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*

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

NOVARTIS PHARMACEUTICALS CORPORATION'S OPPOSITION TO MSN'S MOTION FOR RECONSIDERATION AND PETITION FOR REHEARING EN BANC

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JANUARY 30, 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 the 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 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, or 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

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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 30, 2025

/s/ Deanne E. Maynard
Deanne E. Maynard

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INTRODUCTION

On January 10, 2025, this Court issued a unanimous, precedential decision reversing the district court's invalidity judgment. Without that erroneous invalidity judgment, MSN's ANDA would not have final FDA approval today. This Court's reversal entitles Novartis to a mandatory remedy in this Hatch-Waxman suit resetting that approval—a remedy binding precedent has already held survives expiration of Novartis's patent on January 15, 2025. That precedent, which MSN accepts, recognized that Congress mandated post-patent-expiration relief in the Hatch-Waxman context to protect an important incentive for studying the benefits of drugs in children—an additional six-month marketing exclusivity that Congress expressly attached to a drug innovator's patent protection. This Court's January 21, 2025 order applied that precedent in granting an injunction pending appeal to protect Congress's mandatory remedy by preserving the status quo that has existed throughout this litigation: no generic versions of ENTRESTO® are (or ever have been) on the market.

Maintaining that status quo even after patent expiration accords with Congress's intent for pediatric exclusivity. Despite stipulating to infringement and losing in this Court on validity, MSN seeks to capitalize on the now-reversed district court judgment by launching its generic products in any window of time needed to complete this appeal and effectuate this Court's judgment. But in seeking the

extraordinary relief of reconsideration of reconsideration, MSN's petition just reargues whether an injunction pending appeal is warranted in the fact-specific circumstances here. Nothing about those made-and-answered arguments warrants further review. MSN merely quotes language about the scope of patent rights without pointing to any actual holding conflicting with the January 21 order. There is no such conflict. Rather than MSN's preferred policy choices, the January 21 order correctly enforces long-settled precedent and the policy Congress enacted to promote drug studies in children by delaying generic entry for six months after patent expiration.

Further review should be denied.

BACKGROUND

A. Legal Framework

In the Hatch-Waxman Act and later amendments, Congress balanced patent rights with concerns about drug safety, efficacy, and cost. *Caraco Pharm. v. Novo Nordisk*, 566 U.S. 399, 404 (2012); *Teva Branded Pharm. v. Amneal Pharms.*, 124 F.4th 898, 903 (Fed. Cir. 2024). To do so, Congress created "a new … act of infringement." *Eli Lilly v. Medtronic*, 496 U.S. 661, 676 (1990). That act includes submitting an ANDA "for a drug claimed in a patent." 35 U.S.C. §271(e)(2).

Congress adopted "specified consequences" for that infringement. *Eli Lilly*, 496 U.S. at 678. "[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.*, 887 F.3d 1117, 1138 (Fed. Cir. 2018). "[O]ne remedy is to set the effective date of [the ANDA's] approval no earlier than the date the brand's patent would expire." *Teva*, 124 F.4th at 904. That remedy is mandatory: "the court *shall* order the effective date of any approval of the drug … involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed." 35 U.S.C. §271(e)(4)(A) (emphasis added). Another remedy is "injunctive relief" against a §271(e)(2) ANDA-filing "infringer to prevent the commercial manufacture" and sale "of an approved drug." *Id.* §271(e)(4)(B).

For an unapproved ANDA, "FDA may not approve the ANDA until the effective date specified by the district court under section 271(e)(4)(A)." *In re Omeprazole*, 536 F.3d 1361, 1367-68 (Fed. Cir. 2008). For an approved ANDA, the order alters the effective approval date, "converting a final approval into a tentative approval." *Id.* FDA is "bound" by such a §271(e)(4)(A) reset order. *Mylan Lab'ys v. Thompson*, 389 F.3d 1272, 1281-82 (D.C. Cir. 2004).

In some circumstances, drug patent holders may earn additional marketing exclusivity—beyond patent expiration—by conducting studies FDA believes could benefit children. 21 U.S.C. §355a; *Mylan*, 389 F.3d at 1284. Congress created this pediatric exclusivity because "'there was little incentive for drug sponsors to

perform studies for medications which they intend to market primarily for adults and the use of which in children is expected to generate little additional revenue.'" *Amgen v. Hargan*, 285 F. Supp. 3d 351, 358 (D.D.C. 2018) (citation/alterations omitted).

