Nos. 2023-2317, 2023-2319

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

IN RE ENTRESTO (SACUBITRIL/VALSARTAN)

NOVARTIS PHARMACEUTICALS CORPORATION,

Plaintiff-Appellant

v.

NANJING NORATECH PHARMACEUTICAL CO., LTD.,

Defendant-Appellee

Appeals from the United States District Court for the District of Delaware, Nos. 1:20-md-02930-RGA, 1:23-cv-00401-RGA, Hon. Richard G. Andrews

NOVARTIS PHARMACEUTICALS CORPORATION'S OPPOSITION TO NORATECH'S PETITION FOR REHEARING OR REHEARING EN BANC

NICHOLAS N. KALLAS
CHRISTINA SCHWARZ
VENABLE LLP
151 W. 42nd Street, 49th Floor
New York, NY 10036

DEANNE E. MAYNARD
SETH W. LLOYD
MORRISON & FOERSTER LLP
2100 L Street NW, Suite 900
Washington, DC 20037
Tel.: (202) 887-8740
DMaynard@mofo.com

Counsel for Novartis Pharmaceuticals Corporation

APRIL 24, 2025

CERTIFICATE OF INTEREST

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

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

Novartis Pharmaceuticals Corp.

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

None.

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

Novartis AG

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

McCARTER & ENGLISH, LLP: Daniel M. Silver, Alexandra M. Joyce

VENABLE LLP: Christopher E. Loh, Jared L. Stringham, Melinda R. Roberts

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: April 24, 2025

/s/ Deanne E. Maynard
Deanne E. Maynard

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Other Authorities

TABLE OF ABBREVIATIONS

’659 patent	U.S. Patent No. 8,101,659
ANDA	Abbreviated new drug application
D.Ct.Dkt._	ECF docket number for filings in *Novartis Pharmaceuticals Corp. v. Nanjing Noratech Pharmaceutical Co., Ltd.*, No. 1:23-cv-00401-RGA (D. Del.)
FDA	United States Food and Drug Administration
MSN	*In re Entresto (Sacubitril/Valsartan)*, Nos. 23-2218, *et seq.*, 125 F.4th 1090 (Fed. Cir. Jan. 10, 2025) (opinion and judgment reversing district court)
Noratech’s ANDA	ANDA No. 213671, originally filed by Noratech and later transferred to Gerbera Therapeutics, Inc. D.Ct.Dkt.68. Gerbera agreed to be bound by all future court orders in this action, including this appeal, and that all appeal filings by Noratech are deemed filed on Gerbera’s behalf. *Id.*

INTRODUCTION

The Court's nonprecedential Order vacated and remanded a collateral-estoppel judgment after this Court in a separate appeal reversed the judgment that was the sole basis for collateral estoppel. Nothing about that Order warrants further review, as it will have no effect beyond the unique facts here, presents no question of exceptional importance, and conflicts with no precedent. *See* Fed. R. App. P. 40(b)(2). Indeed, multiple independent grounds support the Order's vacatur, including that the Order implements the very result the parties agreed to and the district court endorsed when entering the appealed collateral-estoppel judgment.

Noratech's petition fails to acknowledge all the grounds for vacatur here, instead presenting only arguments about Article III and mootness that the panel already considered. Such a request for a do-over is not a proper basis for panel or en banc rehearing and is alone reason to deny Noratech's petition.

In any event, as Novartis explained in opposing Noratech's motion to dismiss, Noratech misreads two long-settled decisions, neither of which Noratech asks to be reconsidered: *In re Omeprazole Patent Litigation*, 536 F.3d 1361 (Fed. Cir. 2008); and *AstraZeneca v. Apotex*, 782 F.3d 1324 (Fed. Cir. 2015). *Omeprazole* already answered "yes" to the question Noratech says is unresolved by precedent: whether, in Hatch-Waxman cases like this one, courts maintain jurisdiction after patent expiration to adjudicate infringement under 35 U.S.C. §271(e)(2) and to grant relief

