017); *Fenner Invs., Ltd. v. Cellco P'ship*, 778 F.3d 1320 (Fed. Cir. 2015); *Am. Piledriving Equip., Inc. v. Geoquip, Inc.*, 637 F.3d 1324 (Fed. Cir. 2011); *PODS, Inc. v. Porta Stor, Inc.*, 484 F.3d 1359 (Fed. Cir. 2007); *Springs Window Fashions LP v. Novo Indus., L.P.*, 323 F.3d 989 (Fed. Cir. 2003); *Southwall Techs., Inc. v. Cardinal IG Co.*, 54 F.3d 1570 (Fed. Cir. 1995).

Based on my professional judgment, I believe this appeal requires an answer to the following precedent-setting question of exceptional importance:

> Do clear and unmistakable arguments by a patentee during prosecution create an estoppel, regardless of whether the Patent Office agreed with the patentee's arguments?

/s/ George C. Lombardi
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Attorney of Record for
Defendants-Appellants

INTRODUCTION

Amneal seeks rehearing of a panel decision that conflicts with the settled law of this Court that clear and unambiguous disclaimers of claim scope during prosecution can create an estoppel, *regardless* of whether the Patent Office agrees with those disclaimers. In breaking with this Court's precedent, the panel created an exception to the doctrine of prosecution-history estoppel, which will obscure the boundaries of patented inventions, complicate litigation, and discourage innovation by competitors. Rehearing *en banc* is needed.

The panel recognized that "'statements made by a patent owner'" during either patent examination or IPR proceedings "'support a finding of prosecution disclaimer' so long as the statements are 'both clear and unmistakable.'" Op. 6 (quoting *Aylus Networks, Inc. v. Apple Inc.*, 856 F.3d 1353, 1361-62 (Fed. Cir. 2017)). But the panel split from this Court's previous decisions when it then held—without citing any precedent—that patentees are "not precluded by these statements from asserting the doctrine of equivalents" if the patentee's "statements were clearly and expressly rejected by the Patent Office." Op. 7.

The panel's new rule that a patentee's rejected arguments cannot create an estoppel is contrary to this Court's previous rulings that a patentee's clear and unmistakable statements *can* result in prosecution-history estoppel "*regardless* of whether the examiner agreed with [the patentee's] arguments." *Am. Piledriving*

Equip., Inc. v. Geoquip, Inc., 637 F.3d 1324, 1336 (Fed. Cir. 2011) (emphasis added). Until now, this Court had repeatedly held that what the Patent Office says (or does not say) about a patentee's statements is irrelevant to prosecution-history estoppel. "Clear assertions made during prosecution in support of patentability, *whether or not actually required to secure allowance* of the claim, may … create an estoppel." *PODS, Inc. v. Porta Stor, Inc.*, 484 F.3d 1359, 1368 (Fed. Cir. 2007) (emphasis added); *see also Springs Window Fashions LP v. Novo Indus., L.P.*, 323 F.3d 989, 995 (Fed. Cir. 2003) (holding that "the examiner's remarks do not negate the effect of the applicant's disclaimer").

These principles are consistent with the equally well-established principle that "[t]he public notice function of a patent and its prosecution history requires that a *patentee be held to what he declares* during the prosecution of his patent. A patentee may not state during prosecution that the claims do not cover a particular device and then change position and later sue a party who makes that same device for infringement." *Springs Window*, 323 F.3d at 995 (emphasis added); *see also Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1124 (Fed. Cir. 2004) ("It is well settled … that it is the *applicant*, not the examiner, who must give up or disclaim subject matter that would otherwise fall within the scope of the claims."); *PODS, Inc.*, 484 F.3d at 1368 ("The relevant inquiry is

whether a competitor would reasonably believe that *the applicant* had surrendered the relevant subject matter.") (emphases added).

This precedent reflected a system in which the public had a right to rely on an inventor's statements about the invention, "without attempting to decipher whether the examiner relied on them, or how much weight they were given." *Fenner Invs., Ltd. v. Cellco P'ship*, 778 F.3d 1320, 1325 (Fed. Cir. 2015). That system placed all risk associated with prosecution disclaimers on the patentee, who is in the best position to know what the invention is (and is not), and to weigh the risk of deciding to surrender claim scope. That system provided needed certainty for competitors trying to innovate and design around patented inventions.

