Nos. 23-2317, 23-2319

IN THE

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, Judge Richard G. Andrews

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CORRECTED PETITION OF NANJING NORATECH PHARMACEUTICAL CO., LTD FOR PANEL REHEARING AND REHEARING EN BANC

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UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF INTEREST

Case Number 23-2317, 23-2319

Short Case Caption In re Entresto (Sacubitril/Valsartan)

Filing Party/Entity Appellee Nanjing Noratech Pharm. Co. Ltd.

Instructions:

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I certify the following information and any attached sheets are accurate and complete to the best of my knowledge.

Date: 04/08/2025 Signature: /s/ Don J. Mizerk

Name: Don J. Mizerk

1. Represented Entities. Fed. Cir. R. 47.4(a)(1).	**2. Real Party in Interest.** Fed. Cir. R. 47.4(a)(2).	**3. Parent Corporations and Stockholders.** Fed. Cir. R. 47.4(a)(3).
Provide the full names of all entities represented by undersigned counsel in this case.	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/Not Applicable	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. ☐ None/Not Applicable
Nanjing Noratech Pharmaceutical Co., Limited	Gerbera Therapeutics, Inc.	

☐ Additional pages attached

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).

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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)?

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RULE 40 STATEMENT

Undersigned counsel certifies:

1. Based on my professional judgment, I believe the panel decision is contrary to the following precedent of this Court: *AstraZeneca AB v. Apotex Corp.*, 782 F.3d 1324 (Fed. Cir. 2015).

2. Based on my professional judgment, I believe the panel decision is contrary to the following decision of the Supreme Court of the United States: *CFTC v. Schor*, 478 U.S. 833 (1986).

3. Based on my professional judgment, I believe this appeal requires an answer to one or more precedent setting questions of exceptional importance: Whether the availability of a pediatric exclusivity period gives a court Article III jurisdiction to adjudicate patent infringement even after the patent has expired.

Dated: April 8, 2025

Respectfully submitted,

/s/ DON J. MIZERK

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INTRODUCTION

The patent-in-suit has expired. No court has at any time found that Nanjing Noratech Pharmaceutical Co., Ltd. (Noratech) infringed the patent at issue in this appeal, U.S. Patent No. 8,101,659 (the '659 patent).[1] No statutorily authorized remedies remain available to Plaintiff-Appellant Novartis Pharmaceuticals Corporation (Novartis) under the Hatch-Waxman Act. The appeal is thus moot, and the Court must dismiss it for lack of Article III jurisdiction. *See eSimplicity, Inc. v. United States*, 122 F.4th 1373, 1376 (Fed. Cir. 2024).

To that end, Noratech moved to dismiss this appeal. The parties filed extensive, thorough briefs. But the panel issued a one-page denial devoid of any meaningful reasoning. The upshot: the panel concluded that it (and the district court) retained Article III jurisdiction.

[1] These consolidated appeals (Nos. 23-2317 and 23-2319) arise from the same final judgment under Fed. R. Civ. P. 54(b), which was based solely on principles of collateral estoppel. One judgment was entered in the MDL, and one in the Civil Action case. *In re: Entresto (Sacubitril/Valsartan) Patent Litigation*, No. 1:20-md02930, Dkt. No. 1144 (D. Del. Aug. 16, 2023); *Novartis Pharms. Corp. v. Nanjing Noratech Pharm. Co., Ltd.*, No. 23-cv-00401-RGA, Dkt. No. 29 (D. Del. Aug. 16, 2023).

The panel overlooked controlling law on Article III jurisdiction in patent cases. In doing so, the panel accepted two of Novartis's arguments, both of which create square conflict with decisions of this Court and the Supreme Court.

First, the panel's decision conflicts with this Court's decision in another Hatch-Waxman case, *AstraZeneca AB v. Apotex Corp.*, 782 F.3d 1324 (Fed. Cir. 2015). There, this Court held that "pediatric exclusivity period is not an extension of the term of the patent" and that "there can be no infringement once the patent expires." *Id.* at 1343 (quoting *Kearns v. Chrysler Corp.*, 32 F.3d 1541, 1550 (Fed. Cir. 1994)); *see* 21 U.S.C. § 355 (b)(1)(B), (c)(1)(B) (regarding pediatric exclusivity). Novartis had argued, however, that even after its patent expired, a court can still find infringement because it has ongoing pediatric exclusivity. The panel accepted Novartis's argument to conclude that it maintains Article III jurisdiction. That conclusion cannot be squared with this Court's holding in *AstraZeneca*.

