NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

NOVARTIS PHARMACEUTICALS CORPORATION,
Plaintiff-Appellant

v.

MSN PHARMACEUTICALS, INC., MSN LABORATORIES PRIVATE LTD., MSN LIFE SCIENCES PRIVATE LTD.,
Defendants-Appellees

GERBERA THERAPEUTICS INC., NANJING NORATECH PHARMACEUTICAL CO., LIMITED,
Defendants

2024-2211, 2024-2212

Appeals from the United States District Court for the District of Delaware in Nos. 1:20-md-02930-RGA, 1:22-cv-01395-RGA, Judge Richard G. Andrews.

Decided: December 4, 2024

DEANNE MAYNARD, Morrison & Foerster LLP, Washington, DC, argued for plaintiff-appellant. Also represented by SETH W. LLOYD; JOEL F. WACKS, San Francisco, CA; REBECCA EMILY WEIRES, Los Angeles, CA;

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Before LOURIE, PROST, and REYNA, *Circuit Judges*.

LOURIE, *Circuit Judge*.

Novartis Pharmaceuticals Corporation ("Novartis") appeals from the district court's denial of its motion for a preliminary injunction. Novartis seeks to enjoin MSN Pharmaceuticals, Inc., MSN Laboratories Private Ltd., and MSN Life Sciences Private Ltd. (collectively, "MSN") from launching its generic version of Entresto®, which Novartis alleges would infringe U.S. Patent 11,096,918 ("the '918 patent"). *In re Entresto (Sacubitril/Valsartan) Pat. Litig.*, No. 20-md-2930, 2024 WL 3756787 (D. Del. Aug. 12, 2024) ("*Preliminary Injunction Order*"). For the following reasons, we *affirm*.

BACKGROUND

I

In 2015, the U.S. Food and Drug Administration ("FDA") approved Novartis's New Drug Application ("NDA") for Entresto, a combination therapy of valsartan and sacubitril. Entresto is indicated "to reduce the risk of cardiovascular death and hospitalization for heart failure in adult patients with chronic heart failure, and for the treatment of symptomatic heart failure with systemic left ventricular systolic dysfunction in pediatric patients aged one year and older." *Id.* at *1 (quoting J.A. 51 ¶ 113). In

2023 alone, sales of Entresto in the United States totaled more than $3 billion.

The '918 patent, which is owned by Novartis and expires on November 8, 2026, is directed to an amorphous solid form of trisodium valsartan sacubitril, or "TVS." The patent contains two claims, which recite:

> 1. An amorphous solid form of a compound comprising anionic [valsartan], anionic [sacubitril], and sodium cations in a 1:1:3 molar ratio.
>
> 2. A pharmaceutical composition comprising the amorphous solid form according to claim 1 and at least one pharmaceutically acceptable excipient.

'918 patent, col. 32 ll. 42–49.

Important here, the '918 patent is not listed in the Orange Book for Entresto. Indeed, Novartis concedes that the '918 patent does not claim the drug product present in Entresto. *See* Oral Arg. at 2:48–52, *available at* https://oralarguments.cafc.uscourts.gov/default.aspx?fl=24-2211_11132024.mp3 ("[W]e have not listed [the '918 patent] in the Orange Book; we don't claim that we practice this patent."). Because the '918 patent is not Orange Book-listed, the filing of Novartis's complaint did not trigger a statutory stay barring the FDA from approving any Abbreviated New Drug Applications ("ANDAs") filed by drugmakers seeking to manufacture and sell generic versions of Entresto.

II

In 2019, MSN, among others, submitted its ANDA for Entresto. Novartis responded, in part, by filing a complaint under 35 U.S.C. § 271(e)(2), alleging that each manufacturer's generic product would infringe the '918 patent because it contains amorphous TVS. J.A. 22–65. The case proceeded to discovery.

