No. 2023-2218, -2220, -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*

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-RGA, 1:19-cv-02021-RGA, 1:19-cv-02053-RGA, and 1:20-md-02930-RGA, Judge Richard G. Andrews

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MSN'S EMERGENCY COMBINED MOTION FOR RECONSIDERATION AND PETITION FOR EN BANC REHEARING OF JANUARY 21, 2025 ORDER (ECF NO. 127) AND MOTION TO EXPEDITE

Dated: January 22, 2025

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CERTIFICATE OF INTEREST FOR DEFENDANTS-APPELLEES

Pursuant to Federal Circuit Rules 27(a)(7) and 47.4, counsel for Defendants-Appellees certifies the following:

1. Represented Entities. Fed. Cir. R. 47.4(a)(1). Provide the full names of all entities represented by undersigned counsel in this case.

MSN Pharmaceuticals Inc., MSN Laboratories Private Limited, and MSN Life Sciences Private Ltd.

2. Real Party in Interest. Fed. Cir. R. 47.4(a)(2). 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.

N/A

3. Parent Corporations and Stockholders. Fed. Cir. R. 47.4(a)(3). 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.

N/A

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. Fed. Cir. R. 47.4(a)(4).

Stamatios Stamoulis, Stamoulis & Weinblatt

5. Related Cases. Whether there are any related or prior cases, other than the originating case number(s), that meet the criteria under Federal Circuit Rule 47.5. Fed. Cir. R. 47.4(a)(5).

Yes, see separately filed notice

6. Required disclosure of information under Fed. R. App. P. 26.1(b) and 26.1(c). Fed. Cir. R. 47.4(a)(6).

N/A

Dated: January 22, 2025

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STATEMENT OF COUNSEL

Based on my professional judgment, I believe the panel's January 21, 2025 order (ECF127, attached hereto as Addm1-4)[1] granting Novartis's motion for reconsideration and ordering that MSN be enjoined from commercial marketing and sale of their generic version of Entresto® until issuance of the mandate in these appeals misapprehended or is contrary to the following decision of the Supreme Court of the United States or the precedent(s) of this court:

- *Kimble v. Marvel Entm't, LLC*, 576 U.S. 446 (2015).
- *Kearns v. Chrysler Corp.*, 32 F.3d 1541 (Fed. Cir. 1994).
- *In re Omeprazole*, 536 F.3d 1361 (Fed. Cir. 2008); and *AstraZeneca AB v. Apotex Corp.*, 782 F.3d 1324 (Fed. Cir. 2015).

Dated: January 22, 2025 /s/ William A. Rakoczy

[1] "Addm_" citations are to the addendum here. "D.Ct.Dkt._" citations are to the docket in *In re Entresto (Sacubitril/Valsartan) Patent Litigation*, No. 1:20-md-02930-RGA (D. Del.).

INTRODUCTION

The ’659 patent has expired. “[W]hen the patent expires, the patentee’s prerogatives expire too, and the right to make or use the article, free from all restriction, passes to the public.” *Kimble v. Marvel Ent., LLC*, 576 U.S. 446, 451 (2015); *see also Kearns v. Chrysler Corp.*, 32 F.3d 1541, 1550 (Fed. Cir. 1994) (“[W]hen the rights secured by a patent are no longer protectable by virtue of expiration or unenforceability, entitlement to injunctive relief becomes moot because such relief is no longer available.”). Thus, the only obstacle preventing MSN from effectuating Congress’ goals and the policies of the Hatch-Waxman Act is this Court’s recent order (ECF127) reversing itself and reinstating the previously-dissolved injunctive relief blocking MSN’s launch. Every day the public is denied the benefits of generic competition to Entresto® matters. Obtaining an injunction is an “extraordinary remedy.” *Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharms. Co.*, 290 F.3d 578, 586 (3d Cir. 2002); *Intel Corp. v. ULSI Sys. Tech., Inc.*, 995 F.2d 1566, 1568 (Fed. Cir. 1993). There is no basis for this Court to have granted Novartis’s most recent request for reconsideration, and no basis to then impose an injunction. MSN respectfully requests the Court to again dissolve the injunction currently in place against MSN.

Between January 10, when this Court lifted its injunction against MSN’s launch (ECF109), and January 15, when Novartis filed its motion for reconsideration

(ECF115), the only changes in factual circumstances weigh *against* imposing an injunction:

The Hatch-Waxman Act and the Public Interest: When the D.C. District Court considered MSN's potential launch, the court recognized that "the public interest weighs against an injunction," because "[w]here a generic manufacturer met all relevant safety and approval standards, there is a clear public interest in receiving generic competition to brand-name drugs as soon as possible." ECF 123 at Add12. This is the precise goal of the Hatch-Waxman Act. Indeed, as the FDA noted in connection with MSN's proposed launch: "The FDCA strikes a balance between protecting the rights of reference drug manufacturers and promoting the speedy entry of generic competition. Sometimes, this will mean that a generic goes to market while the reference manufacturer is still in the process of asserting its rights. That is not absurd—it is part and parcel of the congressional design." *Id*. at Add32.

No Irreparable Harm: The D.C. District Court concluded that an MSN launch would cause no irreparable harm to Novartis during the pediatric exclusivity period. *Id.* at Add11-12. It determined that the monetary loss Novartis alleged it would suffer was "does not constitute irreparable harm," that it will not experience a loss of goodwill, and that it would suffer no clear deprivation of a statutory right to pediatric exclusivity upon MSN's launch. *Id.* If Novartis disagrees with those

assessments then it should address them with the D.C. Circuit. It is not entitled to re-litigate them before this Court.

In fact, on Friday, January 20, Novartis filed a new complaint in the District of Delaware alleging that MSN infringes the '659 patent; this complaint asks specifically for preliminary and permanent injunctive relief. *See* Addm16-17 at ¶54. This is an important new development. If Novartis is looking for an injunction during the pediatric exclusivity period, it should obtain that relief in the new suit it filed against MSN last week, not in the first instance from this Court on a reconsideration motion.

