Nos. 2023-2218, 2023-2220, 2023-2221

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

IN RE ENTRESTO (SACUBITRIL/VALSARTAN)

NOVARTIS PHARMACEUTICALS CORPORATION, *Plaintiff-Appellant*

v.

TORRENT PHARMA INC., TORRENT PHARMACEUTICALS LTD., *Defendants-Appellees*

NOVARTIS PHARMACEUTICALS CORPORATION, *Plaintiff-Appellant*

v.

ALEMBIC PHARMACEUTICALS LIMITED, ALEMBIC PHARMACEUTICALS INC., *Defendants*

NOVARTIS PHARMACEUTICALS CORPORATION, *Plaintiff-Appellant*

v.

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

HETERO USA, INC., HETERO LABS LIMITED, HETERO LABS LIMITED UNIT-III, *Defendants*

Appeals from the United States District Court for the District of Delaware, Nos. 1:19-cv-01979, 1:19-cv-2021, 1:19-cv-02053, and 1:20-md-02930, Judge Richard G. Andrews.

NOVARTIS PHARMACEUTICALS CORPORATION'S EMERGENCY COMBINED MOTION FOR RECONSIDERATION AND PETITION FOR *EN BANC* REHEARING AND MOTION TO EXPEDITE

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January 15, 2025

CERTIFICATE OF INTEREST

Counsel for Novartis Pharmaceuticals Corp. certify under Federal Circuit Rule 47.4 that the following information is accurate and complete to the best of their knowledge:

1. **Represented Entities.** Provide the full names of all entities represented by undersigned counsel in this case.

Novartis Pharmaceuticals Corp.

2. **Real Parties in Interest.** Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities.

None.

3. **Parent Corporations and Stockholders.** Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities.

Novartis AG

4. **Legal Representatives.** List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court.

McCarter & English, LLP: Daniel M. Silver, Alexandra M. Joyce.

Schrader Companion Duff & Law PLLC: Sandra K. Law, James F. Companion.

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5. **Related Cases.** Other than the originating case(s) for this case, are there related or prior cases that meet the criteria under Fed. Cir. R. 47.5(a)?

Yes, see separately filed notice.

6. **Organizational Victims and Bankruptcy Cases.** Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees).

Not applicable.

Dated: January 15, 2025

/s/ Deanne E. Maynard
Deanne E. Maynard

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STATEMENT OF COUNSEL

Based on my professional judgment, I believe the panel's January 10, 2025 order denying Novartis's Rule 8 motion for an injunction pending appeal as moot and lifting the administrative injunction entered on August 14, 2024, misapprehended or is contrary to the following precedent of this court: *In re Omeprazole*, 536 F.3d 1361 (Fed. Cir. 2008).

Dated: January 15, 2025 /s/ Deanne E. Maynard

INTRODUCTION

On January 10, 2025, a three-judge panel of this Court issued a decision reversing the district court's judgment of invalidity. Because MSN has already stipulated that filing an ANDA to sell generic versions of Novartis's patented drug ENTRESTO® was an act of infringement under 35 U.S.C. §271(e)(2), this Court's decision confirmed that Novartis should have been entitled in July 2023 to the mandatory remedy under 35 U.S.C. §271(e)(4) prohibiting the FDA from approving MSN's ANDA at least before patent expiration. And because Novartis earned, at FDA's request, a six-month period of pediatric exclusivity, such an order alone—or combined with clear statutory requirements—would have prevented FDA from finally approving ANDA until after July 15, 2025, when Novartis's statutorily guaranteed period of pediatric exclusivity ends. The Court's correction of the

district court's judgment now entitles Novartis to that previously wrongly denied relief.

Despite MSN's loss on the merits before this Court, and MSN's own stipulation of infringement before the district court, MSN has made clear that only an injunction will prevent it from launching in the time between expiration of Novartis's patent tonight, January 15, 2025, and the FDA's reset of MSN's ANDA approval pursuant to a court order. Because the Court's decision issued just five days before patent expiry and it will take at least 37 days for the Court's mandate to issue, MSN believes it can launch now without any consequence—making it impossible to restore Novartis to the position it would have been but for the now-reversed district court judgment, depriving Novartis of its earned pediatric exclusivity, and ultimately stripping this Court's decision of practical effect.