A. Claim Construction

At claim construction, the parties disputed the meaning of only a single claim term: "an amorphous solid form of a compound." *In re Entresto (Sacubitril/Valsartan) Pat. Litig.*, No. 20-md-2930, 2024 WL 2804788, at *2 (D. Del. May 31, 2024) ("*Claim Construction Order*"). Novartis argued that the term did not require any construction, while MSN argued that the term means "a substantially pure amorphous solid form of a compound." *Id.* That is, the parties disputed the amount of amorphous TVS in the compound relative to the amount of any other non-amorphous TVS component (*e.g.*, crystalline TVS) required by the claim. *Id.*; *see also id.* at *2 n.6.

The court determined that Novartis's position, that *any* presence of amorphous TVS in a solid form would fall within the scope of the claims, "conflict[ed] with the prosecution history," which established that amorphous and crystalline TVS exhibit different properties and are readily distinguishable. *Id.* at *3. In the court's view, a compound that contained only a small amount of amorphous TVS would not "embody" the "certain distinctive properties" of amorphous TVS, but instead those "properties associated with a crystalline solid." *See id.* at *4. It therefore concluded that "amorphous TVS" is mutually exclusive from "crystalline TVS." *Id.* at *3.

But the court likewise took issue with MSN's position that the claimed amorphous compound must be "substantially pure." MSN had relied on language in the specification that the solid form of TVS "can be in the crystalline, partially crystalline, [or] amorphous . . . form," *see* '918 patent, col. 17 ll. 43–45, to argue that, just as amorphous TVS is mutually exclusive of crystalline TVS, it must be mutually exclusive of "partially crystalline" TVS, which the parties agreed "is a mixture of crystalline and amorphous forms." *Claim Construction Order*, at *3. The court disagreed with MSN's construction, noting that there was no

intrinsic evidence that suggested each category to be mutually exclusive. *Id.* The court also cited the parties' agreed understanding of "partially crystalline," which suggested "potential overlap along the spectrum of amorphous, partially crystalline, and crystalline forms." *Id.*

Although the court rejected MSN's proposal, it agreed that "construction of the disputed term must distinguish between the amorphous and crystalline forms." *Id.* It therefore construed "an amorphous solid form of a compound" to mean:

> a solid form of a compound in which the amorphous form of the compound *predominates*. An amorphous solid form is mutually exclusive from a crystalline solid form, but not necessarily mutually exclusive from a partially crystalline form.

Id. at *2 (emphasis added). In doing so, the court "concede[d] the difficulty of pinpointing an appropriate limitation when the intrinsic record provides virtually no useful guidance." *Id.* at *4; *see id.* (rejecting MSN's "substantially pure" construction because "[a] determination that a construction of the terms should include line-drawing . . . is an insufficient reason to adopt a specific demarcation that is unsupported by the intrinsic record"). But given the court's understanding that the claimed amorphous TVS must be distinct from and exhibit different properties from crystalline TVS, it determined that "it follows that an amorphous solid form of a compound must be predominantly amorphous." *Id.*

B. Preliminary Injunction

On July 24, 2024, the FDA granted final approval of MSN's ANDA, clearing the way for an at-risk launch of MSN's valsartan-sacubitril product, which MSN claims includes crystalline TVS, or "Form-S." *Preliminary Injunction Order*, at *1–2. Novartis responded by moving the district court to preliminarily enjoin MSN from launching

its product "for the short time needed to [reach] final judgment" in this litigation. Novartis Br. 1; *see also* J.A. 2467–91.[1]

In its motion, Novartis argued that it was likely to succeed in establishing that MSN's generic product contains the claimed amorphous TVS, and therefore infringes claim 1 of the '918 patent. *See Preliminary Injunction Order*, at *2. Novartis argued that testing by its expert, Dr. Matzger, showed that, contrary to MSN's characterization of its product as crystalline TVS, the product is actually a physical mixture of crystalline valsartan and crystalline sacubitril, with regions of amorphous TVS formed during the manufacturing process. *Id.* That is, in Novartis's view, Form-S is not crystalline TVS at all, but merely a physical mixture of separate crystalline components. Novartis argued that Dr. Matzger found that the Raman spectra for various regions of MSN's final product matched the reference spectra for each of crystalline valsartan, crystalline sacubitril, and amorphous TVS. *Id.*; *see also* Novartis's Br. 16–17. Accordingly, in Novartis's view, "the amorphous TVS compound [in MSN's product] therefore necessarily predominates over the (non-existent) crystalline TVS compound," and thus infringes. *Preliminary Injunction Order*, at *2; *see also* J.A. 2476.