to protect a patent holder's pediatric exclusivity. *Omeprazole*, 536 F.3d at 1366-69. *Omeprazole* squarely held Article III jurisdiction survives patent expiration on these facts because the pre-expiration act of filing an ANDA can still be found to infringe and can serve as the basis for meaningful relief. Rather than show otherwise, Noratech largely ignores *Omeprazole* and relies on *AstraZeneca*. But *AstraZeneca* involved no questions of mootness or Article III jurisdiction. The language Noratech quotes to suggest otherwise addressed a different issue—the availability of royalties for post-patent-expiration sales for infringement "predicated on 35 U.S.C. §271(a)," not §271(e)(2). *AstraZeneca*, 782 F.3d at 1344. *AstraZeneca*'s conclusion that post-patent-expiration sales cannot infringe a patent under §271(a) has no bearing here.

Regardless, Noratech's petition should be rejected at the outset for the simple reason that the Order is supported by independent grounds that Noratech makes no attempt to show warrant further review. As Novartis explained in opposing Noratech's dismissal motion, even were Noratech correct that this appeal is moot, such mootness would be due to happenstance (as Noratech has never contested), and vacatur would thus be warranted under *United States v. Munsingwear*, 340 U.S. 36 (1950). Accordingly, the further review that Noratech seeks would not change the outcome.

Noratech's petition should be denied.

BACKGROUND

Novartis holds U.S. Patent No. 8,101,659 on its blockbuster heart-failure drug ENTRESTO®. FDA granted Novartis six months of marketing exclusivity past the patent's expiration in exchange for Novartis performing requested pediatric studies. 21 U.S.C. §355a(c); FDA, Pediatric Exclusivity Determinations.[1] The pediatric-exclusivity period runs from expiration of the '659 patent on January 15, 2025, through the end of July 15, 2025. *See* Orange Book: Approved Drug Products.[2]

In 2022, Noratech filed an amended ANDA seeking to market generic ENTRESTO®. D.Ct.Dkt.1, 2-6(¶¶5, 29). Noratech's ANDA included a paragraph IV certification that the '659 patent is invalid or not infringed. *Id.* According to Noratech, FDA has yet to approve its ANDA. Noratech.Pet.12-13.

Novartis sued Noratech, alleging that the filing of Noratech's ANDA infringed the '659 patent under 35 U.S.C. §271(e)(2). D.Ct.Dkt.1, 2-6(¶¶5-7, 26-28). This case was designated "a member to" a multidistrict litigation involving several other generic manufacturers, including MSN ("*MSN*"). D.Ct.Dkt (May 3, 2023 note). Because this case was filed later, it was not fully consolidated with the

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

[2] https://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?Product_No=001&Appl_No=207620&Appl_type=N.

multidistrict litigation. Novartis thus proceeded to trial against MSN and others first. After that trial, the district court entered judgment for MSN in July 2023, holding the '659 patent invalid for inadequate written description. Novartis immediately appealed that *MSN* judgment, briefed that appeal promptly, and moved to expedite that appeal as soon as FDA's approval of MSN's ANDA gave Novartis a reasonable basis to do so. *MSN*, ECF64 at 27.

Rather than proceed in district court on noninfringement or invalidity, Noratech stipulated to a final judgment based on the *MSN* judgment. ECF22 at Add1-3. Noratech and Novartis agreed that Novartis's assertion against Noratech of infringement of the '659 patent failed under collateral-estoppel principles, subject to the *MSN* appeal's outcome. *Id.* The parties also agreed, "if the [*MSN*] Final Judgment is reversed or vacated, Novartis would be entitled to an order from the Federal Circuit vacating the judgment in this action and remanding this action to th[e District] Court for further proceedings or an order from th[e District] Court vacating the final judgment under Fed. R. Civ. P. 60(b)(5)." ECF22 at Add2. In August 2023, the district court thus entered judgment on the '659 patent for Noratech under Federal Rule of Civil Procedure 54(b) based solely on collateral estoppel. ECF22 at Add2-3. Novartis appealed. D.Ct.Dkt.31.

