No. 24-1936

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC., NORTON (WATERFORD) LTD., and TEVA PHARMACEUTICALS USA, INC.,

Plaintiffs-Appellants,

v.

AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, AMNEAL IRELAND LIMITED, AMNEAL PHARMACEUTICALS LLC, and AMNEAL PHARMACEUTICALS INC.,

Defendants-Appellees.

Appeal from the U.S. District Court
for the District of New Jersey
No. 23-cv-20964 (SRC), Judge Stanley R. Chesler

APPELLANTS' REPLY BRIEF

Daryl L. Wiesen
Christopher T. Holding
Louis L. Lobel
Jordan Bock
Thomas V. McTigue IV
GOODWIN PROCTER LLP
100 Northern Ave.
Boston, MA 02210
(617) 570-1000

William M. Jay
GOODWIN PROCTER LLP
1900 N Street, N.W.
Washington, DC 20036
(202) 346-4000

Natasha E. Daughtrey
GOODWIN PROCTER LLP
601 South Figueroa Street
Los Angeles, CA 90017
(213) 426-2642

September 11, 2024

CERTIFICATE OF INTEREST

Counsel for Teva Branded Pharmaceutical Products R&D, Inc., Norton (Waterford) Ltd., and Teva Pharmaceuticals USA, Inc. (collectively "Teva" or "Plaintiffs"), certifies the following:

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

   Teva Branded Pharmaceutical Products R&D, Inc.; Norton (Waterford) Ltd.; and Teva Pharmaceuticals USA, Inc.

2. **Real Party 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. Fed. Cir. R. 47.4(a)(2).

   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. Fed. Cir. R. 47.4(a)(3).

   Teva Branded Pharmaceutical Products R&D, Inc.: Teva Pharmaceutical Industries, Ltd.

   Norton (Waterford) Ltd.: Teva Pharmaceutical Industries, Ltd.

   Teva Pharmaceuticals USA, Inc.: Teva Pharmaceutical Industries, Ltd.

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).

   Williams & Connolly LLP: Kathryn S. Kayali

   Walsh, Pizzi, O'Reilly, Falanga LLP: Liza M. Walsh, Selina M. Ellis, Hector D. Ruiz, Christine P. Clark

5. **Related Cases.** Provide the case titles and numbers of any case known to be pending in this court or any other court or agency that will directly affect or

be directly affected by this court's decision in the pending appeal. Do not include the originating case number(s) for this case. Fed. Cir. R. 47.4(a)(5).

Teva Branded Pharm. Prods. R&D, Inc. v. Deva Holding A.S., No. 2:24-cv-04404 (D.N.J. complaint filed March 29, 2024).

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). Fed. Cir. R. 47.4(a)(6).

Not applicable

Dated: September 11, 2024

/s/ *William M. Jay*
William M. Jay

Counsel for Appellants

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases:

Statutes:

Regulations and Other Authorities:

TABLE OF ABBREVIATIONS

Abbreviation	**Description**
’712 patent	U.S. Patent No. 8,132,712
’289 patent	U.S. Patent No. 9,463,289
’587 patent	U.S. Patent No. 9,808,587
’808 patent	U.S. Patent No. 10,561,808
’889 patent	U.S. Patent No. 11,395,889
Amneal	Defendants-Appellees Amneal Pharmaceuticals of New York, LLC, Amneal Ireland Limited, Amneal Pharmaceuticals LLC, and Amneal Pharmaceuticals Inc.
ANDA	Abbreviated New Drug Application
Asserted Patents	’712, ’289, ’587, ’808, and ’889 patents, collectively
FDA	United States Food and Drug Administration
FDCA	Federal Food, Drug, and Cosmetic Act
FTC	United States Federal Trade Commission
GAO	Government Accountability Office
Listing Statute	21 U.S.C. § 355(b)(1)(A)(viii)
MDI	Metered dose inhaler
NDA	New Drug Application
OBTA	Orange Book Transparency Act of 2020, Pub. L. No. 116-290, 134 Stat. 4889 (2021)
Orange Book	*Approved Drug Products with Therapeutic Equivalence Evaluations*

ProAir HFA	ProAir® HFA (albuterol sulfate) Inhalation Aerosol
PTE	Patent term extension
Teva	Plaintiffs-Appellants Teva Branded Pharmaceutical Products R&D, Inc., Norton (Waterford) Ltd., and Teva Pharmaceuticals USA, Inc.