Congress attached this exclusivity to patent protections for the studied drug, ensuring that pediatric exclusivity would be enforceable through the mandatory patent remedy resetting an ANDA's approval date. 35 U.S.C. §271(e)(4)(A); 21 U.S.C. §355a(c)(1)(B). That mandatory remedy survives patent expiry. *Omeprazole*, 536 F.3d at 1367-69. When the patent holder has earned pediatric exclusivity, "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. *Id.* at 1368.

B. Factual and Procedural Background

Novartis's U.S. Patent No. 8,101,659 is the foundational patent claiming a groundbreaking heart-failure treatment. Slip.Op.4-6. Novartis's invention—a combination of the drugs valsartan and sacubitril—was a significant, unexpected advance over then-prevailing heart-failure treatments. Slip.Op.4-5. The '659 patent claims that exact combination, including by chemical name. Slip.Op.4. It is undisputed that FDA awarded Novartis an additional six-month pediatric-exclusivity period. FDA, Pediatric Exclusivity Determinations,

https://www.fda.gov/drugs/development-resources/list-determinations-including-written-request.

Novartis sells its sacubitril-valsartan therapy as ENTRESTO®, which has become the preferred first-line therapy for certain forms of heart failure. Slip.Op.4; Appx3428; Appx8750-8758.[1] As a result, ENTRESTO® is Novartis's top-selling drug, generating U.S. sales in 2023 worth over $3 billion. Add108-09; Slip.Op.4.

1. Hatch-Waxman Act proceedings in district court

MSN and others submitted ANDAs "seeking FDA approval to market and sell a generic version of Entresto." Slip.Op.6. Novartis sued alleging the ANDA filings infringed the '659 patent under §271(e)(2). *Id.* The district court construed the only disputed term as having its ordinary meaning: "wherein said [valsartan and sacubitril] are administered in combination." Slip.Op.7. Before trial, MSN unconditionally stipulated to infringement subject only to invalidity. D.Ct.Dkt.526; D.Ct.Dkt.540. After trial, the district court rejected MSN's invalidity theories except written description, entering judgment in July 2023. Slip.Op.8, 11, 14.

2. Injunction and expedited proceedings

Novartis appealed immediately and briefed promptly, completing briefing in January 2024. ECF51; ECF96. Throughout merits briefing, FDA had not approved

[1] Appx_ cites the joint appendix, ECF39. Add_ cites ECF64-1, the addendum to Novartis's injunction-pending-appeal motion. D.Ct.Dkt._ cites the No. 1:20-md-02930-RGA (D. Del.) docket.

MSN's ANDA. When FDA granted MSN final approval in July 2024, Novartis moved to enjoin any MSN launch, in 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 and disruption of ENTRESTO®'s rapidly expanding and dynamic market; and MSN would be unable to compensate Novartis for its losses. *Id.* at 23-25. Novartis explained the particular threat of irreparable harm during the pediatric-exclusivity period because, in at least one decision, this Court "rejected entitlement to Patent Act damages" during "the pediatric-exclusivity period." *Id.* (citing *AstraZeneca v. Apotex*, 782 F.3d 1324, 1341-45 (Fed. Cir. 2015)).

Novartis explained that prevailing on appeal would entitle it—"without any showing on the equities—to a stay of MSN's ANDA approval until the '659 patent and its exclusivities expire." *Id.* at 24. A premature launch "would render that relief all-but worthless" (*id.*), as rescission of that approval would "come too late if MSN launches, forever disrupting the market" (ECF71 at 10).

In August 2024, this Court expedited Novartis's appeal and ordered MSN "temporarily enjoined from commercial marketing and sale of [MSN's] generic version of Entresto®" until "further notice," also ordering Novartis to file a bond. ECF65 at 3; ECF73 at 3; ECF88 at 3; D.Ct.Dkt.1566.

After MSN indicated it would launch immediately following patent expiration—despite this Court's injunction and Novartis's pediatric exclusivity—Novartis moved to clarify and continue the injunction. ECF105. Among other things, in mid-December 2024, MSN imported nearly 2.5 tons of sacubitril/valsartan, the active pharmaceutical ingredient used to manufacture its generic, and earlier imported 300,000+ bottles of generic tablets. D.Ct.Dkt.1581.