The parties jointly moved to stay the appellate proceedings here pending resolution of the *MSN* appeal, based on their agreement that this Court's *MSN*

decision would govern this appeal's outcome. ECF12 at 1-2. This Court granted the stay and ordered the parties to update the Court following issuance of the *MSN* mandate. *Id.*

On January 3, 2025, Novartis moved for a stay of the judgment here pending this appeal. ECF13. Novartis explained that a stay was necessary to prevent FDA from relying on the appealed collateral-estoppel judgment to prematurely grant final approval of Noratech's ANDA before or during Novartis's pediatric-exclusivity period that would begin on January 16, 2025. ECF13 at 13-15. At the same time, Novartis requested a temporary stay (while this Court considered Novartis's stay motion) and an order requiring Noratech to provide notice before commercial marketing. ECF13 at 16-18. On January 8, 2025, this Court granted the temporary stay and notice requirement. ECF17.

On January 10, 2025, this Court decided *MSN*. In a precedential decision, a unanimous panel reversed the invalidity judgment there and held the '659 patent's claims had adequate written description support. *MSN*, 125 F.4th at 1097-99. The Court also enjoined MSN from commercial marketing and sale of generic versions of ENTRESTO® until issuance of the *MSN* mandate. *MSN*, ECF121, ECF127.

After this Court's reversal and orders in *MSN* protecting Novartis's pediatric exclusivity, and despite previously agreeing that *MSN* would control the outcome of this appeal, Noratech filed an "expedited" motion to dismiss this appeal. ECF20.

Noratech's motion made the same arguments as its current rehearing petition, arguing that patent expiration purportedly mooted Novartis's appeal because the '659 patent can no longer be infringed and that this Court's decision in *AstraZeneca* supposedly means remedies under 35 U.S.C. §271(e)(4) are no longer available. ECF20 at 3-16. Noratech asked the Court to dismiss this appeal yet "leav[e] the existing judgment" of invalidity based on collateral estoppel "in place." ECF20 at 15.

In response, Novartis explained that Noratech failed to prove mootness for multiple, independent reasons. ECF22 at 8-24. For instance, *Omeprazole* already considered and rejected an identical mootness argument. *Id.* Plus, both Novartis and Noratech have concrete interests at stake in this appeal because, under the regulatory scheme here, whether the collateral-estoppel judgment is vacated could affect the timing of FDA approval of Noratech's ANDA. *Id.* Novartis also explained that the outcome of this appeal would be the same even were Noratech correct about mootness because vacatur of the district court's invalidity judgment would still be warranted under *Munsingwear*. ECF22 at 9, 22-23.

The Court issued a short, nonprecedential Order in response to both Novartis's motion to stay the collateral-estoppel judgment pending appeal and Noratech's motion to dismiss. The Order body reads in full:

> Upon consideration of appellant's motion to stay the final judgment pending appeal, appellee's motion to dismiss, the parties' joint statement that if the invalidity judgment in Appeal No. 2023-2218 "is not affirmed," "the judgment in this case should be vacated and the case remanded for further proceedings," ECF No. 9 at 3, and this court's recent decisions and orders in Appeal No. 2023-2218 reversing the relevant aspect of the judgment and enjoining the defendants in that case from launching their generic drug until issuance of mandate in that appeal,
>
> IT IS ORDERED THAT:
>
> (1) The district court's judgment is vacated and the cases remanded to the district court for further proceedings.
>
> (2) The district court's judgment is stayed until issuance of mandate in Appeal Nos. 2023-2317, 2023-2319.
>
> (3) Any pending motion otherwise is denied.
>
> (4) Each party shall bear its own costs.

Order.2 (referring to *MSN* as "Appeal No. 2023-2218").

Since the Order, the Court issued the *MSN* mandate. *MSN*, ECF159. Hours after the mandate issued, the *MSN* district court entered final judgment for Novartis, including an order under 35 U.S.C. §271(e)(4)(A) that the effective date of any approval of MSN's ANDA shall be no earlier than July 16, 2025, after the expiration of Novartis's pediatric exclusivity.

REASONS TO DENY REHEARING

A. Rehearing Should Be Denied Because Noratech Fails to Address Multiple Independent Grounds That Support the Vacatur Order

Noratech's rehearing petition should be denied because it fails to challenge two independent grounds supporting the Court's Order, so granting rehearing on Noratech's challenges would not affect the outcome.