Second, the panel's decision conflicts with the Supreme Court's decision in *CFTC v. Schor*, 478 U.S. 833 (1986). There, the Supreme Court clearly held that parties cannot agree to Article III jurisdiction. Yet the

panel, accepting Novartis's argument, cited "the parties' joint statement" at an earlier stage in the case as a basis for denying Noratech's motion to dismiss. Relying on a joint statement to assert Article III jurisdiction runs headlong into Supreme Court precedent.

This Court should grant rehearing or rehearing en banc to correct the panel's gross error, harmonize its own caselaw, and align it with the Supreme Court's precedent. Granting rehearing will also allow the Court to answer a question of exceptional importance not yet definitively decided: Whether the availability of a pediatric exclusivity period gives a court Article III jurisdiction to adjudicate patent infringement even after the patent has expired.

ARGUMENT

I. The panel decision overlooked core principles of Article III jurisdiction, creating square conflict with precedent of this Court and the Supreme Court.

A. The panel decision overlooked basic principles of Article III jurisdiction in patent cases.

It is blackletter law that moot appeals cannot proceed because Article III jurisdiction is lacking. "If an event occurs while a case is pending on appeal that makes it impossible for the court to grant 'any effectual relief whatever' to a prevailing party, the appeal must be dismissed as

moot." *Nasatka v. Delta Sci. Corp.*, 58 F.3d 1578, 1580 (Fed. Cir. 1995) (citation omitted).

In the patent context, an appeal becomes moot when the patent-in-suit expires and no statutorily authorized remedies remain available. *See INVT SPE LLC v. Int'l Trade Comm'n*, 46 F.4th 1361, 1369–70 (Fed. Cir. 2022); *Douglas Dynamics, LLC v. Buyers Prods. Co.*, 717 F.3d 1336, 1343 (Fed. Cir. 2013).

Here, it is undisputed that the '659 patent expired on January 15, 2025. *Novartis Pharms. Corp. v. Nanjing Noratech Pharm. Co., Ltd.*, No. 23-cv-00401-RGA, Dkt. No. 3 (D. Del. Apr. 10, 2023). No court has at any time found that Noratech infringed the patent. No statutorily authorized remedy remains available to Novartis. *See infra* Argument II.C. The appeal is thus moot, and the Court must dismiss it for lack of Article III jurisdiction. *eSimplicity*, 122 F.4th at 1376.

Yet the panel denied Noratech's motion to dismiss, retaining Article III jurisdiction over a dispute about an expired patent. The only possible explanation for the panel's decision is that it overlooked decades of unbroken precedent on Article III jurisdiction and patent expiration.

The panel's error is underscored by two points. First, the panel offered virtually no reasoning for its decision on Article III jurisdiction. Issuing decisions without reasoning—especially on matters as important as Article III jurisdiction—is "uniformly condemned." William Reynolds & William Richman, *The Non Precedential Precedent—Limited Publication and No Citation Rules in the United States Courts of Appeals*, 78 Colum. L. Rev. 1167, 1174 (1978). Absent explanation, the Court flounders on its duties of accountability, rationality, and accuracy. *See Balt. & Annapolis R.R. Co. v. Wash. Metro. Area Transit Comm'n*, 642 F.2d 1365, 1370 (D.C. Cir. 1980) ("[T]he requirement of reasons imposes a measure of discipline . . . , discouraging arbitrary or capricious action by demanding a rational and considered discussion."); Harold Leventhal, *Appellate Procedures: Design, Patchwork, and Managed Flexibility*, 23 UCLA L. Rev. 432, 438 (1976) ("[T]here is accountability in the giving of reasons."); Mathilde Cohen, *When Judges Have Reasons Not to Give Reasons: A Comparative Law Approach*, 72 Wash. & Lee L. Rev. 483, 504 (2015) (listing "accuracy" among the reasons for giving reasons). The panel's failure to explain should not impede rehearing "particularly where, as here, nonfrivolous challenges to . . . subject matter jurisdiction have been lodged."

Memorylink Corp. v. Motorola, Inc., 676 F.3d 1051, 1053 (Fed. Cir. 2012) (O'Malley, J., dissenting from denial of rehearing en banc).

