Nos. 23-2218, -2220, -2221

In the

United States Court of Appeals

For the Federal Circuit

IN RE: ENTRESTO (SACUBITRIL/VALSARTAN)

NOVARTIS PHARMACEUTICALS CORPORATION, *PLAINTIFF-APPELLANT*

v.

TORRENT PHARMA INC., TORRENT PHARMACEUTICALS LTD., *DEFENDANTS*

NOVARTIS PHARMACEUTICALS CORPORATION, *PLAINTIFF-APPELLANT*

v.

ALEMBIC PHARMACEUTICALS LIMITED, ALEMBIC PHARMACEUTICALS INC., *DEFENDANTS*

NOVARTIS PHARMACEUTICALS CORPORATION, *PLAINTIFF-APPELLANT*

v.

MSN PHARMACEUTICALS, INC., MSN LABORATORIES PRIVATE LTD., MSN LIFE SCIENCES PRIVATE LTD., *DEFENDANTS-APPELLEES*

HETERO USA, INC., HETERO LABS LIMITED, HETERO LABS LTD. UNIT-III, *DEFENDANTS.*

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

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CORRECTED BRIEF OF *AMICUS CURIAE* ASSOCIATION FOR ACCESSIBLE MEDICINES IN SUPPORT OF DEFENDANTS-APPELLEES' PETITION FOR PANEL REHEARING OR REHEARING *EN BANC*

February 18, 2025

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UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF INTEREST

Case Number 23-2218

Short Case Caption Novartis Pharms. Corp. v. Torrent Pharma Inc.

Filing Party/Entity Association for Accessible Medicines

Instructions:

1. Complete each section of the form and select none or N/A if appropriate.
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I certify the following information and any attached sheets are accurate and complete to the best of my knowledge.

Date: 02/18/2025

Signature: /s/ Robert V. Cerwinski

Name: Robert V. Cerwinski

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
Association for Accessible Medicines		

☐ 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)?

☐ Yes (file separate notice; see below) ☐ No ☑ N/A (amicus/movant)

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☑ None/Not Applicable ☐ Additional pages attached

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INTEREST OF *AMICUS CURIAE*[1]

The Association for Accessible Medicines (AAM) is a nonprofit, voluntary association representing manufacturers and distributors of generic and biosimilar medicines, bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic pharmaceutical industry. AAM's members provide patients with access to safe and effective generic and biosimilar medicines at affordable prices. AAM's core mission is to improve the lives of patients by providing timely access to these safe, effective, and affordable prescription medicines. Generic drugs constitute 90% of all prescriptions dispensed in the United States, yet generics account for only 20% of total drug spending. AAM regularly participates in litigation as *amicus curiae*.

AAM and its members have an interest in bringing attention to patent infringement judgments like this one that may bar prompt patient access to less-expensive generic versions of life-saving medicines by contravening the patent laws and the public policies they serve. Here,

[1] Pursuant to this Court's Rule 37.6, *amicus* states that this brief was not authored in whole or in part by counsel for any party, and that no person or entity other than *amicus*, its members, or its counsel made a monetary contribution intended to fund the preparation or submission of this brief.

the district court, at plaintiff-appellant Novartis's urging, broadly construed the term "combination" in the claims of U.S. Patent No. 8,101,659 ("the '659 patent") to include Novartis's drug product ENTRESTO, which contains a valsartan-sacubitril "complex," as well as defendants-appellees MSN's generic version of the same. Because of this construction, MSN stipulated to infringement of those claims. But since the complex was not described in the specification—and could not have been described since it was unknown even to Novartis at the time of filing—the district court found that the claims were invalid under 35 U.S.C. § 112 for lack of written description of the full scope of the claims. On appeal, the panel, however, applied a narrower construction that excluded such complexes to reverse the district court's judgment that the claims are invalid for lack of adequate description. The panel did this despite the fact that *no party had appealed the district court's claim construction*. Even more worrying, the Court appears to have fashioned this narrower construction after applying case law that, in the panel's view, requires that claims be interpreted to "carve out" subject matter unknown to the field at the time of filing, *but only for purposes of adjudicating invalidity under § 112*.