Under these circumstances, the correct course of action was clear. To effectuate its own judgment, undo the effects of the district court's now-reversed judgment, and preserve Novartis's statutory entitlement to its earned period of pediatric exclusivity, the panel should have enjoined MSN's launch through the remainder of this appeal, including mandate issuance. Doing so would have been simple, because Novartis had already moved for an injunction pending appeal under Rule 8 and the panel had already entered an administrative injunction enjoining MSN's launch pending further order of the Court. All the panel had to do to prevent

MSN from capitalizing on the district court's erroneous, now-reversed invalidity decision was to continue its existing administrative injunction or grant Novartis's Rule 8 motion. But instead, on the same day the panel issued its decision on the merits ruling *for* Novartis, it paradoxically denied Novartis's Rule 8 motion as "moot" and lifted its administrative injunction. ECF108.

That order overlooks the effect of the Court's merits decision and misapprehends the statutory scheme that entitles Novartis to an FDA reset order. The Court's decision, standing alone, does not moot Novartis's need for an injunction *pending* appeal because this appeal remains pending. Nor will patent expiration undermine the basis for injunctive relief either. As this Court has recognized, Novartis's entitlement to the reset order is a patent remedy that may be effectuated post-expiration to address pre-expiration infringement. *Omeprazole*, 536 F.3d at 1367-69. The panel's order conflicts with *Omeprazole* and threatens to engender significant confusion regarding the nature of the remedy guaranteed by §271(e)(4)(A) and when it can be enforced in a patent case. Novartis respectfully requests that the panel reconsider its order under Federal Circuit Rule 27(j), or that the Court grant panel or en banc rehearing under Rule 40.

Because the patent is due to expire **tonight, January 15, 2025, at 11:59pm**, Novartis respectfully requests entry of an immediate administrative injunction before that time barring MSN from launching its generic versions until this Court

can resolve this motion. If the panel denies that interim relief, Novartis requests that its request for immediate relief go to the en banc Court, so the full Court will have time to consider Novartis's en banc petition. Before filing this motion and petition, Novartis first sought emergency injunctive relief in the district court, which denied that relief this afternoon, believing it currently lacks jurisdiction under Rule 62(d) until issuance of this Court's mandate.

Novartis notified MSN of this motion.

BACKGROUND

U.S. Patent No. 8,101,659, listed in the Orange Book for Novartis's blockbuster drug ENTRESTO® claims a groundbreaking heart-failure treatment: a combination of the chemicals valsartan and sacubitril in about a 1:1 ratio and a pharmaceutically carrier. Slip op. at 4-6. The sacubitril-valsartan treatment represented a significant advance over previous heart-failure treatments. Slip op. at 4-5. Although the '659 patent expires at 11:59 p.m. on January 15, 2025, it is undisputed that the FDA awarded an additional six-month pediatric-exclusivity period for this Orange Book-listed patent. FDA, Pediatric Exclusivity Determinations, https://www.fda.gov/drugs/development-resources/list-determinations-including-written-request; slip op. at 4.

Statutory and regulatory framework. §271(e)(2) makes it an act of infringement to submit an ANDA "for a drug claimed in a patent or the use of which

is claimed in a patent." 35 U.S.C. §271(e)(2). "[U]pon a finding of patent infringement under §271(e)(2), the district court must order remedies in accordance with §271(e)(4)." *Vanda Pharms. v. West-Ward Pharms. Int'l*, 887 F.3d 1117, 1138 (Fed. Cir. 2018). "[O]ne remedy is to set the effective date of approval no earlier than the date the brand's patent would expire." *Teva Branded Pharm. v. Amneal Pharms.*, No. 24-1936, slip op. at 3-7 (Fed. Cir. Dec. 20, 2024). The FDA is "bound" by a §271(e)(4)(A) order. *Mylan Lab'ys v. Thompson*, 389 F.3d 1272, 1282 (D.C. Cir. 2004).