INTRODUCTION

FDA reviewed and approved the ProAir HFA product as a drug. A component of that product is the dosage form—the inhaler. Patents claiming the dosage form are exactly the type of patent that *must* be listed: the NDA product practices every claim limitation, and the dosage form—as a "component" of the drug—meets the statutory definition of "drug," 21 U.S.C. § 321(g)(1)(D). Listing the patent informs generic manufacturers about it and allows challenges to it to be resolved before a generic launch. Forcing readily listable patents out of the Orange Book does not mean less infringement—it means more preliminary injunctions, more damages trials, and less predictability.

The district court wrongly ordered the Asserted Patents out of the Orange Book on the ground that they do not claim the drug "for which [Teva] submitted the application." On the district court's reasoning, to be listable the Asserted Patents would have to recite "albuterol sulfate HFA Inhalation Aerosol" in its entirety. Appx33, Appx38. But Amneal barely defends the district court's reasoning. Rather, Amneal argues that the patents do not "claim[] the drug" because they do not recite the active ingredient. In order to force that desired result onto the statutory language, Amneal has to argue both for adopting a novel meaning of "claims" (one that requires specific recitation rather than claim construction) *and* for rejecting the statutory definition of "drug"—though solely for purposes of the Listing Statute.

Neither proposition is sustainable. Adopting Amneal's interpretation would result in delisting any genus patent, any patent that claims some but not all components of a drug product, *and* any patent that claims one but not all of the active ingredients in a drug product. And even if claiming the active ingredient were the key, determining whether the Asserted Patents claim an active ingredient would require claim construction, which the district court leapfrogged here.

Amneal relies mostly on an argument the district court never reached: that even if they "claim the drug," the Asserted Patents are not "drug product" patents. The Delisting Statute does not authorize a counterclaim on that basis, but even if it did, the argument is wrong. The 2020 amendment that added the "drug product" phrase to the Listing Statute codified existing FDA practice, under which patents on dosage forms have long been listable. The Asserted Patents claim compositions of matter that readily fit the Listing Statute.

The district court's injunction should be reversed, and Amneal's and its amici's attempts to substitute new reasoning for the court's decision should be rejected.

ARGUMENT

I. To "Claim" Means To Read On, Not To Recite.

The crux of the parties' dispute is the meaning of the verb "claims." As Teva explained (at 21-24), it is well-established that a patent "claims" a product if it "reads

on" that product, *i.e.*, each of the claim limitations is present in the product. *Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1343-44 (Fed. Cir. 2003); *Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1344 (Fed. Cir. 2002). What a patent "claims" thus aligns with what will infringe the patent: when a patent's claim limitations are found in a product, "infringement is normally made out." *Envirotech Corp. v. Al George, Inc.*, 730 F.2d 753, 759 (Fed. Cir. 1984). In particular, when claims define the invention as "comprising" a set of elements, then making, selling, or offering a composition of matter containing *at least* those elements will infringe. Teva Br. 23; *see, e.g.*, *CIAS, Inc. v. Alliance Gaming Corp.*, 504 F.3d 1356, 1360 (Fed. Cir. 2007). As a result, a claim need not "read on the entirety of an accused device in order to infringe." *SunTiger, Inc. v. Sci. Rsch. Funding Grp.*, 189 F.3d 1327, 1336 (Fed. Cir. 1999); Teva Br. 22.

Amneal proposes a far narrower interpretation, equating "claiming" with "mentioning" or "reciting," Amneal Br. 20, and arguing that the Court should "requir[e] a specific reference to the NDA drug substance in the claims of a drug product for it to be listable." *Id.* at 25. But Amneal's explanation is a combination of truisms and non sequiturs; it has no grounding in the term "claims."

No one disagrees that claims must "particularly point[] out and distinctly claim[] the subject matter which the inventor or a joint inventor regards as the invention." 35 U.S.C. § 112(b). And of course it is true that "the *words of the claim*

do the claiming" (though sometimes the words are aided by formulae). Amneal Br. 24. But it does not remotely follow that an accused product must be explicitly recited in the claim language—which would reduce both claim construction and infringement findings to ministerial exercises.

To start, § 112(b) does not limit a patent to embodiments expressly recited in the claims. To the contrary, it imposes a definiteness requirement—that a claim must "inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014). This doctrine would be unnecessary if the entire scope of a patent were explicitly recited in detail in the claims. Rather, as this Court has recognized, the "principal function" of claims "is to provide notice of the *boundaries* of the right to exclude and to define *limits*"—"not to describe the invention." *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1348 (Fed. Cir. 2010) (en banc) (emphases added). So long as the claims recite the boundaries, they need not catalog what products fall within them.