Second, the panel's order is internally inconsistent. The panel ordered both that "[t]he district court's judgment is vacated and the cases remanded to the district court for further proceedings" and that "[t]he district court's judgment is stayed until issuance of [the] mandate." How can a district court judgment be both "vacated" and "stayed"? The panel does not say.

B. The panel decision conflicts with this Court's decision in *AstraZeneca*.

The panel's decision is far from simple error—it creates square conflict with this Court's precedent that necessitates en banc review.

This is a Hatch-Waxman case, with Novartis alleging infringement under 35 U.S.C. § 271(e)(2). In its response to Noratech's motion to dismiss for lack of Article III jurisdiction, Novartis argued that it is entitled to a six-month period of pediatric exclusivity[2] *beyond* the patent's

[2] Rather than being an issue for a court in an infringement lawsuit, pediatric exclusivity is a complex regulatory exclusivity implemented by FDA. *See Mylan Labs., Inc. v. Thompson*, 389 F.3d 1272, 1280 (D.C. Cir. 2004). It is the FDA, not a court in connection in a patent suit, that determines the applicability and duration of any pediatric exclusivity,

expiration. *See* 21 U.S.C. § 355 (b)(1)(B), (c)(1)(B). That pediatric exclusivity period would expire on July 15, 2025. The panel appears to have tacitly accepted Novartis's argument and reasoned that a party like Noratech can still be liable for patent infringement—and that a court retains Article III jurisdiction—even after a patent expires but during a period of pediatric exclusivity.

The panel's conclusion conflicts with this Court's decision in another Hatch-Waxman case, *AstraZeneca*, 782 F.3d 1324. There, the Court held that a "pediatric exclusivity period is not an extension of the term of the patent." *AstraZeneca*, 782 F.3d at 1343. Instead, just like in any patent infringement case, the relevant date for patent infringement is the *patent* expiration date. *See id.* The party in Noratech's position, Apotex, "did not infringe Astra's patents during the [pediatric] exclusivity period, since those patents had expired." *Id.* "[I]f Apotex had launched its generic product during the exclusivity period, Astra could not have sued Apotex for patent infringement based on those sales." *Id.*

subject to appellate review of that decision. *Id.* at 1281–82; *AstraZeneca*, 782 F.3d at 1341.

AstraZeneca was consistent with this Court's prior caselaw confirming that infringement in a Hatch-Waxman case is "determined by traditional patent law principles." *Ferring B.V. v. Watson Lab'ys., Inc.-Florida*, 764 F.3d 1401, 1408 (Fed. Cir. 2014). Here, it is undisputed that under traditional patent law principles, if Noratech's ANDA product were sold tomorrow, it would not infringe the '659 patent because it expired. *See AstraZeneca*, 782 F.3d at 1343. Indeed, "there can be no infringement once the patent expires." *Id.* The availability of pediatric exclusivity does absolutely nothing to change that unavoidable fact.

C. The panel decision conflicts with the Supreme Court's decision in *Schor*.

The panel decision also conflicts with the Supreme Court's decision in *Schor*, 478 U.S. 833.

In its otherwise delphic decision, the panel referred "to 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.'" Based on this statement, one can infer that the panel relied on the parties' "joint statement" not only to decide the motion to dismiss, but also (necessarily) to conclude that it retained Article III jurisdiction notwithstanding the patent's expiration.

But parties' agreements cannot form the basis for Article III jurisdiction. *Schor*, 478 U.S. at 850–51; *accord Metzinger v. Dep't of Veterans Affs.*, 20 F.4th 778, 781 n.2 (Fed. Cir. 2021). By concluding otherwise, the panel decision conflicts with controlling Supreme Court precedent.

II. This appeal requires an answer to a question of exceptional importance about Article III jurisdiction.

This appeal raises a question of exceptional importance: Whether the availability of a six-month pediatric exclusivity period, 21 U.S.C. § 355 (b)(1)(B), (c)(1)(B), gives a court Article III jurisdiction to adjudicate patent infringement even after the patent has expired. The answer to that question is clearly no.

Noratech moved to dismiss this appeal for lack of Article III jurisdiction. The patent-in-suit has expired and there has been no finding of infringement; that much is undisputed. Novartis argued that even though the patent has expired, it still has ongoing pediatric exclusivity—and, based solely on that exclusivity, infringement could still be found and Article III jurisdiction still existed. Although the panel appears to have tacitly accepted Novartis's argument, this Court has never determinatively resolved this issue. It should now.