3. This Court's validity decision

On January 10, 2025, before the '659 patent expired, this Court issued a unanimous, precedential decision reversing the invalidity judgment. Slip.Op.17. The Court concluded that the claimed pharmaceutical composition comprising valsartan and sacubitril administered "in combination" is "plainly described throughout the specification." Slip.Op.12. The Court thus held the claims "supported by an adequate written description." Slip.Op.13. It did so without changing claim construction, which MSN conceded was "unchallenged." Oral.Arg.Audio.20:45. This Court affirmed the rejection of MSN's other invalidity arguments and issued judgment. Slip.Op.15-17; ECF107.

4. Post-decision proceedings

Later that day, stating it had "entered judgment resolving the underlying appeal," this Court issued an order denying Novartis's motion to clarify or continue

the administrative injunction, denying Novartis's motion for an injunction pending appeal as "moot," and lifting the administrative injunction. ECF109.

Early the next day, January 11, 2025, Novartis moved for immediate issuance of the mandate so the district court could enter the mandatory remedy under §271(e)(4)(A) requiring FDA to reset MSN's ANDA's effective approval date. 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." *Id.* at 2. MSN opposed. ECF112. On January 14, 2025, the Court denied mandate expedition. ECF114.

Meanwhile, following this Court's January 10, 2025 order lifting the administrative injunction, Novartis again moved in district court under Rule 62(d) for an injunction against MSN marketing. D.Ct.Dkt.1713 at 1. The district court dismissed that motion on January 15, 2025, concluding it lacks jurisdiction to issue injunctive relief absent issuance of the mandate. D.Ct.Dkt.1738.

Novartis then moved in this Court for reconsideration or rehearing of the January 10, 2025 order. ECF115. Novartis explained that the Court's merits decision did not moot Novartis's request for an injunction pending appeal because, so long as the mandate has not issued, this appeal remains "pending." *Id.* at 10 (citing *GPX Int'l Tire v. U.S.*, 678 F.3d 1308, 1312 (Fed. Cir. 2012)). An injunction remains necessary to preserve meaningful relief given MSN's clear intent to launch,

which would render Novartis's earned pediatric exclusivity worthless. *Id.* at 10-15. The '659 patent expired hours after Novartis filed its request. Slip.Op.4.

On January 16, 2025, this Court "temporarily enjoined [MSN] from commercial marketing and sale of their generic version of Entresto® until further notice while the court consider[ed]" Novartis's request. ECF121. MSN opposed Novartis's reconsideration motion (ECF123), making the same arguments MSN now repackages into its own reconsideration motion and petition. But even in that opposition, MSN never contended that this Court's merits decision rendered Novartis's injunction-pending-appeal motion moot. ECF126 at 2.

On January 21, 2025, "[b]ased on further consideration of Novartis's request, in view of the more developed arguments in the reconsideration papers," this Court granted reconsideration. ECF127. The Court enjoined MSN "from commercial marketing and sale of their generic version of Entresto®" "until issuance of the mandate in these appeals." ECF127 at 3. It also directed Novartis "to file a bond in the district court." ECF127 at 3-4.

REASONS FOR DENIAL

A. MSN Shows No Conflict with Precedent

Nothing in MSN's petition warrants reconsideration of reconsideration, much less the full Court's review. The Court's January 21 order corrected a misunderstanding about mootness—the order recognized that, because this appeal

remains pending, this Court's validity judgment did not render moot Novartis's motion for an injunction pending appeal. ECF126. MSN never contests (or even acknowledges) that basis for the reconsideration order, nor does MSN argue that issue warrants further review. Instead, MSN has simply repackaged its opposition to Novartis's reconsideration motion as a petition (*compare* MSN.Pet.iii *with* ECF123 at iii)—laying bare that MSN just seeks a do-over of made-and-answered, case-specific arguments, without any colorable basis for further review. This alone calls for denial.

Although MSN asserts that the January 21 order conflicts with *Kimble v. Marvel Entertainment* and *Kearns v. Chrysler*, MSN never discusses those decisions' holdings, let alone how the order conflicts with either. MSN.Pet.1 (citing 576 U.S. 446 (2015); 32 F.3d 1541 (Fed. Cir. 1994)). Nothing in *Kimble* or *Kearns* addresses the Hatch-Waxman context, where Congress provided protection for patent *and* pediatric-exclusivity rights.