Far from insisting on express recitations in the claim language, this Court explained in its last case involving the Listing Statute that determining "what does [a] patent claim" requires "using the tools and framework of patent law, including claim construction." *Jazz Pharms., Inc. v. Avadel CNS Pharms., LLC*, 60 F.4th 1373, 1379 (Fed. Cir. 2023); *see also* Opening Br. 25-27. And when construing the

claims, courts consider not just "the words of the claims themselves," but also "the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005) (en banc) (citation omitted).

By contrast, Amneal's approach refuses to pick up the "tools and framework of patent law" as *Jazz* directs—indeed, Amneal never even cites *Jazz*—and limits itself to asking what words are "present in" the claims and what words are "absent." Amneal Br. 24. This Court has rejected precisely that approach in the indefiniteness context: "'Claim language, standing alone' is not the correct standard of law and is contrary to uniform precedent." *Nature Simulation Sys. Inc. v. Autodesk, Inc.*, 50 F.4th 1358, 1364 (Fed. Cir. 2022) (reversing a district court decision that had held, without claim construction and without consulting other sources of intrinsic or extrinsic evidence, that the existence of questions left unanswered by "the claim language, standing alone" rendered the claims indefinite on their face).[1]

Claim language is a boundary, not a laundry list. A genus claim unambiguously encompasses every species in the genus without mentioning any one

[1] Amneal states that the listing analysis does not involve claim construction "where, as here, the claims on their face do not particularly point out" a drug substance "or require it to be present in the claimed invention." Opening Br. 48. In fact, Amneal's approach will *never* require claim construction: under that approach, if a patent does not recite a drug substance, it is not listable.

of them. That is the point Amneal misses: while it is correct that "the affirmative limitations" must be "expressly recited in the claims," Amneal Br. 24, it is quite wrong to leap to the conclusion that the remaining aspects of an accused product must be recited there as well. Any product that meets "the affirmative limitations" is claimed.

II. A Patent "Claims [A] Drug" If It Claims A Component Of The Drug Product.

A. The Listing Statute turns on whether a patent reads on the drug product.

Applying the longstanding definition of "claims" to the Listing Statute, this Court held that a patent "claims the drug for which the applicant submitted the application" "if it contains a product claim that reads on the drug that is the subject of the NDA." *Apotex*, 347 F.3d at 1343-44. "The listing decision thus requires what amounts to a finding of patent infringement, except that the 'accused product' is the drug that is the subject of the NDA." *Id.* And as explained, a "comprising" claim reads on the NDA product if the NDA product contains all the limitations of that claim.[2] *See supra*, p. 3. That alone is sufficient to reverse the district court's misinterpretation.

[2] Thus, contrary to amicus 52 Professors of Law, Economics, and Medicine ("52 Professors"), Teva's argument is *not* that the presence of some but not all limitations in the NDA product is sufficient to satisfy this requirement. Br. of 52 Professors 4-5.

To be sure, as Teva has already made clear (repeatedly), the statute's use of the word "claims" means that this "finding of patent infringement" must be *literal* infringement—not infringement under the doctrine of equivalents, which goes beyond what is literally "claimed." Teva Br. 21 n.7, 41 n.12, 42 n.13; *Hoechst-Roussel Pharms., Inc. v. Lehman*, 109 F.3d 756, 759 & n.2 (Fed. Cir. 1997). It must be based on "the drug," not on some product that results from using the drug. *Id.* at 759 (claim to metabolite does not claim the drug, even if it might "entitle[] [the patentee] to exclude others from administering" the drug). And it disregards defenses to infringement *liability*, which might cause a plaintiff to lose a suit even if the accused product is literally "claimed." *United Food & Com. Workers Local 1776 v. Takeda Pharm. Co.*, 11 F.4th 118, 134 (2d Cir. 2021).[3] Amneal simply disregards Teva's explanation of these points in the opening brief. As a result, Amneal's attempts (at 26-27) to make something of the modest distinctions between the scope of a claim and the scope of infringement fall flat. Just as *Apotex* explains, the Listing Statute asks whether the patent reads on the NDA product—*i.e.*, whether the NDA product itself practices the claimed invention—and no more. *See* 347 F.3d at 1343-44.

[3] The rarely-invoked "'reverse' doctrine of equivalents," which Amneal emphasizes (at 27), is such a defense. *See SmithKline Diagnostics, Inc. v. Helena Laby's Corp.*, 859 F.2d 878, 889 (Fed. Cir. 1988).