No Likelihood of Success on the Merits: There is no way for Novartis to ultimately succeed in this case and obtain the injunctive relief it has asked for during the pediatric exclusivity period, notwithstanding this Court's January 10 decision regarding MSN's Section 112 defenses. This Court held that the '659 patent does *not* claim sacubitril-valsartan complexes *as a matter of law*. *See* ECF106 at 14 n.5. Accordingly, the '659 patent must now be delisted in light of this Court's written description opinion. *See* ECF123 at 14-15. MSN also does not infringe the '659 patent by virtue of this Court's decision. *See id.* at 16-18. Thus, if this Court's January 10 decision stands, under either of these two scenarios, Novartis will *not* be entitled to pediatric exclusivity. Alternatively, MSN maintains that an *en banc* rehearing on the merits of MSN's written description defense is appropriate. *See id.*

at 13-14. And under that scenario, if MSN's petition is granted, the '659 patent will be invalid. There can be no pediatric exclusivity for an invalid patent. Novartis did not even address the likelihood-of-success in its reconsideration motion. On that basis alone, Novartis's motion should have been denied. Whatever the outcome going forward, Novartis cannot ultimately succeed in this case and it is not entitled to the injunctive relief currently in place.

Nothing Novartis said in its reconsideration motion in support of the injunction was "more developed argument[]" that would require this Court to reverse itself. ECF127 at 3. Novartis already sought relief from this Court *twice* based on the theory that it had a statutory right to block MSN, and this Court twice rejected Novartis's requested relief after receiving complete briefing from the parties. Specifically, Novartis argued in its January 9 motion to clarify and continue the Court's injunction that MSN should be enjoined during the pediatric exclusivity period. ECF105 at 1-2. The Court denied that request and lifted the last-remaining injunction that impeded MSN's launch. ECF109. Novartis tried again on January 11, when it asked this Court to immediately issue the mandate, arguing that refusing to issue an immediate mandate "could allow MSN to launch during Novartis's earned pediatric exclusivity period, as MSN has made clear it intends to do." ECF110 at 2. The Court nonetheless properly denied that relief after hearing from MSN and considering the parties' submissions. ECF114. Novartis's third try, however, was

not a charm; nor did it address changed circumstances that could possibly warrant relief on reconsideration.

All of this means that the Court's current injunction is inconsistent with *In re Omeprazole*, 536 F.3d 1361 (Fed. Cir. 2008), which this Court also considered prior to rejecting Novartis's reconsideration request for injunctive relief. *See* ECF105 at 3-5 (Novartis's discussion of *Omeprazole* in its failed motion to clarify and continue injunction); ECF110 at 2 (Novartis's discussion of *Omeprazole* in its failed motion to expedite issuance of the mandate). Consistent with this Court's previous decisions denying Novartis further injunctive relief, *Omeprazole* confirms that an alleged entitlement to a pediatric exclusivity period does not automatically arise and immediately entitle a patentee to block generic competition. Pediatric exclusivity and a re-setting of FDA approval is not guaranteed relief. The generic product in *Omeprazole* was on the market for *over two months after* expiration of the valid patent and well into the pediatric exclusivity period, while the patentee pressed its rights in court. *Infra* § IV; *see also* ECF123 at 9-12.

Further, that Novartis was ordered to file a bond (ECF127 at 3) also does not warrant maintaining the injunction, nor does a bond absolve or diminish the extraordinary nature of the injunctive relief Novartis seeks and the harm that MSN and the public will suffer by blocking the launch of MSN's generic ANDA product.

Requiring Novartis to post a bond does not justify Novartis's reconsideration motion and keeping an injunction in place.

The '659 patent is now expired, and although in a different context, the Supreme Court has held that "when the patent expires, the patentee's prerogatives expire too, and the right to make or use the article, free from all restriction, passes to the public." *Kimble*, 576 U.S. at 451. In these times of high drug prices, each day the public is denied the benefits of generic competition to Entresto® counts. Accordingly, MSN requests expedited treatment of this motion and requests the Court to immediately stay its January 21 injunctive relief pending resolution of this motion. MSN notified Novartis of this motion.

ARGUMENT

I. LEGAL STANDARD

A motion for reconsideration is proper "to correct manifest errors of law or fact or to present newly discovered evidence." *Harsco Corp. v. Zlotnicki*, 779 F.2d 906, 909 (3d Cir. 1985); *see also Delaware Valley Floral Grp., Inc. v. Shaw Rose Nets*, LLC, 597 F.3d 1374, 1383 (Fed. Cir. 2010) ("The three primary grounds that justify reconsideration are: (1) an intervening change in the controlling law; (2) the availability of new evidence; and (3) the need to correct clear error or prevent manifest injustice.") (internal quotation and citation omitted). MSN submits that the Court's January 21, 2025 Order granting Novartis's motion for reconsideration and

ordering that MSN be enjoined, "until issuance of the mandate in these appeals, from commercial marketing and sale of their generic version of Entresto®" (ECF127 at 3), is an error of law—one that results in manifest injustice to MSN—that warrants correcting.

II. NO FACTS OR ARGUMENTS CHANGED IN NOVARTIS'S FAVOR FOLLOWING THE COURT'S LIFTING OF TEMPORARY INJUNCTIVE RELIEF.

The Court granted Novartis's motion for reconsideration "[b]ased on further consideration of Novartis's request, [and] in view of the more developed arguments in the reconsideration papers." ECF127 at 3. Importantly, however, MSN has pointed out that in the time period between the Court's January 10 Order *removing* any injunction barring MSN's launch (ECF109) and Novartis's January 15 motion for reconsideration (ECF115), nothing changed that would have made injunctive relief more appropriate. To the contrary, the only relevant *factual* developments suggest that injunctive relief is even more improper now than when it was initially imposed in August 2024.

A. All courts that considered the facts refused injunctive relief.

First, between January 10 and January 15, all courts considering Novartis's various requests to block MSN denied that relief and/or lifted any injunctions. Most importantly, *this* Court lifted the injunctive relief it had put in place in August and refused to issue additional injunctive relief "upon consideration" of all of Novartis's

arguments. ECF109; ECF114. This Court considered and denied Novartis's motion to continue injunctive relief past the date of patent expiration on January 15 (ECF109), and considered and denied Novartis's January 11 motion to immediately issue the mandate, which Novartis viewed as a means to have the District Court of Delaware immediately enjoin MSN (ECF 114). The district court below also refused to enter additional injunctive relief. *See* D.Ct.Dkt.1738.