First, even assuming arguendo that this case were moot, vacatur would still be the correct result under *Munsingwear*. The "established practice" for appellate courts "dealing with a civil case from a court in the federal system which has become moot" is "to reverse or vacate the judgment below." *Munsingwear*, 340 U.S. at 39-40. This Court regularly orders vacatur of an invalidity ruling or judgment if it finds mootness "due to the intervening happenstance of the patent's expiration," the same basis for mootness Noratech alleges. *INVT SPE v. ITC*, 46 F.4th 1361, 1369-70 (Fed. Cir. 2022); *e.g.*, *Kinzenbaw v. Deere*, 741 F.2d 383, 386-87 (Fed. Cir. 1984); *Sumitomo Pharma v. Vidal*, No. 22-2276, 2024 WL 1478446, at *2-3 (Fed. Cir. Apr. 5, 2024).

Noratech's petition ignores this independent ground even though Novartis expressly moved for *Munsingwear* vacatur if the Court concluded the case is moot. ECF22 at 22-23; ECF24 at 1-3. Instead, Noratech asserts in passing that the appeal should be dismissed while "leaving the existing judgment in place"—citing, as it did in its original motion, inapposite decisions where no party appears to have requested

Munsingwear vacatur. *Compare* Pet.20 (citing *Yeda Rsch. v. Abbott*, 837 F.3d 1341 (Fed. Cir. 2016), and *Metaullics Sys. v. Cooper*, 100 F.3d 938 (Fed. Cir. 1996)) *with* ECF20 at 15 (identical sentence and citations in Noratech's dismissal motion); *see* ECF24 (Novartis explaining *Yeda* and *Metaullics* distinguishable for this reason).

Noratech has never contested that the conditions for *Munsingwear* vacatur are satisfied if Novartis's appeal is moot: mootness would be by happenstance and not through any fault of Novartis. Where a "controversy has become entirely moot" in these circumstances, the Supreme Court has emphasized "it is the *duty* of the appellate court to set aside the decree below." *Great W. Sugar v. Nelson*, 442 U.S. 92, 92-94 (1979) (granting certiorari and summarily reversing court of appeals for failing to vacate; emphasis by Supreme Court; citation omitted); *see Acheson Hotels v. Laufer*, 601 U.S. 1, 5 (2023) (declining to reconsider "well settled" "*Munsingwear* practice"); *Uniloc v. ADP*, 772 F. App'x 890, 895-96 (Fed. Cir. 2019) (reversing district court's refusal to vacate, as vacatur "should have been granted" following happenstance mootness).[3]

[3] Noratech does not repeat its prior mistaken reliance on standards for vacatur under the different circumstances where the party seeking vacatur had "voluntarily forfeited" its legal remedy by settling without conditioning the settlement on vacatur. ECF24 at 1-2 (Novartis replying to Noratech's reliance on *U.S. Bancorp Mortgage v. Bonner Mall*, 513 U.S. 18 (1994) and similar decisions).

The equities, which Noratech's petition never address, also support this Court's Order. As Novartis explained in opposing Noratech's dismissal motion, the invalidity judgment appealed here was based solely on collateral-estoppel principles. ECF22 at 23. Noratech acquiesced in that judgment to avoid litigating the parties' other disputes, including the infringement issue Noratech wrongly argues can no longer be decided. ECF22 at Add1-2. Yet the underlying basis for collateral estoppel no longer exists—this Court reversed that judgment in *MSN*, upholding the validity of Novartis's patent. 125 F.4th at 1097-100. Even were the invalidity judgment here unreviewable due to mootness, vacatur would thus be the proper outcome because allowing an unreviewable collateral-estoppel judgment to spawn additional collateral consequences after elimination of the sole basis for estoppel is exactly the kind of inequitable result *Munsingwear* prohibits. 340 U.S. at 39-41.