It is settled law that a patent claim is not "like a nose of wax." It cannot be twisted one way to find infringement and then the other way to avoid invalidity. *See Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1351 (Fed. Cir. 2001). The purpose of this settled law is to prevent a patentee like Novartis from using over-broad claims to control the making, using, selling or offering for sale of subject matter beyond what it actually invented and disclosed to the public in its patent application. *Id.*

The public hazards of such an over-reach are on display here. After representing that the '659 patent claims cover ENTRESTO, Novartis has hobbled generic competition for that drug product by obtaining a patent term extension ("PTE") and pediatric exclusivity for the patent and listing it in the Orange Book. But Novartis cannot have it both ways. Either the '659 patent claims cover ENTRESTO and must satisfy the dictates of § 112 for that embodiment, or they do not and Novartis cannot use them to block generic equivalents of ENTRESTO. The pharmaceutical industry is watching this case closely. If Novartis succeeds in this over-reach, others will see a new strategy they can employ to fashion over-broad claims to delay generic competition and yet

evade the requirements of § 112 that protect the public's interests in ensuring that patents do not let inventors control more than they invented.

In light of the importance of these issues to AAM's mission, AAM submits this brief as *amicus curiae* in support of panel reconsideration or rehearing *en banc* and asks this Court to either (1) rectify the panel's mistaken reversal of the district court's judgment regarding written description, or (2) clarify that the claims of the '659 patent do not cover the complex in ENTRESTO or the appellees' generic equivalents, not just for purposes of its § 112 analysis but for all purposes, including infringement.

PROCEDURAL BACKGROUND

The '659 patent claims are directed to pharmaceutical compositions containing valsartan and sacubitril "in combination." ENTRESTO contains valsartan and sacubitril linked together by non-covalent bonds to form a "complex." It is undisputed that as of the 2002 priority filing date of the '659 patent, formulations in which valsartan and sacubitril are "complexed" together were unknown and would have required more than ordinary skill to devise. Indeed, Novartis filed separate patents to

this complex several years later. *See In re Entresto*, 125 F.4th 1090, 1099 (Fed. Cir. 2025).

After ENTRESTO was approved, Novartis represented to the FDA and PTO that the '659 patent claims cover the complex in that product. Novartis listed the patent in the Orange Book for ENTRESTO and added both a PTE and six months of pediatric exclusivity to its term. *See In re Entresto (Sacubitril/Valsartan) Pat. Litig.*, No. 20-MD-2930-LPS, 2021 WL 2856683, at *3 (D. Del. July 8, 2021) ("*Markman*") ("In seeking and obtaining the [PTE], Novartis represented to the Patent Office that the ['659 patent] cover[s] Entresto, a drug consisting solely of non-separate, complexed valsartan and sacubitril."). With these product-specific exclusivities in hand, Novartis asserted the '659 patent against all filers of ANDAs referencing ENTRESTO, thereby obtaining an automatic 30-month stay of their FDA approval.

In the litigation that followed, Novartis asserted that the claim term "in combination" should be given its plain meaning, and that this meaning was broad enough to cover the valsartan-sacubitril complex in ENTRESTO and MSN's generic product. Novartis did so even though the '659 patent only disclosed conventional mixtures of the two active

ingredients and, as Novartis acknowledged, it was not until years after the priority filing date that it actually created and disclosed to the public a complex of the two ingredients. The district court adopted the construction urged by Novartis, but in so doing, warned that because Novartis had admitted that the patent did not disclose the complex, "at the very least, there [is] a non-frivolous issue of written description and/or lack of enablement as this case proceeds on Novartis's preferred construction." *Markman* at *4.

With no triable issue of infringement remaining after this construction became law of the case, MSN stipulated to infringement but pressed for a judgment of invalidity for lack of written description and enablement of the complex. MSN prevailed on the question of written description. The district court found that because a formulation containing the valsartan-sacubitril complex was unknown at the time of filing and the structural features disclosed in the patent specification could not help a skilled artisan visualize such a complex, the claims were invalid for failing to meet the written description requirements of § 112. *In re Entresto (Sacubitril/Valsartan) Pat. Litig.*, No. CV 19-1979-RGA, 2023 WL 4405464, at *21-22 (D. Del. July 7, 2023) ("Decision").