The panel decision dismantles that system. It forces parties and courts to now litigate disputes about what the Patent Office "accepts" or "rejects," and whether any "rejection" of a disclaimer is sufficiently clear and express to avoid an estoppel. The decision also places on the public the risk that an unmistakable disavowal of claim scope during Patent Office proceedings might be rejected years later by a reviewing authority such as the PTAB, this Court, or the Supreme Court. And the decision will severely hamper the ability of competitors to bring innovative, design-around products to market, for fear that a patentee's clear and unmistakable disavowal of claim scope will be "rejected."

Amneal thus respectfully requests *en banc* rehearing to restore the rule that a patentee must be held to its statements during prosecution, regardless of whether the Patent Office agrees with those statements.

BACKGROUND

The facts relevant to this petition are undisputed and supported by the panel decision. Galderma's "Chang" patents relate to compositions of a drug called doxycycline, which Galderma markets as ORACEA® for the treatment of a skin disorder called rosacea. The Chang claims generally cover doxycycline compositions with two components: an immediate-release ("IR") portion and a delayed-release ("DR") portion. Op. 3.

Several years before this litigation began, Amneal initiated *inter partes* review proceedings to invalidate the Chang patents as obvious. *Id*. Amneal asserted that the claimed DR portion was disclosed in a prior-art reference called Sheth, in the form of "slow-release pellets that *begin dissolving in the stomach*." Op. 3-4 (emphasis added). Galderma distinguished this aspect of Sheth by repeatedly arguing that Chang's DR portion requires "no substantial release" of doxycycline in the stomach. Op. 4. For example, Galderma argued that:

- Chang's DR portion "requires ***no substantial release*** … until after the DR portion passes through the acidic stomach";
- Chang's DR portion has "***no substantial release*** of doxycycline in the acidic stomach environment";

- Sheth "shows a substantial portion is dissolving in the acidic environment of the stomach," which is "not delayed release"; and
- Sheth's approach "is substantially different from the claimed IR/DR formulations …, and in fact would ***teach away*** from the claimed formulations."

Id.

The Board, however, held "that the broadest reasonable construction of 'delayed release,'… is *not* limited to formulations requiring that there be no substantial release in the stomach." *Id*. (emphasis added). The Board then upheld the Chang patents as valid under this broader construction of DR. Op. 5.

Meanwhile, Amneal relied on Galderma's public IPR statements about the DR portion to design a generic doxycycline product that would not infringe the Chang patents. Instead of using a DR portion with "no substantial release of doxycycline in the acidic stomach environment," Op. 4, Amneal designed its product with a portion that undisputedly "releases in the acidic environment of the stomach." Appx46. Despite this uncontested fact, Galderma sued Amneal and argued that the product infringed the DR limitation under the doctrine of equivalents. Amneal responded, in part, that Galderma was precluded from making that argument by the doctrine of argument-based estoppel, stemming from Galderma's clear and unmistakable description of the DR portion in the IPR. The district court rejected Amneal's arguments and found infringement under the doctrine of equivalents. Op. 5.

On appeal, the panel acknowledged that "'statements made by a patent owner during an IPR proceeding can … support a finding of prosecution disclaimer' so long as the statements are 'both clear and unmistakable.'" Op. 6 (quoting *Aylus*, 856 F.3d at 1361-62). The panel did not disagree that Galderma's IPR statements met this standard. Judge Moore, who authored the decision, agreed at oral argument that Galderma's statements were "clear as day," that they would be "hands down, [a] disclaimer" "if they were all that were in the record," and that "there's no doubt … that all of those statements amount to disclaimer if [read] in isolation." Oral Arg. Recording 1:20-33, 11:03-09, 2:24-30.

Nevertheless, the panel concluded that Galderma's "clear and limiting statements" did not constitute a disclaimer "in this case where those statements were clearly and expressly rejected by the Patent Office." Op. 7. According to the panel, "[b]ecause the record makes clear to a skilled artisan that Patent Owner's arguments were rejected, those arguments do not impact claim scope." *Id*. The panel did not cite any precedent for the purported rule that a patentee's rejected arguments "do not impact claim scope." *Id*.

ARGUMENT

I. Rehearing is needed because the panel decision conflicts with precedent.

A. Contrary to the panel decision, this Court has repeatedly held that a patentee's clear and unmistakable arguments create an estoppel regardless of whether the Patent Office agrees with them.

The panel decision conflicts with this Court's case law holding that clear and unmistakable disclaimers during prosecution create an estoppel *even if* the Patent Office disagrees with the patentee's statements.