A. The question is exceptionally important.

The question at issue is one of exceptional importance. "Few, if any, concepts in civil procedure are more important than subject-matter jurisdiction." Bradley Scott Shannon, *Reconciling Subject-Matter Jurisdiction*, 46 Hofstra L. Rev. 913 (2018); *see* Charles Alan Wright & Arthur R. Miller, 13 *Fed. Prac. & Proc. Juris.* § 3522 (3d ed.) (regarding Article III jurisdiction issues as "so important"). Because Article III jurisdiction "involves a court's power to hear a case," courts always maintain "an independent obligation to determine whether subject-matter jurisdiction exists." *Arbaugh v. Y & H Corp.*, 546 U.S. 500, 501, 514 (2006). Answering questions about patent validity and infringement in the absence of Article III jurisdiction constitutes an advisory opinion. *Superior Indus., Inc. v. Masaba, Inc.*, 553 F. App'x 986, 989 (Fed. Cir. 2014).

In addition, the answer to the question—both in this case and in similar ones—has significant practical implications. The purpose of the Hatch-Waxman Act is "to enable generic manufacturers to be ready to enter the market once patents expired," thereby increasing competition and improving access to life-saving and life-improving drugs. *H. Lundbeck A/S v. Lupin Ltd.*, 87 F.4th 1361, 1370 (Fed. Cir. 2023)

(citation omitted); *see also Mylan Inc & Subsidiaries v. Comm'r of Internal Revenue*, 76 F.4th 230, 245 & n.23 (3d Cir. 2023) (characterizing the "very purpose of the Hatch-Waxman Act" as "encourag[ing] generic drug development" and "improving access to lower-cost generic drugs"). Because Novartis's patent has expired, Noratech is entitled to obtain FDA approval, market its drug, and ultimately improve lower-cost access. Allowing Novartis to unlawfully extend its monopoly privilege would undermine the Hatch-Waxman Act's purpose and delay public benefit.

The panel got the answer to this important question wrong. There is no longer Article III jurisdiction to decide this appeal.

B. The patent-in-suit is expired and can no longer be infringed—regardless of pediatric exclusivity.

The '659 patent expired on January 15, 2025. Novartis had claimed "artificial" infringement of its '659 patent under the Hatch-Waxman Act. *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1365–66 (Fed. Cir. 2003). In such a case, "[t]he infringement action is a hypothetical case that asks the factfinder to determine whether the drug that will be sold *upon approval of the ANDA* will infringe the asserted patent." *In re Brimonidine Pat. Litig.*, 643 F.3d 1366, 1377 (Fed. Cir. 2011), *as corrected* (Aug. 8, 2011) (emphasis added). With respect to induced infringement,

this Court has held that a Hatch-Waxman plaintiff "can satisfy its burden to prove the predicate direct infringement by showing that *if the proposed ANDA product were marketed*, it would infringe the asserted patent." *Vanda Pharms. Inc. v. West-Ward Pharms. Int'l Ltd.*, 887 F.3d 1117, 1130 (Fed. Cir. 2018) (emphasis added). Here, Novartis has not disputed that if Noratech's ANDA product is approved and sold tomorrow, it would not infringe the '659 patent because it is expired. *See AstraZeneca*, 782 F.3d at 1343.

In a Hatch-Waxman case, § 271(e)(4) sets forth the remedies available for infringement. These are "the *only* remedies which may be granted," and they depend *on a predicate finding of infringement* under § 271(e)(2). 35 U.S.C. § 271(e)(4) (emphasis added). Here, because the district court did not find infringement, and because "there can be no infringement once the patent expires," a finding of infringement under § 271(e)(2) is no longer possible. *AstraZeneca*, 782 F.3d at 1343. That means none of the remedies under § 271(e)(4) is available.

Fighting this point in its opposition, Novartis claimed that it could still prove infringement because, in its view, infringement is determined "at the time of ANDA filing." Opp.19. Novartis is wrong: ANDAs are

routinely amended, and the relevant date is the time the infringement determination is made. *Ferring*, 764 F.3d at 1405 (addressing "amended ANDA").[3]

In the end, even if Novartis has pediatric exclusivity through July 15, 2025, it is undisputed that its patent expired on January 15. A "pediatric exclusivity period is not an extension of the term of the patent." *AstraZeneca*, 782 F.3d at 1343. Thus, no court can find infringement. Because the remedies under § 271(e)(4) all require a predicate finding of infringement, none of them remains available to Novartis. The appeal is thus moot and must be dismissed for lack of Article III jurisdiction.