On appeal, the panel reversed the judgment of invalidity, holding that, *inter alia*, the patent contained sufficient written description for what it claimed, leaving untouched MSN's stipulation of infringement.

ARGUMENT

As explained in MSN's petition for panel rehearing and rehearing *en banc*, the panel's decision conflicts with this Court's precedents regarding the requirements of § 112. The panel's decision also blesses Novartis's efforts to interpret its claims broadly to capture generic competitors' products, but then narrowly to avoid invalidity under § 112, in contravention of settled law that requires claims to be construed the same way for both infringement and validity. This Court should reconsider or rehear the case *en banc* and reverse the panel's judgment of no invalidity under § 112, or in the alternative, clarify that the claims of the '659 patent exclude complexes like the one in ENTRESTO and MSN's generic equivalent for all purposes, including infringement.

I. The District Court Properly Found That The '659 Patent Claims Lack Written Support Under Its Claim Construction

In *Ariad*, the Court explained that a patent specification must reasonably convey to skilled artisans that the inventor had "possession

as shown in the disclosure" of the claimed subject matter as of the filing date. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351(Fed. Cir. 2010). For genus claims, "merely drawing a fence around a perceived genus" and "leaving it to others to explore the unknown contours of the claimed genus" is insufficient. *AbbVie Deutschland GmbH & Co., KG v. Janssen Biotech, Inc.*, 759 F.3d 1285, 1300 (Fed. Cir. 2014). Rather, as the Court confirmed in *Ariad* and a number of later cases, when a patent claims a genus, its specification must disclose "either a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can visualize or recognize the members of the genus." *Ariad*, 598 F.3d at 1349-50 (internal citations and quotes omitted); *see also, e.g.*, *Hynix Semiconductor Inc. v. Rambus Inc.*, 645 F.3d 1336, 1352 (Fed. Cir. 2011); *Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, 10 F. 4th 1330, 1335 (Fed. Cir. 2021). The Court has also explained that the written description test should also consider, *e.g.*, "'the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, [and] the predictability of the aspect at issue.'" *Ariad*, 598

F.3d at 1351 (quoting *Capon v. Eshhar*, 418 F.3d 1349, 1359 (Fed. Cir. 2005)).

Here, the district court followed this precedent when it ruled that the asserted claims lack written support. Decision at *21 (citing *Ariad*). There was no dispute below that "the claims at issue are directed to a ***genus*** of 'combinations' of sacubitril and valsartan, which, as construed by the district court, includes complexes of sacubitril and valsartan." *Id.* at *13 (emphasis added). At Novartis's urging, the district court construed the term "combination" to broadly cover pharmaceutical formulations containing *any* combination of valsartan and sacubitril, including complexes. But the patent disclosed only non-complexed, conventional mixtures, since complexes had not yet been created. *Id.* at *15 ("the parties agree that, as of the 2002 priority date, a POSA with the '659 Patent in hand would not have known of or contemplated complexes of valsartan and sacubitril or foreseen that a complex of valsartan and sacubitril would exist."). It was thus undisputed that a skilled artisan would not have been able to "visualize or recognize" the complexed members of the claimed genus, and no representative species of complex could have been disclosed. *Id.* at *21. Given these undisputed

facts, no reasonable factfinder could have found that a skilled artisan would have understood Novartis to be in possession of the full scope of the claimed genus of all "combinations."

While claim construction is an issue of law that this Court approaches *de novo*, the Court has cautioned against exercising this review where, as here, the parties stipulated to infringement in the wake of a district court claim construction and did not appeal that construction (or infringement), but did appeal the issue of written description. *See Idenix Pharms. LLC v. Gilead Sciences Inc.*, 941 F.3d 1149, 1156 n.5 (explaining that applying "newly-invented claim construction to find a hypothetical claim valid but not infringed . . . is no way to conduct an appeal."). The panel should have exercised that caution here, applied the district court's undisputed and un-appealed claim construction, and affirmed the district court's judgment of invalidity for lack of written description.