MSN's other cited decisions—*Omeprazole* and *AstraZeneca*—address that context and actually confirm that the January 21 order fully accords with settled precedent. As explained, Congress created "a new" act of infringement under 35 U.S.C. §271(e)(2): the submission of an ANDA for a patented drug. *Eli Lilly*, 496 U.S. at 676; *Salix Pharms. v. Norwich Pharms.*, 98 F.4th 1056, 1068 (Fed. Cir. 2024) ("submission of the ANDA" during the patent's term is the relevant infringing

act). And Congress created a new set of remedies in §271(e)(4) for that new form of liability. *Vanda*, 887 F.3d at 1138. These remedies include subparagraph (A)'s "unique" mandatory remedy requiring a court order resetting " 'the effective date of any approval' " of an ANDA for the innovative drug. *AstraZeneca*, 782 F.3d at 1342 (quoting 35 U.S.C. §271(e)(4)(A)). Such an order is akin to an automatic injunction, because it revokes an ANDA filer's final approval, thus preventing any commercial marketing or sales. *Vanda*, 887 F.3d at 1123, 1138-39 (affirming district court grant of injunctive relief to enforce requirements of §271(e)(4)(A)).

Omeprazole—which MSN accepts as settled law—held this relief survives patent expiration "to enforce [the patentee]'s right to market exclusivity": §271(e)(4)(A) "provide[s] a post-expiration remedy for infringement under section 271(e)(2)" based on filing an ANDA pre-patent expiration. *Omeprazole*, 536 F.3d at 1367. In this way, §271(e)(4) relief is no different from other forms of relief for past infringement, like damages, that survive patent expiration. *See id.* In *Omeprazole*, although the patents expired before a court decision, this Court affirmed post-expiration authority to order FDA to reset the effective date of already-approved ANDAs and preserve the patentee's pediatric exclusivity. *Id.* at 1366-69, 1381-82. And the Court specifically considered and rejected any alleged conflict with decisions like *Kearns* involving other forms of infringement and relief: "*Kearns*, however, 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)." *Omeprazole*, 536 F.3d at 1368-69.[2]

MSN does not dispute that issuance of the mandatory reset order under §271(e)(4)(A), even after patent expiration, will necessarily prevent marketing of its generic products until after July 15, 2025. Rightly so. A §271(e)(4)(A) order "convert[s] a final approval into a tentative approval." *Omeprazole*, 536 F.3d at 1368. And under 21 U.S.C. §355a(c)(1)(B), FDA is barred from finally approving such a converted ANDA until after the pediatric-exclusivity period—whether the district court specifies that date or simply orders approval "not earlier than" patent expiration. *Omeprazole*, 536 F.3d at 1368.

MSN is wrong that *Omeprazole* and *AstraZeneca* "indicate that MSN has the right to launch its finally approved products" until that §271(e)(4)(A) order. MSN.Pet.17-18. The generics in those cases launched only *before* any court determination of infringement of a valid patent. *Omeprazole*, 536 F.3d at 1366. Nothing about that means courts may permit a generic launch *after* such a determination, contravening §271(e)(4) and 21 U.S.C. §355a(c)(1)(B)(ii). Rather,

[2] Novartis's new suit is distinguishable for the same reason. *Contra* MSN.Mot.4. It stems from MSN's infringement under 35 U.S.C. §271(a), (b), and (c), based in part on MSN's importation into the United States of ANDA products and their active ingredients. MSN.Pet.Addm11-14. The issue here is Novartis's entitlement to the statutory remedies for MSN's infringement under 35 U.S.C. §271(e)(2) based on the ANDA filing itself.

once a court determined infringement of a valid patent, the generics in *Omeprazole* were blocked from marketing during the pediatric-exclusivity period, including pending appeal. 536 F.3d at 1366; *Omeprazole*, No. 07-1414, ECF24 (Fed. Cir. June 26, 2007) (denying ANDA filer's stay-pending-appeal motion seeking to market).

Because there is no conflict, MSN actually seeks new law: a ruling that this Court is powerless to protect the effectiveness of its own judgment reversing a district court while the ministerial acts of implementing that judgment are carried out. As Novartis has repeatedly explained, and MSN has not disputed, MSN's current FDA approval to market generic ENTRESTO® is predicated on the now-reversed invalidity judgment. ECF126 at 2 (Novartis making same point); MSN.Pet.1-2 (MSN asserting right to launch without disputing). Given MSN's infringement stipulation, if the district court in 2023 had entered the validity judgment this Court has now held was required, MSN would currently lack FDA approval and would lack it until after Novartis's pediatric-exclusivity period. The mandatory §271(e)(4)(A) order will remedy that error.