FDA's approval of an ANDA following a § 271(e)(4)(A) order can also be affected by a patent holder's entitlement to an additional six-month period of marketing exclusivity under 21 U.S.C. § 355a, often called "pediatric exclusivity." Under that statute, the FDA can request the holder of a new drug application to perform certain pediatric studies if the FDA "determines that information relating to the use of a new drug in the pediatric population may produce health benefits." 21 U.S.C. §355a(b). If the holder performs those studies, "the period during which the FDA is barred from approving an ANDA filed by competing drug manufacturers is extended by six months" after patent expiration. *Omeprazole*, 536 F.3d at 1368.

§271(e)(2) proceedings. In 2019, MSN and other generic manufacturers submitted ANDAs "seeking FDA approval to market and sell a generic version of Entresto." Slip op. at 6. Novartis sued, alleging that under §271(e)(2) the ANDA

filing infringed the '659 patent. Slip op. at 6. After claim construction, MSN stipulated to infringement. Slip. op. at 14. "The case proceeded to a three-day bench trial" on invalidity issues. Slip op. at 8. In July 2023, the district court rejected all of MSN's invalidity theories except written description, on which it based its invalidity judgment. Slip op. at 11.

Injunction and expedited proceedings. Novartis appealed immediately and briefed the appeal without delay, completing briefing by the end of January 2024. Appx51; Appx196. For the entire period of the appeal's merits briefing, the FDA had not granted MSN approval. When the FDA granted MSN final approval on July 24, 2024, Novartis promptly moved to enjoin any MSN launch, first in the district court and then in this Court. ECF64 at viii-ix.

Novartis showed it would suffer irreparable harm, including: a premature generic launch would cause irreversible price erosion; the rapidly expanding and dynamic nature of the ENTRESTO® market makes Novartis's harm unquantifiable; generic entry would disrupt the growth of the ENTRESTO® market in a way that could never be regained; and MSN would be unable to compensate Novartis for its losses. ECF64 at 23-25. Novartis explained the particular irreparability of its harm after patent expiry and before the end of the pediatric-exclusivity period, given that "this Court has rejected entitlement to Patent Act damages for an invention's unauthorized use during the pediatric-exclusivity period." ECF64 at 25.

Novartis's motion further explained that "if Novartis proves infringement under 35 U.S.C. §271(e)(2) (as is likely), it will be entitled—without any showing on the equities—to a stay of MSN's ANDA approval until the '659 patent and its exclusivities expire." ECF64 at 24. A premature launch "would render that relief all-but worthless" (ECF64 at 24), as rescission of MSN's ANDA approval would "come too late if MSN launches, forever disrupting the market" (ECF70 at 10).

This Court expedited this appeal and ordered MSN "temporarily enjoined from commercial marketing and sale of [its] generic version of Entresto®." ECF65 at 3; ECF73 at 3. The Court also ordered Novartis to file a bond "deemed appropriate by the district court." ECF88 at 3.

This Court heard argument on November 13, 2024. Responding to questions about the '659 patent's expiration date, Novartis's counsel explained that §271(e)(4)(A)'s remedy remained enforceable after patent expiration. Oral.Arg.Audio(14:18-15:42). Novartis requested the Court, if it reversed on invalidity, to maintain its injunction until the FDA resets MSN's ANDA's effective date. Oral.Arg.Audio(15:04-15:24). Post-argument, Novartis submitted the citation for *Omeprazole* to which counsel had referred. ECF101.

Novartis's motion to clarify or continue this Court's injunction. After statements and actions by MSN indicating it might launch immediately following patent expiration, regardless of this Court's injunction and Novartis's entitlement to

pediatric exclusivity, Novartis moved to clarify and continue this Court's August 14, 2024 administrative injunction. ECF105. Novartis explained that nothing in the Court's injunction order had tied the order's duration to the '659 patent's expiration date. ECF105 at 11. Nor should it have, because "[a]n injunction that expired on January 15, 2025 would not preserve Novartis's right to the mandatory remedy under 35 U.S.C. §271(e)(4)(A). ECF105 at 11.