Second, vacatur is independently warranted by Noratech's prior agreement that the collateral-estoppel judgment should not survive a reversal in *MSN*. As the Court's Order noted, Noratech expressly agreed that the district court's collateral-estoppel judgment should be vacated "if the [*MSN*] Final Judgment is reversed or vacated," and the district court incorporated that agreement into its judgment. ECF22 at Add2; Order.2. Noratech's agreement, coupled with the reversal in *MSN*, thus alone supports the Court's vacatur Order, even were Noratech correct about mootness. Even when appellate courts lack Article III jurisdiction due to an appeal's

mootness and thus "may not consider its *merits*," they maintain jurisdiction to "make such disposition of the whole case as justice may require." *Walling v. James V. Reuter, Inc.*, 321 U.S. 671, 677 (1944) (emphasis added); *Bancorp*, 513 U.S. at 21-22 (explaining same).

Noratech's petition makes no argument that rehearing is warranted to review this basis for vacatur. Instead, Noratech attacks the Court's reference to the parties' agreement by imagining something the Court did not do—"[r]ely[] on a joint statement to assert Article III jurisdiction." Pet.3-4, 9-10 (citing *CFTC v. Schor*, 478 U.S. 833 (1986)). Nothing in the Court's Order supports that strawman. Order.2. Rather, for the reasons explained, regardless of whether the Court has Article III jurisdiction over the merits of this appeal, it could still order vacatur and a remand in the interests of justice and thus enforce the parties' prior agreement. *Accord Serta Simmons Bedding v. Casper Sleep*, 950 F.3d 849, 854-55 (Fed. Cir. 2020) (holding that, even after settlement mooted case, district court retained jurisdiction to enforce terms of agreement where request "to enforce is filed before the case is dismissed").

*****

In sum, multiple independent grounds support the Court's vacatur Order even were Noratech correct that mootness has deprived this Court of Article III jurisdiction to address any "merits" of the appealed collateral-estoppel judgment. Because Noratech's petition makes no showing that these independent grounds for

the Order warrant further review, Noratech's petition should be denied, as granting the further review Noratech does seek would not affect the outcome here.

B. Rehearing Also Should Be Denied Because Noratech Merely Rehashes Its Already-Considered Arguments and the Court's Order Accords with Precedent

Even considering the sole ground that Noratech's petition does address, no further review of the nonprecedential Order is warranted.

1. Noratech's recycling of its prior arguments cannot support further review

Noratech's petition asks for a do-over. Noratech's motion to dismiss fully aired its views about *AstraZeneca*, *Omeprazole*, and mootness. ECF20 at 3-16. By recycling those arguments now, Noratech disregards this Court's directive that "[p]etitions for rehearing should not be used to reargue issues previously presented that were not accepted" during "initial consideration of the appeal."[4] *See also* Practice Notes to Rule 40 (warning that en banc review "is rarely appropriate" of "a nonprecedential opinion or Rule 36 disposition"). The petition should be denied for this reason alone.

[4] https://www.cafc.uscourts.gov/home/case-information/case-filings/petitions-for-rehearing-rehearing-en-banc/.

2. Noratech's misreading of settled and unchallenged precedent cannot support further review

a. **Omeprazole** *already answered the question Noratech identifies as warranting review*

First, *Omeprazole* already answered the purportedly unresolved question about whether the availability of pediatric exclusivity preserves Article III jurisdiction to decide patent infringement after patent expiration. *Contra* Pet.1, 10-20. *Omeprazole* involved Astra's claims of infringement under §271(e)(2) against ANDA filer Impax (and also Apotex). 536 F.3d at 1364-65. Despite originally asserting damages claims against Impax under 35 U.S.C. §271(a)-(c), Astra stipulated to dismiss those claims with prejudice before trial. *Id.* at 1366. After trial but before the district court issued a decision or judgment on infringement and validity, Astra's patents expired. *Id.* Impax moved for immediate dismissal, arguing that upon expiration "the case became moot because Astra, having already dismissed its claims for damages, had no remaining claim for any possible relief to which it might be legally entitled." *Id.* at 1367-68 (noting argument that "patents' expiration rendered the claim of infringement moot").