In contrast to MSN's request for new law, settled law supports the Court's injunction. In addition to §271(e)(4)'s express statutory authority here, Rule 8 and the All Writs Act reflect courts' inherent authority to issue "orders to preserve the existing conditions" so that relief for the prevailing party will be effective. *United*

States v. Shipp, 203 U.S. 563, 573 (1906); Fed. R. App. P. 8(a); 28 U.S.C. §1651; 35 U.S.C. §271(e)(4)(A), (B); ECF105 at 9 (citing authorities). Before the '659 patent expired, this Court properly enjoined MSN's commercial marketing pending appeal to preserve the status quo and prevent MSN from benefitting from a then-likely erroneous judgment. The current injunction serves the same end even after patent expiry.

B. The Court's Order Granting Reconsideration and An Injunction Is Correct and Certainly Not Manifest Error Warranting Further Review

The lack of any conflict alone warrants denial. So does the fact that all relevant factors support the Court's injunction.

Novartis's likely success. This Court's decision reversed the invalidity judgment; MSN stipulated to infringement; and FDA granted Novartis pediatric exclusivity for ENTRESTO® based on the '659 patent. Slip.Op.8, 11-14, 17; ECF64-1 at Add2. Under the plain terms of governing statutes, regulations, and precedent, Novartis is thus entitled to the mandatory statutory remedy of an order requiring FDA to reset the effective approval date of MSN's ANDA. 35 U.S.C. §271(e)(4)(A); 21 U.S.C. §355a(c)(1)(B); *Omeprazole*, 536 F.3d at 1367-69.

MSN's contrary arguments depend on *undoing* this mandatory relief. MSN.Pet.14-17. Those arguments rely on the same flawed reasoning this Court rejected, conflating the question of what a patent claims as the invention with what

may infringe a patent's claims. Slip.Op.13-14. For example, relying solely on a footnote in this Court's decision, MSN argues the Court changed the claim construction, so MSN's ANDA products no longer infringe. MSN.Pet.15-16 (quoting Slip.Op.14 n.5). But that footnote merely further explained this Court's ruling; it did not change the "unchallenged" claim construction, nor would any change permit MSN to escape its own stipulation in any event. Oral.Arg.Audio.20:45 (MSN's counsel: "no one has asked to overturn the claim construction").

MSN similarly hypothesizes a potential post-judgment delisting cause of action based on misconstruing this Court's recent *Teva* decision. There, the patents "relate[d] to improvements in the device parts of inhalers"—not (as here) a patent on a drug's active ingredients. *Teva*, 124 F.4th at 908.

Novartis's irreparable harm. Novartis showed massive and unrecoverable financial losses, lost market share, and loss of goodwill. MSN's reconsideration opposition never disputed, given the specifics of this market, that those consequences will likely follow from even a brief launch. ECF123 at 18-21 (MSN's reconsideration opposition not contesting); ECF126 at 4 (Novartis's reconsideration reply pointing this out). MSN's rehearing petition is too late to contest these issues. And MSN never disputes that the threat of irreparable harm is even greater now that the '659 patent has expired, as Novartis could be left with no remedy for a launch

during the pediatric exclusivity period. *See* ECF115 at 15 (Novartis reconsideration motion, citing *AstraZeneca*, 782 F.3d at 1341-45).

Instead, MSN repeats arguments based on an oral ruling from a D.C. district court in an APA case against the FDA. *Compare* MSN.Pet.13-14 *with* ECF123 at 20-21. Again, those made-and-answered arguments provide no basis for further review. Although MSN's petition quotes that ruling at more length, that too is not new: MSN's reconsideration opposition had attached the entire transcript. ECF123 at Add1-14. And while MSN gestures at collateral estoppel (MSN.Pet.12), it rightly does not contend there is any from that unappealable TRO ruling involving distinct legal claims. Nor, of course, is that ruling binding on this Court. If anything, the rulings of other courts emphasize the need for this Court's intervention. For example, the D.C. district court's primary rationale was that this Hatch-Waxman litigation, not an APA action against the FDA, is the avenue Congress provided for enforcement of Novartis's pediatric-exclusivity period. ECF123 at Add7-8.