This Court's decision. On January 10, 2025, the Court issued a unanimous, precedential decision reversing the district court's written description decision and affirming its rejection of MSN's other invalidity arguments. Slip op. at 17. The Court explained that "[t]he issue on appeal is whether the '659 patent describes what is claimed, viz., a pharmaceutical composition comprising valsartan and sacubitril administered 'in combination.'" Slip op. at 11-12. The Court held, based on this Court's "long recogni[tion]" that a patent must describe only what is claimed, that the relevant issue was "*not* whether the '659 patent describes valsartan-sacubitril complexes." Slip op. at 12. Such a complex was not claimed—only a combination of valsartan and sacubitril was, and "[t]hat invention is plainly described throughout the specification." Slip op. at 12. The Court went on to affirm the district court's holdings on enablement and nonobviousness. Slip op. at 15-17.

Post-judgment proceedings. Just hours after it issued its opinion, the panel issued a per curiam order, denying Novartis's motion to clarify or continue the

August 14, 2024 administrative injunction, denying Novartis's motion for an injunction pending appeal as "moot," and lifting the administrative injunction. ECF109. Other than noting that the Court had "entered judgment resolving the underlying appeal" the panel's order did not explain further.

In the early hours of the following day, Novartis moved for immediate issuance of the Court's mandate. ECF110. Novartis explained that there was good cause to expedite the mandate for the district court to enter the mandatory statutory remedy provided under 35 U.S.C. §271(e)(4)(A). ECF110 at 2-3. "Absent the district court's erroneous invalidity judgment—which this Court has now reversed—Novartis would have received that relief long ago." ECF110 at 3. Novartis therefore requested that the Court issue its mandate "immediately to allow the district court to grant §271(e)(4)(A) relief now." ECF110 at 3. The panel denied Novartis's motion in a per curiam order yesterday, January 14, 2025. ECF114.

Meanwhile, following this Court's decision reversing the invalidity decision, Novartis again moved in the district court for an injunction under Rule 62(d), requesting an injunction against MSN's marketing of its generic product and an order that would "enforce the '659 Patent's pediatric exclusivity period by appropriately preventing any launch by MSN at this time." D.Ct.Dkt.1713 at 1. Novartis explained that this Court's judgment "entitles it to the relief mandated by 35 U.S.C. §271(e)(4)(A), *i.e.* an order resetting FDA's approval date of MSN's

ANDA" and that such an order would enable FDA to enforce Novartis's pediatric exclusivity. D.Ct.Dkt.1713 at 1. It asked the district court to "ensure MSN cannot vitiate that relief by launching during the interim period needed to issue that mandatory § 271(e)(4)(A) statutory relief." D.Ct.Dkt.1713 at 1. This afternoon, January 15, 2025, the district court denied Novartis's motion, concluding that it currently lacks jurisdiction to issue any injunctive relief. D.Ct.Dkt.1738.

ARGUMENT

I. THE ORDER DENYING NOVARTIS'S RULE 8 MOTION AS "MOOT" AND LIFTING THE ADMINISTRATIVE INJUNCTION ERRONEOUSLY OVERLOOKED THAT INJUNCTIVE RELIEF CONTINUES TO BE NECESSARY

Issuance of this Court's decision did not moot Novartis's need for injunctive relief; it confirmed it. That is plain from Novartis's motion, which was titled "Motion for Injunction Pending Appeal." ECF64 at cover, viii (Novartis seeks "an emergency injunction pending appeal enjoining MSN from launching"), 27 (injunction "until the appeal is resolved"). When the "mandate ha[s] not yet issued," a "case [i]s still pending on appeal." *GPX Intern. Tire Corp. v. U.S.*, 678 F.3d 1308, 1312 (Fed. Cir. 2012).