American Piledriving exemplifies this law. The patentee in that case argued that a disclaimer it made during prosecution was not binding in a later infringement suit because "the examiner explicitly disagreed with" the disclaimer. 637 F.3d at 1336. This Court, however, held that the patentee's disclaimer was binding "regardless of whether the examiner agreed with [the patentee's] arguments." *Id*. The Court reiterated that a patentee "cannot attempt to distance itself from the disavowal of broader claim scope" by contending that the disavowal was rejected. *Id*. Yet that is exactly what the panel's new rule allows patentees to do.

Similarly, in *Springs Window*, the patentee argued that its prosecution statements were not binding in subsequent litigation because "the examiner did not agree" with them. 323 F.3d at 994. Again, however, this Court held that "the examiner's remarks do not negate the effect of the applicant's disclaimer." *Id*. at 995. As the Court explained, "it is not surprising that an examiner would not be satisfied with the applicant's insistence that particular claim language distinguishes

a prior art reference, but that a court would later hold the patentee to the distinction he pressed during prosecution." *Id*. Regardless of whether the Patent Office agrees or not, "[t]he public notice function of a patent and its prosecution history *requires that a patentee be held to what he declares* during the prosecution of his patent. A patentee may not state during prosecution that the claims do not cover a particular device and then change position and later sue a party who makes that same device for infringement." *Id.* (emphasis added).

These rulings follow the settled principle that prosecution disclaimer turns on what the patentee says, not what the Patent Office says. "It is well settled … that it is the applicant, not the examiner, who must give up or disclaim subject matter that would otherwise fall within the scope of the claims." *Innova/Pure Water*, 381 F.3d at 1124. "The relevant inquiry is whether a competitor would reasonably believe that *the applicant* had surrendered the relevant subject matter." *PODS*, 484 F.3d at 1368 (emphasis added).

Likewise, this Court has repeatedly held that "[c]lear assertions made during prosecution in support of patentability, *whether or not actually required to secure allowance* of the claim, may also create an estoppel" that limits the doctrine of equivalents. *PODS*, 484 F.3d at 1368 (emphasis added) (quoting *Southwall Techs., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1583 (Fed. Cir. 1995)); *accord Amgen Inc. v. Coherus BioSciences Inc.*, 931 F.3d 1154, 1159 (Fed. Cir. 2019). Thus, the fact

that a patentee's arguments were "not actually required" by the Patent Office cannot avoid an estoppel. *Id.*[1]

The panel's holding that a patentee's arguments "do not impact claim scope" if they "were rejected [by the Patent Office]" contradicts this precedent, no matter how "clearly and expressly [the patentee's arguments are] rejected." Op. 7. Tellingly, the panel cited no case for its new rule. The only support cited by the panel in its entire discussion of this issue is the general principle recited in *Wang Labs., Inc. v. Toshiba Corp.*, 993 F.2d 858, 867 (Fed. Cir. 1993), that "[t]he prosecution history must be examined as a whole in determining whether estoppel applies." Op. 6. But that principle does not allow courts to ignore clear and unmistakable arguments by patentees when those statements are rejected by the Patent Office. Nothing in *Wang* supports that result.

The Court in *Wang* only assessed what the *applicant* said during prosecution, not what the examiner said. And the Court restated the principle—

[1] Years before this precedent, the Court stated in dicta that "[a]lthough actual reliance by the examiner need not be shown, if an estoppel is to rest upon argument made during the examination process, the circumstances must be such as to permit the inference that such reliance in fact occurred." *Zenith Labs., Inc. v. Bristol-Myers Squibb Co.*, 19 F.3d 1418, 1425 n.8 (Fed. Cir. 1994). Neither Galderma nor the panel cited *Zenith*, presumably because it is no longer good law given the contrary precedent discussed above. To the extent *Zenith* remains as precedent, however, this case is an excellent vehicle for the *en banc* Court to reconcile the conflict between *Zenith* and later cases which hold that reliance by the Patent Office is not required. *See* Fed. R. App. P. 35(a)(1) (rehearing *en banc* is warranted if "necessary to secure or maintain uniformity of the court's decisions").

consistent with *American Piledriving* and *Spring Windows*—that "[a] patent attorney should not be able … to choose one course of action within the PTO with the anticipation that, if later checked, he or she can always choose an alternate course of prosecution in a trial before a federal judge." 993 F.2d at 868. Yet that is exactly what the panel decision here allows patentees to do: disavow claim scope when that is helpful to show patentability in the Patent Office, and then reclaim that scope during litigation when that is helpful to show infringement.