The district court rejected that mootness argument, and this Court affirmed. This Court held that federal courts continue to have jurisdiction after expiration to resolve §271(e)(2) infringement claims. *Id.* at 1368. Courts have jurisdiction both to find infringement for the first time after patent expiration, as the district court did

in *Omeprazole*, and to "grant relief relating to the period of market exclusivity," also "known as a period of 'pediatric exclusivity.'" *Id.* That relief includes an order under §271(e)(4)(A) to set or "reset the effective date" of an ANDA, which has the effect of preventing marketing during the pediatric-exclusivity period. *Id.* at 1367-69, 1382.

Given *Omeprazole*'s clear holding that courts maintain post-patent-expiration jurisdiction to resolve §271(e)(2) infringement claims at least because of the availability of §271(e)(4)(A) relief to enforce pediatric exclusivity, Noratech is wrong that "this Court has never determinatively resolved this issue." Pet.10. Noratech misses the point by focusing on whether *Omeprazole* resolved what wording a §271(e)(4)(A) order should use—whether it should list the patent's expiration date or the date for "the end of pediatric exclusivity." Pet.17-20. *Omeprazole*'s holding was about jurisdiction, not the wording of a §271(e)(4)(A) order: "We reject Impax's argument as to the district court's jurisdiction because we believe the district court correctly interpreted section 271(e)(4)(A) to provide a post-expiration remedy for infringement under section 271(e)(2)" committed by filing an ANDA before the patents expired. *Omeprazole*, 536 F.3d at 1367-68. That the Court declined to resolve what "particular terms" should go in the post-patent-expiration §271(e)(4)(A) order only shows that those terms do not undermine

jurisdiction, which is based on "the availability of any relief at all under section 271(e)(4)(A)." *Id.* at 1369.

b. There is no conflict with* AstraZeneca*, which involved §271(a) infringement and had no occasion to address mootness or Article III jurisdiction

Second, Noratech is wrong that anything in *AstraZeneca* supports rehearing. Pet.4-9. Noratech argues the Court's nonprecedential Order, and *Omeprazole* itself, conflict with *AstraZeneca* because the Court there stated that pediatric exclusivity "is not an extension of the term of the patent" and "there can be no infringement once the patent expires." *AstraZeneca*, 782 F.3d at 1343.

Taking language out of context, Noratech once again ignores the Court's actual holding. *AstraZeneca*—a subsequent appeal from the same action as *Omeprazole*—was express that the "sole claim for relief" before this Court "was predicated on 35 U.S.C. §271(a)" infringement and so "[t]he only issue" was damages "under section 284." 782 F.3d at 1342-44. That is, although *AstraZeneca* had previously involved Hatch-Waxman infringement claims under 35 U.S.C. §271(e)(2), those claims had long since been resolved—in *Omeprazole*—and were no longer at issue. *Id.* Rather than reach any holding about jurisdiction to decide §271(e)(2) infringement in Hatch-Waxman claims, *AstraZeneca* merely held that the reasonable royalty base for damages to compensate for §271(a) infringement must

be limited to "activities that constitute actual infringement," such as "pre-expiration sales." *Id.*

The statements Noratech quotes were thus not addressing any issue here. And far from suggesting doubt about *Omeprazole*, *AstraZeneca* repeatedly relied on it, including by distinguishing "the remedy under subparagraph (A)," which "is unique to section 271(e)(2) infringement," from the issue the Court was resolving about damages under §284 for §271(a) infringement. *AstraZeneca*, 782 F.3d at 1342-44 (citing *Omeprazole*, 536 F.3d at 1367). Noratech's misreading of *AstraZeneca* thus shows no basis for further review.

c. The Court correctly ordered vacatur and a remand because this appeal is not moot