Because the Court's merits decision standing alone has not ended this appeal, Novartis continues to have a substantial, and legally cognizable, interest in obtaining that requested relief. Absent the district court's erroneous invalidity judgment, MSN would currently lack effective FDA approval and would continue to do so until after

July 15, 2025. But MSN has made clear it intends to launch at midnight tonight and thereby benefit from the judgment this Court reversed. An injunction now, and through issuance of this Court's mandate, is thus needed to protect Novartis's ability to be restored to the position it would already be in but for the now-reversed judgment. That is precisely the purpose of injunctive relief pending appeal.

These conclusions follow from settled law, creating a clear conflict between that law and the panel's denial of Novartis's request as moot.

First, it is settled that "upon a finding of patent infringement under §271(e)(2), the district court must order remedies in accordance with §271(e)(4)." *Vanda*, 887 F.3d at 1138 (emphasis added). That includes the *mandatory* remedy under 35 U.S.C. §271(e)(4)(A) "to set the effective date of approval no earlier than the date the brand's patent would expire." *Teva*, No. 24-1936, 2024 WL 5176737, at *2; 35 U.S.C. §271(e)(4)(A) ("court *shall* order"); *see Vanda*, 887 F.3d at 1138. For an unapproved ANDA, the effect of such an order is that "the FDA may not approve the ANDA until the effective date specified by the district court." *Omeprazole*, 536 F.3d at 1367.

Here, had the district court concluded in July 2023 that Novartis's patent claims are valid, as this Court has now held was required, the district court would have been required to issue such a §271(e)(4)(A) order given MSN's stipulation of patent infringement. And because MSN's ANDA lacked approval at that time, such

an order would have barred FDA from granting MSN final approval at least any time before July 16, 2025. Thus, FDA could not have granted MSN final effective approval in July 2024, as occurred under the district court's now-reversed judgment.

Second, although the FDA did finally approve MSN's ANDA under the now-reversed judgment, this Court's reversal still entitles Novartis to the same relief under §271(e)(4)(A), and that relief will survive the expiration of Novartis's patent at midnight on January 15, 2025. Again, binding precedent from this Court has already considered and resolved any question about that. When FDA already has approved an ANDA—the filing of which has been found to be an act of infringement under 35 U.S.C. §271(e)(2)—a court still must grant the mandatory relief under §271(e)(4)(A), which "alter[s] the effective date of the [approved] application, thereby converting a final approval into a tentative approval." *Omeprazole*, 536 F.3d at 1367-68.

The right to that relief survives patent expiration: §271(e)(4)(A) "provide[s] a post-expiration remedy for infringement under section 271(e)(2)" occurring pre-patent expiration. *Omeprazole*, 536 F.3d at 1367. In *Omeprazole*, although the patents had expired before decision, the district court ordered the FDA to reset the effective date of approval of the defendants' already-approved ANDAs until after pediatric exclusivity. *Id.* at 1366-67. This Court affirmed. *Id.* at 1367-69, 1381-82. This Court reasoned that, even after patent expiration, the patentee continues to be

entitled to §271(e)(4)(A)'s mandatory remedy. *Id* at 1367-69. Although MSN has argued that *Kearns v. Chrysler* precludes post-patent-expiration relief, *Omeprazole* already rejected that view. *Contra* ECF102 at 1 (citing 32 F.3d 1541 (Fed. Cir. 1994)). As *Omeprazole* explains, *Kearns* "addressed the availability of relief under 35 U.S.C. §283; it did not address the availability of relief under section 271(e)(4)(A)." 536 F.3d at 1367-69.

Third, just as in *Omeprazole*, Novartis has now, and will continue to have after midnight tonight, a cognizable interest in receiving that remedy, including post-expiration. As in *Omeprazole*, that interest is because, as MSN has never disputed, FDA already granted Novartis entitlement to pediatric exclusivity for ENTRESTO®. ECF64-1 Add2. Under 21 U.S.C. §355a(c)(1)(B), Novartis's granted pediatric exclusivity prohibits FDA from approving an ANDA related to ENTRESTO® for "six months after" patent expiration for any "listed patent for which a certification has been submitted." Here, MSN submitted a certification for the '659 patent, which is the basis for this very litigation. D.Ct.Dkt.270 ¶36. Thus, Novartis's pediatric exclusivity attaches to the '659 patent, barring FDA approvals of drugs for 6 months following expiration. Here, had the district court correctly entered judgment and a §271(e)(4)(A) order in July 2023, FDA thus would have been barred from granting MSN approval until after July 15, 2025.