Two other courts reached similar conclusions. The D.C. District Court received an emergency motion from Novartis asking to block MSN's launch on January 13. It denied that motion on January 15. *See generally* ECF123 at Add1-14. Separately, on January 15, the D.C. Circuit Court of Appeals temporarily enjoined MSN's launch pending resolution of Novartis's emergency motion. *Novartis Pharms. Corp. v. Becerra*, No. 24-5235, slip op. (D.C. Cir. Jan. 15, 2025) (Doc. No. 2094402). MSN opposed that relief on January 14, and the D.C. Circuit promptly lifted its launch ban on January 16. *Novartis Pharms. Corp. v. Becerra*, No. 24-5235, slip op. (D.C. Cir. Jan. 16, 2025) (Doc. No. 2094572). At that point, the *status quo* was that MSN had full FDA-approval to launch its generic Entresto® product after no fewer than three separate courts had lifted *all* injunctive relief affecting that opportunity to provide the product to U.S. patients.

The only impediment came shortly thereafter, when this Court *re*-instituted temporary injunctive relief based on Novartis's emergency motion for

reconsideration and rehearing. ECF121. But Novartis's motion did not add anything to the record. It rehashed old arguments this Court had already considered. Specifically:

- Novartis had told this Court *twice* that MSN may launch during Novartis's alleged pediatric exclusivity period and that such a launch would (allegedly) irreparably harm Novartis. *See* ECF105 at 12 ("If MSN launches, Novartis will suffer the irreparable harms described in its Rule 8 filings . . . ."); ECF110 at 2 ("[D]elay in [issuance of the mandate] would be inequitable and irreparable. Delay could allow MSN to launch during Novartis's earned pediatric-exclusivity period, as MSN has made clear it intends to do."). The Court considered those arguments and denied Novartis's requested injunctive relief. ECF109; ECF114.
- Novartis's argument that the Court's decision "has not ended this appeal," and thus "Novartis continues to have a substantial, and legally cognizable, interest in obtaining that requested relief" (*see* ECF115 at 10-11), is the same argument that Novartis made (and that the Court rightly rejected) in its motion to clarify and continue the August 14, 2024 temporary injunction. *See* ECF105 at 13-15.
- Novartis's arguments based on *Omeprazole* (*see* ECF115 at 12-14) are the same arguments that it made before this Court on several occasions. *See, e.g.*,

ECF101; ECF105 at 10-12; ECF 110 at 2. The Court rightly imposed no additional injunctive relief based on those arguments.

- Novartis's final argument is based on "all the reasons in Novartis's Rule 8 motion" (*see* ECF115 at 14-15), and thus expressly relies on the same arguments made in its August 13, 2024 Rule 8 motion (ECF64).

In view of the fact that none of the facts or arguments changed, the Court's grant of Novartis's motion for reconsideration was, respectfully, improper, as motions for reconsideration are only appropriate to correct manifest errors of law or fact, none of which were present here. *See Harsco*, 779 F.2d at 909; *Delaware Valley*, 597 F.3d at 1383.

III. NOVARTIS HAS NOT MET THE STANDARDS FOR OBTAINING INJUNCTIVE RELIEF

A. The D.C. District Court determined that an MSN launch would be in the public interest.

Far from being warranted, several courts have already denied Novartis's requests for injunctive relief in part because they found that injunctive relief is not in the public interest and does not further Congress' goals of the Hatch-Waxman Act. For example, both the Delaware and D.C. District Courts have recognized that permitting MSN to launch its approved, lower cost generic version of Entresto® would be in the public interest. *See In re Entresto (Sacubitril/Valsartan) Pat. Litig.*, No. 19-cv-2053-RGA, 2024 WL 3757086, at *5 (D. Del. Aug. 12, 2024) ("I also

agree with MSN that the possible decrease in public awareness is likely outweighed by the increased accessibility and affordability of sacubitril/valsartan drugs that would result from generic competition."); ECF123 at Add12 ("[T]he public interest weighs against an injunction. Where a generic manufacturer met all relevant safety and approval standards, there is a clear public interest in receiving generic competition to brand-name drugs as soon as possible."). The Delaware District Court likewise recognized that the harm to MSN—insofar as it would be unable to launch its generic Entresto® product despite being finally approved to do so—would be severe and outweighed any alleged harm to Novartis. *See In re Entresto*, 2024 WL 3757086, at *5 ("I am further convinced that MSN's potential harm from the loss of its first-mover advantage would outweigh the potential harm to Novartis."). These findings only bolster the conclusion that the equitable considerations that must be considered before imposing an injunction do not support to the current injunction.

There is no reason to relitigate that issue and deviate from that determination in this forum. *Cf. Parklane Hosiery Co. v. Shore*, 439 U.S. 322, 326 (1979) ("Collateral estoppel, like the related doctrine of *res judicata*, has the dual purpose of protecting litigants from the burden of relitigating an identical issue with the same party or his privy and of promoting judicial economy by preventing needless litigation.").

B. The D.C. District Court determined that a MSN launch would not irreparably harm Novartis.

Novartis's irreparable harm arguments have also already been rejected by the D.C. District Court (among other courts).

First, Novartis claimed that it will experience "irreversible price erosion, lost market share, or both." ECF115 at 15; *see also* ECF126 at 4 (claiming that MSN's launch would cause "massive and unrecoverable financial losses [and] market share"). But the D.C. District Court found that "even if the Court were to credit Novartis's worst-case scenario, the loss of 90 percent of Entresto's sales revenue would amount to only a 5.7 percent loss in Novartis's total global revenue over a three-month period, . . . [which] does not constitute irreparable harm." ECF123 at Add11. The District Court also rejected Novartis's price erosion argument as "unduly speculative," particularly insofar as "Novartis offer[ed] no evidence or projections suggesting that it actually plans to lower Entresto's prices." *Id.*

Second, Novartis claims that it will experience loss of goodwill. *See* ECF126 at 4. The D.C. District Court also rejected this argument, finding that "[t]here is no reason to conclude that patients and prescribers would attribute negative outcomes from MSN's label to Novartis." ECF123 at Add11.