Third, rehearing should be denied because the Court's Order is correct, as this appeal presents a continuing, live dispute. Noratech argues that there can be no infringement after a patent expires, and so expiration of the patent here mooted this appeal and left Novartis with no possible infringement remedies. Pet.2-9. But *Omeprazole*'s holding shows Noratech is wrong on the facts here. As in *Omeprazole*, Novartis sued Noratech alleging infringement under §271(e)(2) based on Noratech's filing during the patent term of an ANDA seeking to market generic versions of Novartis's FDA-approved ENTRESTO®. As in *Omeprazole*, Novartis requested the statutory remedies Congress provided for §271(e)(2) infringement—an order under §271(e)(4)(A), the relief granted and affirmed in *Omeprazole*, and

injunctive relief under §271(e)(4)(B). D.Ct.Dkt.1, 12(¶¶46-47). Also as in *Omeprazole*, although Novartis's '659 patent expired during the litigation, FDA has already awarded Novartis a six-month period of market exclusivity beyond that patent's expiration. *Supra* p.3. *Omeprazole*'s express holding that, in these circumstances, relief under §271(e)(4)(A) continues "to provide a post-expiration remedy for infringement under section 271(e)(2)" ends any question of mootness here. 536 F.3d at 1367-68.

Nor is the availability of §271(e)(4) relief the only grounds for continuing jurisdiction. Noratech's entire petition is premised on attacking whether Novartis can still prove and obtain relief for infringement after patent expiration. Pet.1-20. Yet as Novartis previously explained, under the statutory scheme here, the Court's vacatur Order provides meaningful relief now, even before any dispute of infringement is resolved. ECF22 at 10-13. Were the district court's collateral-estoppel invalidity judgment to remain in place, that erroneous judgment could affect the timing of FDA approval, potentially allowing Noratech to be prematurely approved before the end of Novartis's earned pediatric-exclusivity period. *Id.* (further explaining same). The outcome of this appeal—that is, whether the collateral-estoppel invalidity judgment is vacated or instead remains in place—thus has real consequences for both Novartis and Noratech in terms of when Noratech's ANDA might be approved, as Noratech's lengthy fight to try to preserve that

judgment confirms. This Court has held that just such consequences suffice to establish a live controversy. *Apotex v. Daiichi Sankyo*, 781 F.3d 1356, 1358, 1363 (Fed. Cir. 2015) (holding a dispute over whether an ANDA filer is entitled to a judgment that would "advance its entry into the market" involves "concrete, potentially high-value stake[s]" sufficient for Article III jurisdiction).

Noratech is thus wrong to dismiss questions about whether FDA can approve Noratech's ANDA during Novartis's pediatric-exclusivity period as merely an issue for FDA. Pet.7 & n.2. Likewise, rather than being "internally inconsistent" (Pet.7), the Court's Order logically granted meaningful interim and permanent relief to ensure that the district court's collateral-estoppel judgment would have no effect for the duration of this appeal and going forward. Order.2. And given the settled nature of the precedent here and the multiple independent grounds supporting vacatur, there is no basis for Noratech's complaints that the Court should have given further explanation. Pet.6-7. If anything, the petition's failure to address all the grounds supporting that Order is further reason to deny. *Supra* Part A.

*****

The Court's Order broke no new ground in ordering vacatur following reversal in *MSN* of the invalidity judgment providing the sole basis for the collateral-estoppel judgment appealed here. None of Noratech's arguments comes close to justifying the extraordinary step of granting further review.

CONCLUSION

Noratech's petition should be denied.

Dated: April 24, 2025

Respectfully submitted,

/s/ Deanne E. Maynard

NICHOLAS N. KALLAS
CHRISTINA SCHWARZ
VENABLE LLP
151 W. 42nd Street, 49th Floor
New York, NY 10036

DEANNE E. MAYNARD
SETH W. LLOYD
MORRISON & FOERSTER LLP
2100 L Street NW, Suite 900
Washington, DC 20037
Tel.: (202) 887-8740
DMaynard@mofo.com

Counsel for Novartis Pharmaceuticals Corporation

CERTIFICATE OF COMPLIANCE

The foregoing filing complies with the relevant type-volume limitations and typeface and type-style requirements of the Federal Rules of Appellate Procedure and Federal Circuit Rules because the filing has been prepared using a proportionally spaced typeface and includes 3,874 words, excluding the parts of the filing exempted by the Rules.

Dated: April 24, 2025

/s/ Deanne E. Maynard
Deanne E. Maynard

ny-2942721