B. The holding of *American Piledriving* cannot be distinguished.

Under *American Piledriving*, among other precedent discussed above, the panel should have found that a patentee's arguments to the Patent Office are binding "regardless of whether the examiner agreed with" them. 637 F.3d at 1336. The panel's attempts to distinguish this precedent lack merit.

First, the panel noted that the patentee's statements in *American Piledriving* "were not made during *inter partes* review," but instead were made during initial prosecution. Op. 8. That is irrelevant. This Court rejected that distinction in *Aylus*, which confirmed that "statements made by patent owners during an IPR can be considered for prosecution disclaimer," just like statements made during initial prosecution. 856 F.3d at 1361.

Second, the panel noted that the patentee's "statements were used to inform claim construction[,] not prosecution history disclaimer" under the doctrine of

equivalents. Op. 8. That is also irrelevant. Just as a patentee's arguments during prosecution can narrow the construction of a claim term, the doctrine of prosecution-history estoppel "limits the range of equivalents available to a patentee by preventing recapture of subject matter surrendered during prosecution of the patent." *PODS*, 484 F.3d at 1367 (quotation omitted). Indeed, this Court applies "the same standard" to prosecution statements by patentees in the context of prosecution-history estoppel as it does for claim construction. *Omega Eng'g, Inc., v. Raytek Corp.*, 334 F.3d 1314, 1326 n.1 (Fed. Cir. 2003).

Applying that same standard, this Court has consistently held that "[t]he same distinctions of the prior art that inform the claim construction … give rise to prosecution history estoppel." *Ballard Med. Prods. v. Allegiance Healthcare Corp.*, 268 F.3d 1352, 1363 (Fed. Cir. 2001); *see also Spectrum Int'l, Inc. v. Sterilite Corp.*, 164 F.3d 1372, 1380 (Fed. Cir. 1998) (after construing claims based on prosecution statements, holding that the same statements "trigger application of prosecution history estoppel, precluding infringement under the doctrine of equivalents as a matter of law").

A contrary result would defeat the purpose of prosecution-history estoppel. If an argument that is rejected by the Patent Office can constitute disclaimer in the context of construing a claim term (as *American Piledriving* holds), it must also limit the range of equivalents associated with that term. Otherwise, the narrowed

claim construction would be meaningless, as the patentee would always be able to recapture surrendered scope under the doctrine of equivalents.

Third, although the patentee in *American Piledriving* argued that its statement did not constitute a disclaimer because "the examiner explicitly disagreed with it," 637 F.3d at 1336, the panel noted that the Court in *American Piledriving* "did not *find* that the examiner had clearly and expressly rejected the patentee's proposed construction." Op. 8 (emphasis added). But there was no need for the Court to make any finding about what the examiner said, because "whether the examiner agreed with [the patentee's] arguments" is legally irrelevant. 637 F.3d at 1336. The Court confirmed as a matter of law that a patentee "cannot attempt to distance itself from the disavowal of broader claim scope" by alleging that its argument was rejected. *Id*.

Fourth, the panel noted that "[a] prosecution history statement may inform the proper construction of a term without rising to the level of a clear and unmistakable disclaimer," and that "[i]n *American Piledriving*, the claim language and specification compelled a particular construction and the statements made during prosecution merely served as additional support." Op. 8. But *American Piledriving* was not a situation where a patentee's statement merely "inform[ed] the proper construction of a term." The Court in that case found "a clear and unmistakable disclaimer," *id*., without regard for whether the examiner adopted or

rejected it. 637 F.3d at 1336. The panel here departed from that precedent by making a new and unsupported rule that arguments cannot be disclaimers if the Patent Office rejects them.

II. Left uncorrected, the panel decision will undermine the public notice function of the file history, create uncertainty, and hinder the ability to design around claimed inventions.

Until now, this Court had held that "[c]ompetitors are entitled to rely on" patentee representations in both initial prosecution and IPRs "when determining a course of lawful conduct, such as launching a new product or designing around a patented invention." *Aylus*, 856 F.3d at 1359 (quotation omitted). This principle "promotes the public notice function of the intrinsic evidence and protects the public's reliance on definitive statements made during prosecution." *Id*. (quotation omitted).

The panel decision undermines that policy and penalizes competitors who rely on patentees' clear and unmistakable representations about the scope of their inventions. By allowing patentees to walk away from clear statements about the scope of their claims in litigation, the decision threatens to "undercut the public's reliance on a statement that was in the public record and upon which reasonable competitors formed their business strategies." *Springs Window*, 323 F.3d at 995 (quotation omitted). In place of that system of notice and reliance, the decision creates "[a] zone of uncertainty which enterprise and experimentation may enter

only at the risk of infringement claims." *United Carbon Co. v. Binney & Smith Co.*, 317 U.S. 228, 236 (1942). For at least two reasons, this result will harm competitive efforts to design around claimed inventions.