A §271(e)(4)(A) order now, or after patent expiration, will produce the same result, as Congress intended. In *Omeprazole*, that happened when the district court expressly stated in its §271(e)(4)(A) order that the effective date would not be sooner than the end of pediatric exclusivity. *Omeprazole*, 536 F.3d at 1366-1367. District courts regularly follow the same practice. *See*, *e.g.*, *Janssen Prods., L.P.*, 109 F. Supp. 3d at 708-09; *Sumitomo Dainippon Pharma Co., Ltd. v. Emcure Pharm. USA, Inc.*, No. 15-280, 2017 WL 9362572, at *3 (D.N.J. Feb. 14, 2017); *Alcon, Inc. v. Teva Pharm. USA, Inc.*, No. 06-234, 2010 WL 3081327, at *1 (D. Del. Aug. 5, 2010). But the same result would occur even if a §271(e)(4)(A) order issued (before or after patent expiration) and stated only that the effective date of any approval "is not earlier than" patent expiration. That's because, as *Omeprazole* recognized, a §271(e)(4)(A) order issued even after patent expiration "convert[s] a final approval into a tentative approval." *Omeprazole*, 536 F.3d at 1368. And any FDA approval of a tentatively approved ANDA is subject to the terms of pediatric exclusivity under 21 U.S.C. §355a(c)(1)(B).

Fourth, for all the reasons in Novartis's Rule 8 motion, Novartis's cognizable interest in obtaining that relief will be irreparably harmed absent an injunction pending appeal, including until issuance of the mandate. If MSN makes good on its threats to launch prematurely, Novartis will be permanently denied the benefits of that relief. MSN's concrete steps towards launching—including importing massive

quantities of sacubitril/valsartan, the active pharmaceutical ingredient in its generic version of ENTRESTO® as well as over 300,000 bottles of tablets of its generic product—make clear that this risk is real. D.Ct.Dkt.1581 Exs. C & D. If MSN launches, Novartis will suffer the irreparable harms described in its Rule 8 filings preceding this Court's order enjoining MSN's commercial launch, including being forced into a Catch-22 of irreversible price erosion, lost market share, or both. ECF64 at 21-25; ECF70 at 9-12; Add124-125. And for all the reasons explained in Novartis's Rule 8 briefing, there will be no way to restore those benefits after MSN launches, even if this Court subsequently reverses the district court's erroneous invalidity judgment. ECF64 at 21-25; ECF71 at 9-12. Indeed, the threat of irreparable harm is even greater post-patent expiration because, as Novartis's Rule 8 motion explained, Novartis could be left with no remedy at all because this Court has held that patent damages can be unavailable for loss of market exclusivity after a patent expires. ECF64 at 25 (citing *AstraZeneca v. Apotex*, 782 F.3d 1324, 1341-45 (Fed. Cir. 2015)).

II. THE FULL COURT'S REVIEW IS NEEDED NOW

For all the reasons explained, the panel's denial of Novartis's Rule 8 motion as moot will destroy the relief *Omeprazole* already held a prevailing patent owner like Novartis is entitled to even post-patent-expiration. Because that result is

irreconcilable with *Omeprazole*'s holding, immediate en banc action is needed to preserve the uniformity of this Court's precedent.