MSN countered that Novartis is not likely to succeed in establishing that MSN's product contains any amorphous TVS. *Preliminary Injunction Order*, at *2. It first challenged Novartis's expert testing on the basis that Dr. Matzger "made no attempt to distinguish the amorphous material he supposedly found [in MSN's product] from Form-S," *i.e.*, crystalline TVS. J.A. 6374. Had that comparison been made, MSN argued, it would have been "clear that the peaks [Dr.] Matzger found [for the allegedly

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[1] This case is currently scheduled to go to trial on December 9, 2024.

amorphous TVS in MSN's product] align closely with the Form-S reference." J.A. 6376. MSN also argued that Novartis could not establish that Form-S is a physical mixture of separate crystalline components, as opposed to crystalline TVS. In support, MSN pointed to the testing data it had submitted to the FDA with its ANDA, which it argued demonstrates that Form-S is a crystalline compound. *Preliminary Injunction Order*, at *3; *see* J.A. 6379–81.

Considering the evidence and testimony of both parties, the district court concluded that Novartis had not met its burden of showing that it is likely to succeed in proving that MSN's ANDA product contains amorphous TVS. *Preliminary Injunction Order*, at *2. It noted that, even if Novartis was correct that Form-S is a physical mixture of crystalline valsartan and crystalline sacubitril, it had not adequately established that the amorphous regions of MSN's product identified by Dr. Matzger are actually amorphous TVS. *Id.* It further found that, with respect to whether Form-S is crystalline TVS or a physical mixture of crystalline valsartan and crystalline sacubitril, that "[i]n the face of supporting test data and what appear to be valid criticisms of said test data from both sides, I am unable to find that the record favors finding Form-S to be one of a physical mixture or a crystalline complex." *Id.* at *3. Because Novartis bore the burden of proof on that issue, the court determined that it had not established that Form-S is a physical mixture and not crystalline TVS.

The district court also concluded that Novartis had failed to establish that it would suffer irreparable harm absent an injunction. *Id.* at *3–4. It was unmoved by Novartis's arguments that its damages could not be remedied through monetary damages, and it found it inappropriate to attribute any loss in Entresto's market momentum to MSN when that loss would be the result of actions taken not only by MSN, but also by other generic drugmakers launching a competing product. *Id.* at *3.

Though its findings on likelihood of success and irreparable harm alone called for the denial of Novartis's request for injunctive relief, the court nevertheless addressed the balance of equities and public interest in the preliminary injunction inquiry and found that neither favored enjoining MSN's launch. *Id.* at *4. It therefore denied Novartis's motion for a preliminary injunction.

Novartis timely appealed. We have jurisdiction under 28 U.S.C. § 1292(c)(1).

DISCUSSION

"A preliminary injunction is an extraordinary remedy never awarded as of right." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 24 (2008). To establish a right to a preliminary injunction, a party "must make a clear showing that '[it] is likely to succeed on the merits, that [it] is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in [its] favor, and that an injunction is in the public interest." *Starbucks Corp. v. McKinney*, 602 U.S. 339, 346 (2024) (quoting *Winter*, 555 U.S. at 20).

We review a district court's denial of a preliminary injunction for abuse of discretion, and its underlying factual findings for clear error. *Takeda Pharms. U.S.A., Inc. v. Mylan Pharms. Inc.*, 967 F.3d 1339, 1345 (Fed. Cir. 2020). "To the extent a decision to grant [or deny] a preliminary injunction rests on questions of law, including claim construction, our review is *de novo*." *Tate Access Floors, Inc. v. Interface Architectural Res., Inc.*, 279 F.3d 1357, 1364 (Fed. Cir. 2002) (citations omitted). In other words, "[a]n abuse of discretion in granting or denying a preliminary injunction may be found 'by showing that the court made a clear error of judgment in weighing relevant factors or exercised its discretion based upon an error of law or clearly erroneous factual findings.'" *Abbott Lab'ys v. Andrx Pharms., Inc.*, 452 F.3d 1331, 1335 (Fed. Cir. 2006)

(quoting *Novo Nordisk of N. Am., Inc. v. Genentech, Inc.*, 77 F.3d 1364, 1367 (Fed. Cir. 1996)).