Finally, Novartis claims that it showed "loss of a clear statutory right." ECF126 at 5. The D.C. District Court recognized that "a statutory harm is relevant to but not dispositive of an irreparable harm," but rejected Novartis's argument

because Novartis's alleged "economic losses [were] not catastrophic," and because "it [was] not clear that Novartis has yet suffered a clear-cut deprivation of its statutory right to pediatric exclusivity." ECF123 at Add11-12.

C. Novartis is not likely to succeed on the merits.

This Court should also reconsider the granted Rule 8 relief because it is inconsistent with the fact that, for several reasons, Novartis is unlikely to ultimately prevail in its '659 patent claims against MSN and successfully obtain pediatric exclusivity.

First, as MSN previously explained in its opposition to Novartis's motion for immediate issuance of a mandate, MSN has a meritorious argument for rehearing. ECF112 at 4-5. But even if the Federal Circuit's January 10 decision remains and the claims of the '659 patent are valid, the Court's decision is fatal to Novartis's request for injunctive relief. This is because pediatric exclusivity *only* attaches to a validly-listed Orange Book patent, which the '659 patent is not. *See* 21 U.S.C. § 355a(b)(1)(B). As this Court recently explained in detailing the requirements for patents listed in the Orange Book, "in order to be listed [in the Orange Book], a patent must both *claim the drug and be infringed by the NDA product*." *Teva Branded Pharm. Prods. R&D, Inc. v. Amneal Pharms. of New York, LLC*, 124 F.4th 898, 912 (Fed. Cir. 2024) (emphasis added). Yet in this matter, the Court held to the extent Novartis "construed [the claims of the '659 patent] to *claim* valsartan-

sacubitril complexes . . . , that construction would have been error." ECF106 at 14 n.5; *see also id.* ("[T]he '659 patent *could not have been construed* as *claiming* those complexes as a *matter of law*.") (emphasis added). But the valsartan and sacubitril salts in Novartis's Entresto® product are, by Novartis's own admission, present in a single chemical structure called a "compound" or "complex," where the components are associated by non-covalent bonds. *See* D.Ct.Dkt.253 at 6 (Novartis admitting it told the Patent Office the same). Accordingly, the '659 patent cannot be listed in the Orange Book in connection with Entresto® and must be delisted. Once delisted, a patent does not benefit from the regulatory pediatric exclusivity period. *See, e.g.*, *Mylan Lab'ys, Inc. v. Leavitt*, 495 F. Supp. 2d 43, 46 (D.D.C. 2007) ("Pfizer's pediatric exclusivity privilege (which was set to expire on September 25, 2007) prevented new generic manufacturers from entering the market. This changed on June 22, 2007, when the FDA delisted Pfizer's patent."). As such, even if the Court denies MSN's rehearing petition and issues its mandate, Novartis will ultimately be unsuccessful in its pursuit of injunctive relief and § 271(e)(4)(A) relief at the District Court because the '659 patent has no place in the Orange Book and should be delisted.

Second, even if MSN is ultimately found to be incorrect in its understanding of Orange Book listing requirements as discussed above, then relief from the District Court's judgment is *still* warranted because this Court's opinion means that the '659

patent does *not* cover valsartan-sacubitril complexes as a matter of law—in which case MSN does not infringe. *See* ECF106 at 14 n.5. As this Court noted, MSN argued for a claim construction that would have excluded from infringement MSN's ANDA product that contains a valsartan-sacubitril complex. *Id.* at 12. The district court ultimately disagreed and adopted Novartis's proposed claim construction, determining that the '659 patent's plain and ordinary meaning covered valsartan and sacubitril as a physical combination and as a complex. *See In re Entresto (Sacubitril/Valsartan) Pat. Litig.*, No. 20-md-2930-LPS, 2021 WL 2856683, at *3 (D. Del. July 8, 2021). In view of that construction, MSN then stipulated to infringement. ECF106 at 14. But as the Court now explained, to the extent the '659 patent claims were "construed to *claim* valsartan-sacubitril complexes (*i.e.*, to the extent MSN alleges that its stipulation of infringement was made on that basis), that construction would have been error." *Id*. at 14 n.5. This unequivocal holding fundamentally changes the claim construction (an issue of law) on which MSN relied in its stipulation to infringement of the '659 patent, which warrants vacatur of any infringement judgment. *See, e.g.*, *Blazer v. Best Bee Bros. LLC*, No. 2022-1033, 2022 WL 16954848, at *1 (Fed. Cir. Nov. 16, 2022) (Federal Circuit rejecting a district court's claim construction and inputting its own requires vacatur of the district court's judgment regarding infringement); *see also* Fed. R. Civ. P. 60(b)(5)-(6).

Following vacatur of the infringement stipulation, MSN will not be found to infringe the '659 patent in view of this Court's claim construction. As a result, because the law is clear that pediatric exclusivity attaches to a product only if "the court determines that the patent is valid *and would be infringed*" (21 U.S.C. § 355a(b)(1)(B)(ii) (emphasis added)), there is no pediatric exclusivity available to Entresto® based on the '659 patent.

Novartis has no "clear" statutory right to pediatric exclusivity here. Novartis did not show that it is likely to succeed in its claim for a six-month pediatric exclusivity. And because it cannot succeed in that regard, Novartis should not have been awarded that relief with its reconsideration motion.

IV. THE INJUNCTION IS CONTRARY TO *OMEPRAZOLE*

All of the above facts and arguments call for lifting injunctive relief barring MSN's launch. Maintaining this Court's injunction is now inconsistent with *In re Omeprazole Patent Litigation*, 536 F.3d 1361 (Fed. Cir. 2008). *See also AstraZeneca AB v. Apotex Corp.*, 782 F.3d 1324 (Fed. Cir. 2015).[2] MSN previously explained that *Omeprazole* and *AstraZeneca* indicate that MSN has the right to launch its finally approved products while the court system determines whether or not pediatric exclusivity applies. *See* ECF123 at 9-12. They support that conclusion even if a

[2] Both *Omeprazole* and *AstraZeneca* relate to the generic launch of omeprazole.

generic launch occurs *during* the alleged exclusivity period and thus *de facto* shortens it.