The public interest and balance of the equities. Equally unavailing, and no basis for rehearing, is MSN's rehashing of nonbinding district court rulings about the public interest and the balance of the equities. MSN.Pet.12. This Court resolves Rule 8 motions de novo and has already correctly refused MSN's invitation to substitute those courts' conclusions for its own. 20 Moore's Fed. Prac. Civil §308.40 (2024).

Here, the Court's injunction appropriately recognizes that the public interest favors honoring the bargain Congress struck in the statutory scheme governing the approval of pharmaceutical products, the pediatric-exclusivity framework, and suits like this one. *Mylan*, 389 F.3d at 1284 (noting pediatric exclusivity is offered "in return for" the valuable and helpful information the innovator manufacturer created). After an innovative drug manufacturer performs studies requested by FDA to show that a new drug works for children, "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. As explained, Congress attached that exclusivity to the innovator's patent protections for the drug that was the subject of the pediatric studies. 21 U.SC. §355a(c).

MSN's argument that the pediatric-exclusivity period cannot be protected by injunctive relief after the patent's expiration would nullify the congressional scheme at the very time it would matter most: when the patent term has ended, but the period of pediatric exclusivity is supposed to be in force. And if that were so, it would deprive innovator drug manufacturers of the incentive Congress provided to conduct these important studies. Yet far from leaving pediatric exclusivity toothless, Congress enacted 35 U.S.C. §271(e)(4) to ensure patentees would have recourse for "post-expiration" relief. *Omeprazole*, 536 F.3d at 1367-68.

The balance of hardships also tips fully to Novartis. Novartis will lose mandatory statutory rights, market share, and more that MSN never asserts can be recompensed. Were MSN to launch in defiance of this Court's validity decision and Novartis's rights, each lost day of marketing exclusivity would be lost forever. Yet MSN makes no serious argument that it cannot be fully protected by the ordered bond. ECF127 at 3-4.

CONCLUSION

MSN's motion and petition should be denied. If the court orders further proceedings, the current injunction should be maintained, given the bond fully protecting MSN. If the Court lifts the injunction, Novartis respectfully requests 48 hours to seek further relief.

Dated: January 30, 2025

Respectfully submitted,

/s/ Deanne E. Maynard

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STATUTORY ADDENDUM

IN RE: ENTRESTO (SACUBITRIL/VALSARTAN)

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

STATUTORY ADDENDUM
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21 U.S.C. § 355a(c)

§355a. Pediatric studies of drugs

(c) Market exclusivity for already-marketed drugs

(1) In general

Except as provided in paragraph (2), if the Secretary determines that information relating to the use of an approved drug in the pediatric population may produce health benefits in that population and makes a written request to the holder of an approved application under section 355(b)(1) of this title for pediatric studies (which shall include a timeframe for completing such studies), the holder agrees to the request, such studies are completed using appropriate formulations for each age group for which the study is requested within any such timeframe, and the reports thereof are submitted and accepted in accordance with subsection (d)(4)—

(A)(i)(I) the period referred to in subsection (c)(3)(E)(ii) of section 355 of this title, and in subsection (j)(5)(F)(ii) of such section, is deemed to be five years and six months rather than five years, and the references in subsections (c)(3)(E)(ii) and (j)(5)(F)(ii) of such section to four years, to forty-eight months, and to seven and one-half years are deemed to be four and one-half years, fifty-four months, and eight years, respectively; or

(II) the period referred to in clauses (iii) and (iv) of subsection (c)(3)(E) of such section, and in clauses (iii) and (iv) of subsection (j)(5)(F) of such section, is deemed to be three years and six months rather than three years; and

(ii) if the drug is designated under section 360bb of this title for a rare disease or condition, the period referred to in section 360cc(a) of this title is deemed to be seven years and six months rather than seven years; and

(B)(i) if the drug is the subject of—

(I) a listed patent for which a certification has been submitted under subsection (b)(2)(A)(ii) or (j)(2)(A)(vii)(II) of section 355 of this title and for which pediatric studies were submitted prior to the expiration of the patent (including any patent extensions); or

(II) a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iii) or (j)(2)(A)(vii)(III) of section 355 of this title,

the period during which an application may not be approved under section 355(c)(3) of this title or section 355(j)(5)(B)(ii) of this title shall be extended by a period of six months after the date the patent expires (including any patent extensions); or

(ii) if the drug is the subject of a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 355 of this title, and in the patent infringement litigation resulting from the certification the court determines that the patent is valid and would be infringed, the period during which an application may not be approved under section 355(c)(3) of this title or section 355(j)(5)(B) of this title shall be extended by a period of six months after the date the patent expires (including any patent extensions).