On appeal, Novartis contends that "the only fault that the district court found with [Dr. Matzger's] testing was that he should have compared his Raman spectra to the reference spectra for MSN's isolated API [*i.e.*, active pharmaceutical ingredient]." *See* Oral Arg. at 8:51–9:00; *see also* Novartis Br. 32–35. That conclusion, Novartis argues, was infected by clear error because "comparing Raman mapping of MSN's final products to a reference spectrum from MSN's isolated API would just beg the question of whether MSN's isolated API itself contains amorphous TVS." Novartis Br. 33. Novartis argues that the comparison "demand[ed]" by the district court would not resolve the relevant inquiry: whether MSN's *final product* contains amorphous TVS. *Id.* at 32. We disagree.

As an initial matter, we do observe that the district court stated that "MSN notes that Dr. Matzger did not compare the spectra he obtained from MSN's API to Form-S reference spectra," and that "MSN asserts that, when the comparison is made between MSN's API spectra and the Form-S reference spectra, the peaks in MSN's API spectra that Dr. Matzger points to as proving the presence of amorphous TVS more closely match the peaks in MSN's Form-S reference spectra than those in amorphous reference spectra." *Preliminary Injunction Order*, at *2. That is, the court did, as Novartis asserts, appear to characterize MSN's argument as a failure of Novartis to compare the spectra from MSN's *API*—not MSN's final product—with a Form-S reference spectrum. We generally agree with Novartis's contention that that comparison would not be dispositive of the ultimate infringement inquiry, which requires a showing that MSN's *final product* contains amorphous TVS. *See* Oral Arg. at 9:05–17 (counsel for Novartis arguing that "[t]hat comparison would be beside the point because our view is that it's not the API that has the

amorphous [TVS], it's the finished products that we accuse and that is created in the tableting process." (cleaned up)).

However, a closer review of the record establishes that MSN did *not* argue to the district court that Novartis had failed to compare the spectra obtained from MSN's API with a Form-S reference spectrum. Instead, its argument was that Novartis had failed to compare the spectra Dr. Matzger obtained from MSN's *final product* with a Form-S reference spectrum. *See* J.A. 6374 (noting that, although Dr. Matzger compared the MSN final product spectra to an amorphous TVS reference spectrum, he "made no attempt to distinguish the amorphous material he supposedly found from Form-S. That is, [Dr.] Matzger had no reference spectra for Form-S to conclude what he found matches amorphous TVS or crystalline Form-S" (citation omitted)); J.A. 6945 ¶ 137 (MSN's expert report explaining that "Dr. Matzger did not find Form-S [in MSN's final product] because he did not look for Form-S."); J.A. 9168 (MSN counsel arguing that the "fundamental problem" with Novartis's testing is that it was "taking reference spectra for sacubitril and valsartan and amorphous [TVS], but . . . not running th[ose] data to see if there's even a match with the Form-S reference spectra"). Put otherwise, MSN's argument was that Novartis had not shown that MSN's final product contained amorphous TVS because it did not consider the possibility that the regions in the Raman spectra that Dr. Matzger identified as amorphous TVS could have been a closer match to crystalline TVS. That argument, regardless how it was characterized by the district court, properly goes to the relevant infringement inquiry.

With that understanding in mind, we see no clear error in the district court's analysis and consideration of the evidence. MSN rebutted Novartis's argument by putting forth evidence to show that the supposed amorphous TVS regions identified by Dr. Matzger in the final product were actually indicative of crystalline TVS. It did so through its own expert, Dr. Steed, who compared the spectra Dr.