These cases do not, however, support the current *injunctive* relief that stops an FDA-approved generic product from coming to market while a patentee argues to courts about its exclusivity rights. Instead, only if infringement and validity are decided in the patentee's favor and the *district court* orders § 271(e)(4)(A) relief, can the FDA convert a generic's final approval to tentative approval (thus foreclosing further sales) for the remainder of the pediatric exclusivity period. That has not happened. And, as explained above, Novartis is not likely to ever obtain such relief. *Supra* § III.C.

V. THE FULL COURT'S REVIEW IS NEEDED NOW

For all the reasons explained, the panel's institution of injunctive relief is inconsistent with *Kimble*, *Kearns*, and *Omeprazole* and wrongfully blocks MSN's launch based on an expired patent. Accordingly, if the panel does not reconsider and reverse its current ruling with respect to an injunction pending issuance of the mandate, immediate *en banc* action is needed to conform to Supreme Court precedent and/or preserve the uniformity of this Court's precedent, and to afford MSN its statutory right to market its FDA-approved generic Entresto® product.

CONCLUSION

For the foregoing reasons, the Court, as a panel or *en banc*, should immediately lift the temporary injunction currently in place (ECF127).

Dated: January 22, 2025

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

The foregoing filing complies with the relevant type-volume limitations of the Federal Rules of Appellate Procedure and Federal Circuit Rules because:

1. The filing has been prepared using a proportionally-spaced typeface and includes 4,123 words.

2. The brief has been prepared using Microsoft Word for Office 365 in 14-point Times New Roman font. As permitted by Fed. R. App. P. 32(g), the undersigned has relied upon the word count feature of this word processing system in preparing this certificate.

Dated: January 22, 2025

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Addendum

IN RE: ENTRESTO (SACUBITRIL/VALSARTAN)

Nos. 23-2218, -2220, -2221 (Fed. Cir.)

ADDENDUM TABLE OF CONTENTS

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, and 1:20-md-02930-RGA, Judge Richard G. Andrews.

ON MOTION AND PETITION

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

PER CURIAM.

O R D E R

On January 10, 2025, the panel denied Novartis Pharmaceuticals Corporation's motions at ECF Nos. 63 and 105 seeking to enjoin, pending appeal, MSN Pharmaceuticals, Inc., MSN Laboratories Private Ltd., and MSN Life Sciences Private Ltd. (collectively, "MSN") from marketing and sale of a generic version of Entresto®. ECF No. 109. Novartis then filed this combined motion for reconsideration, panel rehearing, and rehearing en banc, seeking an injunction "until issuance of the mandate." ECF No. 115 at 23. The panel directed a response and temporarily enjoined MSN while it considered the motion. ECF Nos. 120,

121. MSN opposes reconsideration. ECF No. 123. Novartis moves for leave to file a reply, ECF No. 124, which MSN also opposes, ECF No. 125.

Based on further consideration of Novartis's request, in view of the more developed arguments in the reconsideration papers, we grant reconsideration and enjoin MSN, until issuance of the mandate in these appeals, from commercial marketing and sale of their generic version of Entresto®. Novartis has stated that it is willing to "post an appropriate bond to protect MSN at least through issuance of this Court's mandate," ECF No. 124-2 at 10.

Accordingly,

IT IS ORDERED THAT:

(1) Novartis's motion to file a reply is granted. ECF No. 124-2 is accepted for filing.

(2) Novartis's motion for reconsideration is granted such that ECF No. 109 is vacated and ECF Nos. 63 and 105 are granted to the extent that MSN Pharmaceuticals, Inc., MSN Laboratories Private Ltd., and MSN Life Sciences Private Ltd. are enjoined, until issuance of the mandate in these appeals, from commercial marketing and sale of their generic version of Entresto®.

(3) Novartis is directed to file a bond in the district court in an amount, and subject to terms and conditions,

deemed appropriate by the district court.

(4) The petition for rehearing is moot.

FOR THE COURT

Jarrett B. Perlow
Clerk of Court

January 21, 2025
Date

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff, v. MSN LABORATORIES PRIVATE LIMITED, MSN LIFE SCIENCES PRIVATE LIMITED, MSN PHARMACEUTICALS INC., NOVADOZ PHARMACEUTICALS, LLC, Defendants.	DEMAND FOR JURY TRIAL C.A. No. _____

COMPLAINT

Novartis Pharmaceuticals Corporation ("Novartis"), by its attorneys, hereby alleges as follows:

NATURE OF THE ACTION

1. This is a patent infringement action arising under Title 35 of the United States Code and concerning infringement by MSN Laboratories Private Limited, MSN Life Sciences Private Limited, MSN Pharmaceuticals Inc., and Novadoz Pharmaceuticals, LLC (collectively, "Defendants" or "MSN") under 35 U.S.C. §§ 271(a), 271(b), and 271(c) of Novartis's patents by engaging in the commercial manufacture, use, sale, offer for sale, and/or importation of MSN's generic versions of Novartis's ENTRESTO® tablets, 24 mg/26 mg, 49 mg/51 mg, and 97 mg/103 mg, prior to the expiration of Novartis's U.S. Patent No. 8,101,659 ("the '659 patent").

PARTIES

A. Novartis

2. Novartis Pharmaceuticals Corporation is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business in East Hanover, New Jersey.

B. Defendants

3. On information and belief, MSN Laboratories Private Limited is a corporation organized and existing under the laws of India, having a principal place of business at MSN House, C-24, Sanathnagar Industrial Estate, Hyderabad, 500018, Telangana, India.

4. On information and belief, MSN Life Sciences Private Limited is a corporation organized and existing under the laws of India, having a principal place of business at Sy No - 21/A & 21AA, Mambapur (Village), Gummadidala (Mandal), Sangareddy (District) - 502313, Telangana, India. On information and belief, MSN Life Sciences Private Limited is a wholly owned subsidiary of MSN Laboratories Private Limited.