(2) Exception

The Secretary shall not extend the period referred to in paragraph (1)(A) or (1)(B) if the determination made under subsection (d)(4) is made later than 9 months prior to the expiration of such period.

35 U.S.C. § 271(e)

§271. Infringement of patent

(e)(1) It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

(2) It shall be an act of infringement to submit—

(A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent,

(B) an application under section 512 of such Act or under the Act of March 4, 1913 (21 U.S.C. 151–158) for a drug or veterinary biological product which is not primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques and which is claimed in a patent or the use of which is claimed in a patent, or

(C)(i) with respect to a patent that is identified in the list of patents described in section 351(l)(3) of the Public Health Service Act (including as provided under section 351(l)(7) of such Act), an application seeking approval of a biological product, or

(ii) if the applicant for the application fails to provide the application and information required under section 351(l)(2)(A) of such Act, an application seeking approval of a biological product for a patent that could be identified pursuant to section 351(l)(3)(A)(i) of such Act,

if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug, veterinary biological product, or biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

(3) In any action for patent infringement brought under this section, no injunctive or other relief may be granted which would prohibit the making, using, offering to sell, or selling within the United States or importing into the United States of a patented invention under paragraph (1).

(4) For an act of infringement described in paragraph (2)—

(A) the court shall order the effective date of any approval of the drug or veterinary biological product involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed,

(B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug, veterinary biological product, or biological product,

(C) damages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug, veterinary biological product, or biological product, and

(D) the court shall order a permanent injunction prohibiting any infringement of the patent by the biological product involved in the infringement until a date which is not earlier than the date of the expiration of the patent that has been infringed under paragraph (2)(C), provided the patent is the subject of a final court decision, as defined in section 351(k)(6) of the Public Health Service Act, in an action for infringement of the patent under section 351(l)(6) of such Act, and the biological product has not yet been approved because of section 351(k)(7) of such Act.

The remedies prescribed by subparagraphs (A), (B), (C), and (D) are the only remedies which may be granted by a court for an act of infringement described in paragraph (2), except that a court may award attorney fees under section 285.

(5) Where a person has filed an application described in paragraph (2) that includes a certification under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), and neither the owner of the patent that is the subject of the certification nor the holder of the approved application under subsection (b) of such section for the drug that is claimed by the patent or a use of which is claimed by the patent brought an action for infringement of such patent before the expiration of 45 days after the date on which the notice given under subsection (b)(3) or (j)(2)(B) of such section was received, the courts of the United States shall, to the extent consistent with

the Constitution, have subject matter jurisdiction in any action brought by such person under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed.

(6)(A) Subparagraph (B) applies, in lieu of paragraph (4), in the case of a patent—

(i) that is identified, as applicable, in the list of patents described in section 351(l)(4) of the Public Health Service Act or the lists of patents described in section 351(l)(5)(B) of such Act with respect to a biological product; and

(ii) for which an action for infringement of the patent with respect to the biological product—

(I) was brought after the expiration of the 30-day period described in subparagraph (A) or (B), as applicable, of section 351(l)(6) of such Act; or

(II) was brought before the expiration of the 30-day period described in subclause (I), but which was dismissed without prejudice or was not prosecuted to judgment in good faith.

(B) In an action for infringement of a patent described in subparagraph (A), the sole and exclusive remedy that may be granted by a court, upon a finding that the making, using, offering to sell, selling, or importation into the United States of the biological product that is the subject of the action infringed the patent, shall be a reasonable royalty.

(C) The owner of a patent that should have been included in the list described in section 351(l)(3)(A) of the Public Health Service Act, including as provided under section 351(l)(7) of such Act for a biological product, but was not timely included in such list, may not bring an action under this section for infringement of the patent with respect to the biological product.

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 the filing has been prepared using a proportionally-spaced typeface and includes 3,747 words, excluding the parts of the filing exempted by the Rules.

Dated: January 30, 2025

/s/ Deanne E. Maynard
Deanne E. Maynard

ny-2876269