Matzger obtained from the final product to a Form-S reference spectrum, finding them to "align closely." *See* MSN Br. 23–24 (citing J.A. 6945–49); J.A. 6949 (Dr. Steed report stating that "a more reasonable conclusion is that the regions that Dr. Matzger believes to be amorphous . . . are actually crystalline Form-S. At the very least, this casts significant doubt on Dr. Matzger's testing and suggests that additional testing . . . should have been conducted to determine whether crystalline or amorphous materials were present in MSN's ANDA product."). Considering this competing evidence, as well as the fact that Novartis bore the burden of proof, the district court found that Novartis did not persuasively show that it was likely to succeed "in proving that MSN's ANDA products contain amorphous TVS." That finding was not clearly erroneous.

Furthermore, we see no clear error in the district court's determination that Novartis failed to establish that Form-S is *not* crystalline TVS. Each party provided ample evidence to support its position in this regard. Namely, MSN submitted the various testing data it had submitted to the FDA with its ANDA establishing that Form-S is crystalline TVS. *See Preliminary Injunction Order*, at *3; *see also Par Pharm., Inc. v. Eagle Pharms., Inc.*, 44 F.4th 1379, 1383 (Fed. Cir. 2022) ("Because drug manufactures are bound by strict statutory provisions to sell only those products that comport with the ANDA, if the ANDA defines a proposed generic drug in a manner that directly addresses the issue of infringement, it controls the infringement inquiry." (cleaned up)). Novartis challenged the reliability of those data, arguing that they do not actually establish that Form-S is crystalline TVS as opposed to a physical mixture. Again faced with compelling evidence from both parties, it was not clearly erroneous for the district court to determine that Novartis, the party bearing the burden of proof, did not establish a likelihood of success on the issue.

At bottom, Novartis's arguments on appeal ask us to reconsider and reweigh this highly factual evidence anew.

We decline to do so. *Mylan Institutional LLC v. Aurobindo Pharma Ltd.*, 857 F.3d 858, 870 (Fed. Cir. 2017) ("We do not reweigh evidence on appeal." (internal quotation marks and citation omitted)). A preliminary injunction "should not issue" if the would-be-enjoined party "raises a substantial question concerning either infringement or validity." *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350–51 (Fed. Cir. 2001). By presenting competent and thorough competing expert testimony and evidence, MSN has done just that. It is not our role to second guess, particularly at this juncture, the factual findings of the district court where those findings do not leave us with "the definite and firm conviction that a mistake has been committed." *Univ. of S. Fla. Bd. of Trustees v. United States*, 92 F.4th 1072, 1079 (Fed. Cir. 2024) (internal quotation marks and citations omitted). Indeed, "[w]here there are two permissible views of the evidence, the fact-finder's choice between them cannot be clearly erroneous." *Hospira, Inc. v. Fresenius Kabi USA, LLC*, 946 F.3d 1322, 1328 (Fed. Cir. 2020) (quoting *Anderson v. City of Bessemer City*, 470 U.S. 564, 574 (1985)).

We therefore hold that the district court did not clearly err in finding that Novartis did not meet its burden to show that it was likely to succeed on the issue of infringement. Given that conclusion, we need not reach the other elements required to establish entitlement to a preliminary injunction, namely, irreparable harm, the balance of equities, and the public interest. *See Amazon.com*, 239 F.3d at 1350 ("Our case law and logic both require that a movant cannot be granted a preliminary injunction unless it establishes *both* of the first two factors, *i.e.*, likelihood of success on the merits and irreparable harm."). The district court did not abuse its discretion in denying injunctive relief.

Before closing, we note that our holding today would be the same even if Novartis is correct that the district court's claim construction, requiring amorphous TVS to "predominate," is erroneous as a matter of law. Indeed, we admit

concern with the district court's construction, particularly in light of its acknowledgement that there is "virtually no useful guidance" in the intrinsic record supporting its conclusion that the claims require any particular amount of amorphous TVS to be present. *Claim Construction Order*, at *4. But because we have affirmed the district court's conclusion that Novartis failed to establish that the accused product contains *any* amorphous TVS, any error in the claim construction, at this stage, is harmless.

CONCLUSION

We have considered Novartis's remaining arguments and find them unpersuasive. For the foregoing reasons, the district court's denial of a preliminary injunction is *affirmed*.

AFFIRMED