C. Relatedly, none of the statutorily authorized remedies could "make a difference to the legal interests of the parties."

Moreover, even if § 271(e)(4) remedies could be applied in this case, none of them would actually "make a difference to the legal interests of the parties." *Nasatka*, 58 F.3d at 1580 (citation omitted). The appeal is moot for that reason, too.

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[3] Not to mention, merely filing an ANDA is *not* infringement. Instead, "the question of infringement must focus on what the ANDA applicant will likely market if its application is approved, an act that has not yet occurred." *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997).

First, § 271(e)(4)**(A)** authorizes a form of declaratory relief: "[T]he 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." In a case where "the date of the expiration of the patent" is in the future, such an order can be significant. But in a case like this one, where the "the date of the expiration of the patent" is in the past, the relief envisioned by § 271(e)(4)(A) becomes meaningless—and any request for it becomes moot.

Pediatric exclusivity does not change this analysis. An order under § 271(e)(4)(A) is tied expressly to "the expiration of the patent." This Court has made clear that the "pediatric exclusivity period is not an extension of the term of the patent." *AstraZeneca*, 782 F.3d at 1343. As explained, moreover, an order under § 271(e)(4)(A)—like any of the remedies authorized by § 271(e)(4)—requires a predicate finding of infringement. Such a finding can no longer be made because "there can be no infringement once the patent expires." *Id.* This Court has previously affirmed district court reasoning that the prospect of pediatric exclusivity "does not provide a sufficient basis for this Court to restrict the FDA's

approval of the ANDA beyond the expiration date of the patent." *Roche Palo Alto LLC v. Apotex, Inc.,* 526 F. Supp. 2d 985, 1000 (N.D. Cal. 2007), *aff'd*, 531 F.3d 1372 (Fed. Cir. 2008). A declaratory order under § 271(e)(4)(A) is not available to Novartis.

Second, § 271(e)(4)**(B)** authorizes injunctive relief against future infringement. But once a patent expires, any request for injunctive relief becomes moot. *Douglas Dynamics*, 717 F.3d at 1343; *Metaullics Sys. Co., L.P. v. Cooper*, 100 F.3d 938, 939 (Fed. Cir. 1996), *abrogated on other grounds by Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448 (Fed. Cir. 1998); *Ill. Tool Works, Inc. v. Grip-Pak, Inc.*, 906 F.2d 679, 681 n.1 (Fed. Cir. 1990). Injunctive relief is not available to Novartis.

Third, § 271(e)(4)**(C)** authorizes money damages for past infringement, but "*only* if there has been commercial manufacture, use, offer to sell, or sale" or "importation" of the drug. 35 U.S.C. § 271(e)(4)(C) (emphasis added); *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990). Here, it is undisputed that there has *not* been any "commercial manufacture, use, offer to sell, or sale" or "importation" on Noratech's part to date. Damages are not available to Novartis.

Again, pediatric exclusivity does not alter this analysis. A court in a patent infringement lawsuit *cannot* award damages for actions taken *after patent expiration* but *during pediatric exclusivity*. *AstraZeneca*, 782 F.3d at 1343. Such actions "do not constitute patent infringement." *Id.*

In sum, no statutorily authorized remedy remains available to Novartis. The appeal is moot.

D. Novartis cannot rely on *Omeprazole* to save this appeal from dismissal.

In response to Noratech's motion to dismiss, Novartis invoked *In re Omeprazole Patent Litigation*, 536 F.3d 1361 (Fed. Cir. 2008). Specifically, Novartis argued that *Omeprazole* authorizes a court to enter an order under § 271(e)(4)(A) setting an "effective date" as the end of pediatric exclusivity (here, July 15, 2025). For several reasons, *Omeprazole* does not save this appeal from being dismissed as moot.

First, *Omeprazole did not hold* that a court can enter a § 271(e)(4)(A) order setting an "effective date" as the end of pediatric exclusivity, as opposed to the date of patent expiration. Instead, the *Omeprazole* Court only *assumed* as much, because the issue was conceded: "Impax does not dispute that, if the district court had issued its decision before the patents expired, section 271(e)(4)(A) would have

authorized the district court to order the effective date of Impax's ANDA to be October 20, 2007, the date on which Astra's period of market exclusivity expired." *Id.* at 1368.