5. On information and belief, MSN Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of Delaware, having a registered agent for the service of process at United States Corporation Agents, Inc., 131 Continental Drive, Suite 305, Newark, Delaware 19713, and having a principal place of business at 20 Duke Road, Piscataway, New Jersey 08854. On information and belief, MSN Pharmaceuticals Inc. is a wholly owned subsidiary of and U.S. agent for MSN Laboratories Private Limited.

6. On information and belief, Novadoz Pharmaceuticals, LLC ("Novadoz") is a corporation organized and existing under the laws of New Jersey, having a principal place of

business at 20 Duke Road, Piscataway, New Jersey 08854. On information and belief, Novadoz is a wholly owned subsidiary of and marketing partner for MSN Laboratories Private Limited.

7. On information and belief, MSN Laboratories Private Limited develops, manufactures, distributes, sells, and/or imports drug products for the entire United States market and does business in every state including Delaware, either directly or indirectly.

8. On information and belief, MSN Life Sciences Private Limited develops, manufactures, distributes, sells, and/or imports drug products for the entire United States market and does business in every state including Delaware, either directly or indirectly.

9. On information and belief, MSN Pharmaceuticals Inc. develops, manufactures, distributes, sells, and/or imports drug products for the entire United States market and does business in every state including Delaware, either directly or indirectly.

10. On information and belief, Novadoz develops, manufactures, distributes, sells, and/or imports drug products for the entire United States market and does business in every state including Delaware, either directly or indirectly.

11. MSN Pharmaceuticals Inc. and MSN Laboratories Private Limited submitted to the FDA ANDA No. 213748 for sacubitril/valsartan tablets, 24 mg/26 mg, 49 mg/51 mg, and 97 mg/103 mg ("MSN ANDA Products"), seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the MSN ANDA Products in or into the United States, including Delaware, prior to the expiration of the '659 patent.

12. ANDA No. 213748 was approved by FDA on July 24, 2024.

13. On information and belief, MSN Laboratories Private Limited has systematic and continuous contacts with Delaware; has established distribution channels for drug products in Delaware; regularly and continuously conducts business in Delaware, including by selling drug

products in Delaware, either directly or indirectly through its subsidiaries, agents, or affiliates, including MSN Pharmaceuticals Inc. and Novadoz; has purposefully availed itself of the privilege of doing business in Delaware; and derives substantial revenue from the sale of drug products in Delaware.

14. On information and belief, MSN Life Sciences Private Limited has systematic and continuous contacts with Delaware; has established distribution channels for drug products in Delaware; regularly and continuously conducts business in Delaware, including by selling drug products in Delaware, either directly or indirectly through its subsidiaries, agents, or affiliates, including MSN Pharmaceuticals Inc. and Novadoz; has purposefully availed itself of the privilege of doing business in Delaware; and derives substantial revenue from the sale of drug products in Delaware.

15. On information and belief, MSN Pharmaceuticals Inc. has systematic and continuous contacts with Delaware; has established distribution channels for drug products in Delaware; regularly and continuously conducts business in Delaware, including by selling drug products in Delaware, either directly or indirectly through its subsidiaries, agents, or affiliates, including Novadoz; has purposefully availed itself of the privilege of doing business in Delaware; and derives substantial revenue from the sale of drug products in Delaware.

16. On information and belief, Novadoz has systematic and continuous contacts with Delaware; has established distribution channels for drug products in Delaware; regularly and continuously conducts business in Delaware, including by selling drug products in Delaware, either directly or indirectly through its subsidiaries, agents, or affiliates, including MSN Pharmaceuticals Inc.; has purposefully availed itself of the privilege of doing business in Delaware; and derives substantial revenue from the sale of drug products in Delaware.

17. MSN Laboratories Private Limited and MSN Pharmaceuticals Inc. have availed themselves of the legal protections of the State of Delaware by, among other things, admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware. *See, e.g.*, *Vanda Pharm. v. MSN Pharm. Inc. et al.*, C.A. No. 19-926 (D. Del.), *Novartis Pharm. Corp. v. Dr. Reddy's Labs., Inc. et al.*, C.A. No. 19-2053 (D. Del.), *Exelixis, Inc. v. MSN Labs. Private Ltd. et al.*, C.A. No. 20-633 (D. Del.).

18. MSN Laboratories Private Limited and MSN Pharmaceuticals Inc., the entities that submitted ANDA No. 213748, have agreed with Novartis to litigate any patent action(s) concerning ANDA No. 213748 in the District of Delaware, and have agreed, only for the purposes of such action(s), not to challenge personal jurisdiction and venue in the District of Delaware.

JURISDICTION AND VENUE

19. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

20. This Court has personal jurisdiction over MSN Laboratories Private Limited, MSN Life Sciences Private Limited, MSN Pharmaceuticals Inc., and Novadoz because, on information and belief, each such Defendant has committed or has aided, abetted, contributed to, or participated in the commission of tortious acts of patent infringement, which acts have led to foreseeable harm and injury to Novartis, a Delaware corporation.

21. This Court has personal jurisdiction over MSN Laboratories Private Limited, MSN Life Sciences Private Limited, MSN Pharmaceuticals Inc., and Novadoz, because, on information and belief, each such Defendant, has committed and will further commit or has aided, abetted, contributed to and participated in, and will further aid, abet, contribute to, or

participate in, past and future tortious acts of patent that are or will be purposefully directed at Delaware, including commercial activities for the MSN ANDA Products in Delaware.

22. This Court also has personal jurisdiction over MSN Laboratories Private Limited, MSN Life Sciences Private Limited, MSN Pharmaceuticals Inc., and Novadoz because each such Defendant's affiliations with the State of Delaware, including MSN Pharmaceuticals Inc.'s incorporation in Delaware, Novadoz's actions by itself and in concert with MSN Pharmaceuticals Inc., MSN Laboratories Private Limited's ownership of and actions in concert with MSN Pharmaceuticals Inc. and Novadoz, and MSN Life Sciences Private Limited's actions in concert with MSN Pharmaceuticals Inc. and Novadoz are sufficiently continuous and systematic as to render each such Defendant essentially at home in this forum.