The panel also should not have found written description support merely because the specification literally referred to "combinations" of valsartan and sacubitril. *See Entresto*, 125 F.4th at 1098. This Court has repeatedly rejected the argument that "the written description

requirement . . . is necessarily met as a matter of law because the claim language appears *in ipsis verbis* in the specification." *Enzo Biochem, Inc. v. Gen–Probe Inc.*, 323 F.3d 956, 968 (Fed. Cir. 2002); *Nuvo Pharms. (Ireland) Designated Activity Co. v. Dr. Reddy's Labs Inc.*, 923 F.3d 1368, 1380 (Fed. Cir. 2019). Adopting such an approach threatens to erode the written description test set forth in *Ariad* that has protected the public against patent claims that seek to capture more than what the inventor contributed to the field.

II. If The Court Believes *De Novo* Claim Construction Is Appropriate Here, The Panel Should Make Its Construction Explicit And Apply It To Both Infringement And Invalidity

Instead of applying the district court's claim construction, the panel appears to have created and applied a narrower construction of "in combination" to its § 112 analysis, even though neither party challenged that construction on appeal. It stated "[t]he fact that the '659 patent does not describe a complexed form of valsartan and sacubitril does not affect the validity of the patent. That complex—not discovered until four years after the priority date of the '659 patent—***is not what is claimed***." *Entresto*, 125 F.4th at 1098 (emphasis added); *see also id.* at 1099, n.5 ("the '659 patent could not have been construed as claiming those

complexes as a matter of law"). Relying on this *sub silentio* construction, the panel reversed the lower court's written description ruling, finding that the patent "plainly described" conventional "combinations" of valsartan and sacubitril, *e.g.*, mixtures. *Id.* at 1098.

One of this Court's core tenets is that "claims are construed the same way for both invalidity and infringement." *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1330 (Fed. Cir. 2003). The panel's decision to depart from the district court's undisputed and un-appealed construction that compelled MSN's stipulated judgment of infringement, however, has given rise to the possibility that Novartis will be able to use the district court's broader claim construction to block generic competition for ENTRESTO while at the same time avoiding invalidity under the panel's narrower construction. To avoid this unjust and untenable outcome, the Court should, at a minimum, grant reconsideration or rehearing *en banc* to clarify that the panel conducted a *de novo* claim construction analysis and that the narrower construction resulting therefrom applies not just to its assessment of compliance with the requirements of § 112, but to the scope of the claims generally, including for purposes of infringement.

CONCLUSION

For the foregoing reasons, *amicus curiae* AAM respectfully submits that panel rehearing or *en banc* review is warranted to rectify the panel's reversal of the district court's judgment of invalidity for lack of written description, or at a minimum, to clarify whether the panel's decision constituted a *de novo* claim construction analysis that departed from the district court's original construction.

Dated: February 18, 2025

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PROOF OF SERVICE

The undersigned counsel for *Amicus Curiae* certifies that, on February 24, 2025, the corrected BRIEF OF *AMICUS CURIAE* ASSOCIATION FOR ACCESSIBLE MEDICINES IN SUPPORT OF DEFENDANTS-APPELLEES' PETITION FOR PANEL REHEARING OR REHEARING *EN BANC* was filed with the Clerk of the United States Court of Appeals for the Federal Circuit via the CM/ECF system, which will send notice of such filing to all registered CM/ECF users.

February 24, 2025

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CERTIFICATE OF COMPLIANCE

This motion complies with the type-volume limitation of Federal Circuit Rule 27(d)(2)(A). The motion contains 2473 words, excluding the parts of the motion exempted by Federal Rule of Appellate Procedure 32(f) and Federal Circuit Rule 32(b)(2).

This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6). The brief has been prepared in a proportionally spaced typeface using Microsoft Word 2016 in 14-point Century Schoolbook font.

February 18, 2025

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