No court, in fact, has ever held that a court can enter a § 271(e)(4)(A) order setting an "effective date" as the end of pediatric exclusivity, as opposed to the date of patent expiration. Since *Omeprazole*, this Court has cast significant doubt on such a proposition, holding that a "pediatric exclusivity period is not an extension of the term of the patent." *AstraZeneca*, 782 F.3d at 1343. Given that § 271(e)(4)(A) speaks expressly in terms of the "the date of the expiration of the patent," it would be inconsistent with statutory text to order an "effective date" untethered to the patent's expiration (here, January 15, 2025).

Second, even if *Omeprazole* could be read to contemplate a § 271(e)(4)(A) order setting an "effective date" as the end of pediatric exclusivity, that case's discussion should be given little weight: subsequent caselaw renders *Omeprazole*'s discussion irrelevant. In *Omeprazole*, the district court had found infringement and entered a § 271(e)(4)(A) order setting an "effective date" as the end of pediatric exclusivity (October 20, 2007). 536 F.3d at 1366. Yet this Court decided whether the district

court's decision was correct on August 20, 2008—well after the pediatric exclusivity period had ended. At the time of *Omeprazole*, the correctness of the district court's § 271(e)(4)(A) order could have conceivably mattered: it was unclear whether a party could recover patent-infringement damages for drug sales made *after patent expiration* but *during pediatric exclusivity*. But after *Omeprazole*, this Court held that patent-infringement damages are *not available* during the period of pediatric exclusivity. *AstraZeneca*, 782 F.3d at 1343. Under current law, then, *Omeprazole*'s discussion of the district court's § 271(e)(4)(A) order would have been wholly pointless. That discussion is thus best viewed as a historical fluke—not as controlling law.

Third, even if *Omeprazole* could stand for the proposition that a court can enter an order under § 271(e)(4)(A) setting an "effective date" as the end of pediatric exclusivity, such an order is not available *in this case*. As explained, an order under § 271(e)(4)(A)—like any of the remedies authorized by § 271(e)(4)—requires a predicate finding of infringement. In *Omeprazole*, the district court had found infringement after a trial, thus authorizing a remedy under § 271(e)(4). Here, by contrast, the district court did not find that Noratech infringed the '659 patent; it never

even considered that question; and the question of infringement is not at issue on this appeal. Neither this Court nor the district court on remand even *could* find infringement at this point, because the patent is expired. *See supra*.

In sum, § 271(e)(4) sets forth the full gamut of remedies available upon a finding of infringement in a Hatch-Waxman case. None of those remedies remains available to Novartis in this case. This appeal is moot. The proper remedy is to dismiss it, leaving the existing judgment below in place. *E.g.*, *Yeda Rsch. & Dev. Co., Ltd. v. Abbott GMBH & Co. KG*, 837 F.3d 1341, 1346 (Fed. Cir. 2016) ("We *dismiss* Yeda's appeal . . . for lack of jurisdiction, as it is now moot."); *Metaullics*, 100 F.3d at 939.

CONCLUSION

The Court should grant the petition and dismiss the appeal.

Dated: April 8, 2025

Respectfully submitted,

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FORM 19. Certificate of Compliance with Type-Volume Limitations **Form 19**
July 2020

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATIONS

Case Number: 23-2317, 23-2319

Short Case Caption: In re Entresto (Sacubitril/Valsartan)

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Signature: /s/ Don J. Mizerk

Name: Don J. Mizerk

ADDENDUM

NOTE: This order is nonprecedential.

United States Court of Appeals for the Federal Circuit

IN RE: ENTRESTO (SACUBITRIL/VALSARTAN)

NOVARTIS PHARMACEUTICALS CORPORATION,
Plaintiff-Appellant

v.

NANJING NORATECH PHARMACEUTICAL CO., LTD.,
Defendant-Appellee

2023-2317, 2023-2319

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

ON MOTION

Before LOURIE, TARANTO, and STOLL, *Circuit Judges*.

PER CURIAM.

O R D E R

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.

FOR THE COURT

March 11, 2025
Date

Jarrett B. Perlow
Clerk of Court