23. This Court also has personal jurisdiction over MSN Laboratories Private Limited and MSN Pharmaceuticals Inc. because each such Defendant has availed itself of the legal protections of the State of Delaware, by admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware.

24. MSN Laboratories Private Limited and MSN Pharmaceuticals Inc., the entities that submitted ANDA No. 213748, have agreed with Novartis to litigate any patent action(s) in the District of Delaware, and have agreed, only for the purposes of such action(s), not to challenge personal jurisdiction and venue in the District of Delaware.

25. For these reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over MSN Laboratories Private Limited, MSN Life Sciences Private Limited, MSN Pharmaceuticals Inc., and Novadoz.

26. Venue is proper in this Court because MSN Pharmaceuticals Inc. is incorporated in the State of Delaware and therefore resides in this judicial district and because MSN Laboratories Private Limited and MSN Life Sciences Private Limited are foreign entities who may be sued in any judicial district, including Delaware. 28 U.S.C. § 1400(b); 28 U.S.C. §§ 1391(c)(2), 1391(c)(3).

THE PATENT-IN-SUIT

27. Novartis is the owner of the '659 patent, titled "Methods of treatment and pharmaceutical composition." The '659 patent was duly and legally issued on January 24, 2012. A true and correct copy of the '659 patent is attached hereto as Exhibit 1.

28. The '659 patent claims, *inter alia*, a pharmaceutical composition comprising (i) valsartan or a pharmaceutically acceptable salt thereof; (ii) sacubitril or sacubitrilat or a pharmaceutically acceptable salt thereof; and (iii) a pharmaceutically acceptable carrier; wherein (i) and (ii) are administered in combination in about a 1:1 ratio.

29. The United States Court of Appeals for the Federal Circuit has held and adjudged that the '659 patent is valid. CAFC Appeal No. 23-2218, D.I. 106, 107.

INFRINGEMENT OF THE PATENT-IN-SUIT

30. Novartis incorporates paragraphs 1 – 29 as if fully set forth herein.

31. The MSN ANDA Products are pharmaceutical compositions comprising (i) a pharmaceutically acceptable salt of valsartan, *i.e.*, valsartan disodium; (ii) a pharmaceutically acceptable salt of sacubitril, *i.e.*, sacubitril sodium; and (iii) a pharmaceutically acceptable carrier; wherein (i) and (ii) are administered in combination in about a 1:1 ratio, as claimed in the '659 patent.

32. MSN has stipulated that the MSN ANDA Products described in MSN's ANDA No. 213748 infringe the '659 patent. 20-md-2930, D.I. 540 at ¶¶ 1-4.

33. On information and belief, MSN Laboratories Private Limited and MSN Pharmaceuticals Inc., by themselves or in concert with MSN Life Sciences Private Limited, submitted to the FDA ANDA No. 213748 under the provisions of 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the MSN ANDA Products prior to the expiration of the '659 patent.

34. In July 2024, MSN Laboratories Private Limited manufactured commercial batches of the MSN ANDA Products that meet the specifications in MSN's ANDA No. 213748. *See* 20-md-2930, D.I. 1581, Exhibit A, MSNSV_037789-834; MSNSV_037903-914 (July 2024 finished product certificates of analysis).

35. On or about August 9, 2024, over 300,000 bottles from those July 2024 batches of the MSN ANDA Products ("the Imported Products") were imported from India into the United States. *See* 20-md-2930, D.I. 1581, Exhibit B, MSNSV_037788; MSNSV_037835-874; MSNSV_037876-901 (August 9, 2024 commercial invoices and packing lists for the Imported Products), Exhibit C (FDA Import Trade Auxiliary Communications System (ITACS) record confirming importation into the United States of sacubitril/valsartan tablets from India with product code 63FCA99 on August 12-14, 2024 and confirming quantities of Imported Products).

36. On or between August 12-14, 2024, the Imported Products were delivered to Chicago in the United States. *See* 20-md-2930, D.I. 1581, Exhibit B (commercial invoices and packing lists naming Chicago as the final destination of the Imported Products); Exhibit C (FDA Import Trade Auxiliary Communications System (ITACS) record confirming importation into the United States of sacubitril/valsartan tablets from India with product code 63FCA99 on August 12-14, 2024); Exhibit D (FDA Imports Entry Data Search (IEDS) record confirming the

same and listing MSN Laboratories Private Limited as the manufacturer of the 63FCA99 tablets).

37. On the August 9, 2024 commercial invoices and packing lists accompanying the Imported Products, MSN Laboratories Private Limited is listed as the "Exporter." *See* 20-md-2930, D.I. 1581, Exhibit B.

38. On the August 9, 2024 commercial invoices and packing lists accompanying the Imported Products, Novadoz is listed as the "Consignee" and "Buyer." *See* 20-md-2930, D.I. 1581, Exhibit B.

39. In August 8 and 9, 2024 letters to the U.S. Department of Agriculture, MSN Laboratories Private Limited described the Imported Products as "consist[ing] of commercial finished pharmaceuticals intended for human use only." *See* 20-md-2930, D.I. 1581, Exhibit E, MSNSV_037875 and MSNSV_037902 (August 8 and 9, 2024 letters from MSN Laboratories Private Limited to the U.S. Department of Agriculture concerning the Imported Products).

40. On or about December 19, 2024, Defendants imported over 2,200 kilograms of sacubitril/valsartan active pharmaceutical ingredient ("the Imported API") from India into the United States. *See* Exhibit 2 (FDA Import Trade Auxiliary Communications System (ITACS) record confirming importation into the United States of sacubitril/valsartan active pharmaceutical ingredient from India with product code 62ODS12 on December 19, 2024); Exhibit 3 (FDA Imports Entry Data Search (IEDS) record confirming the same and listing MSN Life Sciences Private Limited as the manufacturer of the 62ODS12 active ingredient).

41. On information and belief, Defendants imported the Imported API to manufacture the MSN ANDA Products.

42. On information and belief, one or more Defendants retains possession, custody, and control of the Imported Products and the Imported API.

43. On information and belief, MSN Laboratories Private Limited caused the import of the Imported Products and/or induced Novadoz to import the Imported Products into the United States.