First, the panel's decision ignores the reality that how the Patent Office views an inventor's arguments—*i.e.*, acceptance, rejection, or anything in between—is often contested. In many cases, there is no way to know what the examiner thought. Even in cases where the Patent Office's view is ultimately deemed "clear," it may take years of litigation to get to that point, because reasonable litigants may disagree on what is sufficiently "clear." That is why, until now, this Court held that "the interested public has the right to rely on the inventor's statements made during prosecution, without attempting to decipher whether the examiner relied on them, or how much weight they were given." *Fenner Invs.*, 778 F.3d at 1325. Under the panel decision, courts and competitors will bear the burden of trying to "decipher" the Patent Office's assessment of the inventor's clear and unmistakable statements. The added expense and uncertainty of this new rule will complicate litigation and, ultimately, chill competition.

Second, the panel decision ignores the fact that any "rejection" or "acceptance" by the Patent Office lacks finality because of the appeals process. For instance, an examiner may reject a patentee's argument, only to be reversed by the Board, which may accept it. The Board, too, can reverse itself on rehearing, or

be reversed by this Court, which can also revisit its own decisions or be reversed by the Supreme Court. Ultimately, decisions may be remanded to the Patent Office for further proceedings, where the evaluation of a patentee's arguments may change. Or, the case may settle, and a final resolution may never be clear. In the meantime, there may be parallel proceedings (for instance, parallel IPR and district court proceedings) where two tribunals come to two different conclusions about acceptance or rejection of an inventor's statements. That is why the right to rely on the inventor's statements is critically important to the disclaimer analysis: the only relevant question is "what did *the inventor* say its invention is?"

The panel decision thus changes who bears the risk associated with an inventor's clear and unmistakable statements about what the invention is and is not. Until now, inventors bore the sole risk that such statements would constitute disavowal of claim scope and create an estoppel. That makes sense: the inventor is in the best position to say what its invention is. Now, however, competitors—*i.e.*, the "interested public," *Fenner Investments*, 778 F.3d at 1325—will bear the risk of uncertainty over (i) whether a patentee's clear and unmistakable statements about its invention were "rejected" in the first instance; and (ii) whether any such "rejection" will be upheld in years of possible future proceedings.

As one example, the Board could accept a patentee's argument about a claim term in an IPR. Competitors may then rely on that accepted argument to design

noninfringing alternatives. But if this Court in a decision two years later rejects the patentee's argument while upholding the patent, that argument will no longer estop the patentee from asserting infringement under the panel decision. The patentee will get the windfall of winning both an IPR and an infringement suit, while the competitor is punished for relying on what the patentee said about its invention.

Without clear boundaries to the patent grant and with all risk shifted to competitors, those competitors will be discouraged from attempting to design around claimed inventions. That can only have the effect of dampening innovation and reducing alternatives for industry and consumers.

Amneal thus seeks rehearing to restore a system where patentees—who are in the best position to weigh the benefits and risks of making disclaimers—are held to their unambiguous statements, regardless of what can be deciphered from the assessments of various reviewing bodies in years of subsequent proceedings.

CONCLUSION

Rehearing *en banc* should be granted.

Respectfully submitted,

/s/ George C. Lombardi

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April 23, 2020

ADDENDUM

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.

CERTIFICATE OF SERVICE

I certify that on April 23, 2020, the foregoing petition was electronically filed using the Court's CM/ECF filing system. All counsel of record were electronically served by and through the Court's CM/ECF filing system per Federal Rule of Appellate Procedure 25 and Circuit Rule 25.

Dated: April 23, 2020

/s/ George C. Lombardi
GEORGE C. LOMBARDI
Attorney of Record for
Defendants-Appellants

CERTIFICATE OF COMPLIANCE

This petition complies with the type-volume limitation of Federal Rule of Appellate Procedure 35(b)(2)(A) because it contains 3,883 words.

This petition complies with the type-face and type-style requirements of Federal Rules of Appellate Procedure 32(a)(5), 32(a)(6), and 32(c)(2). This petition has been prepared in a proportionally spaced typeface using Microsoft Office Word Version 2016 in 14-point Times New Roman.

Dated: April 23, 2020

/s/ George C. Lombardi
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