III. THE COURT SHOULD IMMEDIATELY ENTER A TEMPORARY INJUNCTION PENDING RESOLUTION OF THIS PETITION

Because MSN has made clear it intends to launch after midnight tonight, Novartis request that the Court, either as a panel or en banc, immediately enter a temporary injunction to maintain the status quo while considering this motion. Federal appellate courts, including this one, regularly grant temporary relief to "freeze legal proceedings until the court can rule on a party's request for expedited relief." *United States v. Texas*, 144 S. Ct. 797, 798 (2024) (Barrett and Kavanaugh, J.J., concurring) (collecting cases); *Marine Polymer Techs. v. HemCon*, 395 F. App'x 701, 702 (Fed. Cir. 2010) (granting administrative stay to preserve status quo). Rather than "consideration of the merits of the stay application" the purpose is to "buy[] the court time to deliberate" on the stay. *Texas*, 144 S. Ct. at 798.

Novartis is exhausting every other avenue for relief. The district court today denied injunctive relief pending this appeal because it believed it lacked jurisdiction to grant any. The FDA has told Novartis it will not act to alter MSN's current approval absent a court order under §271(e)(4)(A). And Novartis has been unable to obtain relief in APA actions against the FDA in federal court.

CONCLUSION

This Court, as a panel or en banc, should enjoin launch of MSN's generic versions of ENTRESTO®, temporarily while resolving this motion and then until issuance of the mandate.

Dated: January 15, 2025

Respectfully submitted,

/s/ Deanne E. Maynard

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Addendum

NOTE: This order is nonprecedential.

United States Court of Appeals for the Federal Circuit

IN RE: ENTRESTO (SACUBITRIL/VALSARTAN)

NOVARTIS PHARMACEUTICALS CORPORATION,
Plaintiff-Appellant

v.

TORRENT PHARMA INC., TORRENT PHARMACEUTICALS LTD.
Defendants

NOVARTIS PHARMACEUTICALS CORPORATION,
Plaintiff-Appellant

v.

ALEMBIC PHARMACEUTICALS LIMITED, ALEMBIC PHARMACEUTICALS INC.,
Defendants

NOVARTIS PHARMACEUTICALS CORPORATION,
Plaintiff-Appellant

v.

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

HETERO USA, INC., HETERO LABS LIMITED, HETERO LABS LIMITED UNIT-III,
Defendants

2023-2218, 2023-2220, 2023-2221

Appeals from the United States District Court for the District of Delaware in Nos. 1:19-cv-01979-RGA, 1:19-cv-02021-RGA, 1:19-cv-02053-RGA, 1:19-cv-02053-RGA, 1:20-md-02930-RGA, Judge Richard G. Andrews.

ON MOTION

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

PER CURIAM.

O R D E R

On August 13, 2024, Novartis Pharmaceuticals Corporation ("Novartis") moved pursuant to Federal Rule of Appellate Procedure 8 to enjoin, pending appeal, MSN Pharmaceuticals, Inc., MSN Laboratories Private Ltd., and MSN Life Sciences Private Ltd. (collectively, "MSN") from the commercial marketing and sale of its generic version of Novartis's Entresto® product. ECF No. 63.

On August 14, 2024, this court temporarily enjoined MSN from the commercial marketing and sale of its generic version of Entresto while the court considered the Rule 8 motion. ECF No. 65.

On January 9, 2025, Novartis moved to clarify and continue the temporary injunction until the U.S. Food and Drug Administration resets the pediatric-exclusivity period for Entresto. ECF No. 105.

On January 10, 2025, the court entered judgment resolving the underlying appeal. ECF No. 107.

Upon consideration of Novartis's motion,

IT IS ORDERED THAT:

(1) The Rule 8 motion, ECF No. 63, is denied as moot.

(2) The motion to clarify and continue the temporary injunction, ECF No. 105, is denied.

(3) The temporary relief provided in the court's August 14, 2024 order is lifted.

FOR THE COURT

Jarrett B. Perlow
Clerk of Court

January 10, 2025
Date

CERTIFICATE OF COMPLIANCE

The foregoing filing complies with the relevant type-volume limitation of the Federal Rules of Appellate Procedure and Federal Circuit Rules because the filing has been prepared using a proportionally spaced typeface and includes 3622 words, excluding the parts of the brief exempted by the Rules.

Dated: January 15, 2025 /s/ Deanne E. Maynard

sf-6292896