44. The importation of the Imported Products by MSN Laboratories Private Limited and/or the inducement by MSN Laboratories Private Limited of Novadoz's importation of the Imported Products constitute acts that directly infringe and/or induce infringement of the '659 patent under 35 U.S.C.§§ 271(a) and/or (b), respectively, because the Imported Products are pharmaceutical compositions comprising (i) a pharmaceutically acceptable salt of valsartan, *i.e.*, valsartan disodium; (ii) a pharmaceutically acceptable salt of sacubitril, *i.e.*, sacubitril sodium; and (iii) a pharmaceutically acceptable carrier; wherein (i) and (ii) are administered in combination in about a 1:1 ratio, as claimed in the '659 patent.

45. On information and belief, Novadoz and/or MSN Pharmaceuticals Inc., in concert with and under the direction of MSN Laboratories Private Limited and/or MSN Life Sciences Private Limited, have offered for sale the Imported Products in the United States, including to third-party purchasers who serve the Delaware market and/or are located in Delaware, and Novadoz and/or MSN Pharmaceuticals Inc. are continuing to do so. *See* 20-md-2930, D.I. 1605, Exhibit 2 (Novadoz communications with third parties "offering pricing" for the MSN ANDA Products). Those offers for sale constitute acts that directly infringe the '659 patent under 35 U.S.C.§ 271(a).

46. On information and belief, one or more Defendants caused the importation into the United States of the Imported API.

47. The use of the Imported API to manufacture the MSN ANDA Products in the United States constitutes an act of induced infringement under 35 U.S.C. § 271(b) because the MSN ANDA Products directly infringe the '659 patent. On information and belief, one or more Defendants actively encouraged such direct infringement with the knowledge that the use of the Imported API to manufacture the MSN ANDA Products directly infringes the '659 patent.

48. The use of the Imported API to manufacture the MSN ANDA Products constitutes an act of contributory infringement under 35 U.S.C. § 271(c) because the Imported API is a material component of the pharmaceutical compositions of the '659 patent, and because one or more Defendants know that (i) the Imported API is especially adapted for use in infringing the '659 patent (*i.e.*, the Imported API is used to manufacture the infringing MSN ANDA Products) and (ii) the Imported API not a staple article or commodity of commerce suitable for substantial non-infringing use.

49. In sum, MSN Laboratories Private Limited, MSN Life Sciences Private Limited, MSN Pharmaceuticals Inc., and/or Novadoz have directly infringed, induced the infringement of, and contributorily infringed one or more claims of the '659 patent under 35 U.S.C. §§ 271(a), 271(b) and 271(c) by engaging in the importation into the United States of the Imported Products and Imported API and by engaging in commercial activities involving the Imported Products and the Imported API, including the offer for sale of the Imported Products and the use of the Imported API to manufacture MSN's ANDA Products with the knowledge that such use infringes the '659 patent.

50. Novartis has been substantially and irreparably damaged by MSN Laboratories Private Limited's, MSN Life Sciences Private Limited's, MSN Pharmaceuticals Inc.'s, and Novadoz's infringement of the '659 patent.

51. Novartis is entitled to the relief provided by 35 U.S.C. §§ 271(a), 271(b), 271(c), 283, and 284, including an award of damages for any commercial manufacture, use, sale, offer for sale and/or importation of the Imported Products and/or Imported API, and any act committed by MSN Laboratories Private Limited, MSN Life Sciences Private Limited, MSN Pharmaceuticals Inc., and Novadoz with respect to the subject matter claimed in the '659 patent, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1).

52. There is a substantial and immediate controversy between Novartis and MSN Laboratories Private Limited, MSN Life Sciences Private Limited, MSN Pharmaceuticals Inc., and Novadoz concerning the '659 patent. Novartis is entitled to judgment under 35 U.S.C. §§ 271(a), 271(b), and 271(c) that MSN Laboratories Private Limited, MSN Life Sciences Private Limited, MSN Pharmaceuticals Inc., and Novadoz have infringed, induced infringement, and contributorily infringed one or more claims of the '659 patent.

PRAYER FOR RELIEF

WHEREFORE, Novartis prays that this Court grant the following relief:

53. Judgment that Defendants MSN Laboratories Private Limited, MSN Life Sciences Private Limited, MSN Pharmaceuticals Inc., and Novadoz have infringed one or more claims of the '659 patent by engaging in the importation into the United States of the Imported Products and/or Imported API and by engaging in other commercial activities involving the Imported Products and/or Imported API prior to the expiration of the '659 patent, inclusive of any extensions and additional periods of exclusivity;

54. A preliminary and permanent injunction restraining and enjoining Defendants MSN Pharmaceuticals Inc., MSN Laboratories Private Limited, MSN Life Sciences Private Limited, and Novadoz and their officers, agents, attorneys, and employees, and those acting in

privity or concert with them, from engaging in the commercial manufacture, use, sale, or offer for sale in the United States, or importation into the United States, of the MSN ANDA Products (including the Imported Products), and the commercial use, sale, or offer for sale in the United States of the Imported API, prior to the expiration of the '659 patent, inclusive of any extensions and additional periods of exclusivity;

55. Damages or other monetary relief from Defendants MSN Laboratories Private Limited, MSN Life Sciences Private Limited, MSN Pharmaceuticals Inc., and Novadoz for the direct, induced, and contributory infringement of the '659 patent, together with pre-judgment and post-judgment interest;

56. Judgment that MSN Laboratories Private Limited's, MSN Life Sciences Private Limited's, MSN Pharmaceuticals Inc.'s, and Novadoz's direct, induced, and contributory infringement of the '659 patent is and has been willful and that the damages awarded be trebled pursuant to 35 U.S.C. § 284;

57. A declaration that this case is an exceptional case pursuant to 35 U.S.C. § 285 and an award of attorney's fees;

58. Novartis's costs and expenses in this action together with pre-judgment and post-judgment interest; and

59. Such other and further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

60. Pursuant to Federal Rule of Civil Procedure 38(b), Novartis demands a trial by jury on all issues so triable.

Dated: January 17, 2025

MCCARTER & ENGLISH, LLP

/s/ Daniel M. Silver

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