Apotex's description accords with the understanding of FDA and of other courts. As Teva explained (at 27-28), FDA has repeatedly justified its approach to patent listings based on its "lack of expertise in patent matters," 59 Fed. Reg. 50,338, 50, 344, 50,345 (Oct. 3, 1994), a point that makes sense only if the listing decision requires claim construction (on which FDA is not expert) rather than checking for the express recitation of an active ingredient (much closer to FDA's expertise). *Accord, e.g.*, *Teva Pharms. USA, Inc. v. Leavitt*, 548 F.3d 103, 106 (D.C. Cir. 2008) (Listing Statute requires "NDA holders to ascertain if, under substantive patent law, any patent claims the drugs for which the NDA holder submitted an application"); *In re Actos End-Payor Antitrust Litig.*, 417 F. Supp. 3d 352, 369 (S.D.N.Y. Sept. 30, 2019) (applying *Apotex*'s "sensible reading" of the Listing Statute to conclude that a patent "claims the NDA drug" if "it literally reads on the drug pursuant to the plain meaning of 'claims'"). Amneal never squares its approach with these repeated statements by FDA.

Instead, Amneal attempts to distinguish *Apotex*, suggesting (at 28) that this language was describing "the infringement clause of the Listing Statute," not the "claims the drug" language. That suggestion is demonstrably incorrect. Under the pre-OBTA version of the statute *Apotex* construed, 21 U.S.C. § 355(c)(2) (2002), the "infringement clause" *did not modify* the language governing the listing of a patent that "claims the drug"; it applied only "with respect to a method of use claim,"

a separate prong of the statute. 347 F.3d at 1344.[4] Thus, the Court's statement that "a patent must be listed if it contains a product claim that reads on the drug that is the subject of the NDA" could only have been referring to the statutory phrase "claims the drug for which the [NDA] was submitted." *Id.* And in the next sentence, the Court confirmed that the "listing decision thus requires what amounts to a *finding* of patent infringement," for product claims as well as method claims. *Id.* (emphasis added).

Amneal's only other response is to dismiss these statements as "dicta" because the *Apotex* panel "was not resolving a dispute over the proper interpretation of the Listing Statute." Amneal Br. 28; *accord* FTC Br. 31. That, too, is incorrect. The Court interpreted the Listing Statute to assess whether the case raised a substantial question of patent law for purposes of this Court's jurisdiction—and because the listing decision "amounts to a finding of patent infringement" for the branded product, the answer was yes. *Apotex*, 347 F.3d at 1344.

But even if *Apotex*'s statements were dicta, it is not this Court's only statement on the subject. Most notably, *Jazz* confirmed that the patent-law terms in the Listing Statute "take [their] meaning from the patent laws," and that the question of what a patent "claims" must be determined "using the tools and framework of patent law,

[4] As Amneal acknowledges elsewhere (at 6), until it was amended in the OBTA, the infringement requirement did not "expressly apply to drug substance and drug product patents."

including claim construction." 60 F.4th at 1379. That approach should apply here too.

B. A patent that claims a component of an NDA drug claims "the drug."

The import of the meaning of "claims" is confirmed by the meaning of "drug," the other key term in the statutory phrase "claims the drug." As all agree, Congress provided an express definition of "drug," 21 U.S.C. § 321(g), which includes any "component" of any article used as a drug. *Id.* § 321(g)(1)(D). That definition governs the Listing Statute. *See id.* § 321. Thus, a patent that claims a "component" of the drug product claims the "drug" and must therefore be listed. Teva Br. 29-30.

This statutory definition refutes the car hypotheticals that Amneal and the FTC deploy. Amneal suggests that it would not make sense to say that a patent for a brake pad "claims" a Ford Bronco just because the Bronco uses the claimed brake assembly. Amneal Br. 25; *see also* FTC Br. 29 (similar). As an initial matter, neither explains why that is so. A patent analogous to the Asserted Patents—say, one for "a vehicle comprising" the patented brake-pad elements—plainly *would* "claim" the Bronco. Even a patent on the brake pad alone still reads on the Bronco that it is sold with. And in any event, the term "drug" is expressly defined to include its components; if the same were true of "car," there would be nothing unusual about saying that the brake-pad patent claims the car. And because selling the car (or a copy of it) would infringe the brake-pad patent, it is exactly the type of patent that a

hypothetical Hatch-Waxman Act for cars would require the patentee to disclose to potential generic carmakers.

Amneal insists (at 34) that the statutory definition of "drug" does not apply to the term "claims the drug" because it somehow would conflict with the distinct statutory provision authorizing the listing of "drug substance" patents. In Amneal's view, because a "drug substance" is a component of a drug product, and a "drug substance patent" is specifically mentioned as listable, patents claiming other components must *not* be listable. That makes no sense. For one thing, until 2020, the statute contained no reference to "drug substance" patents—yet plainly such patents were listable, *see* 21 C.F.R. § 314.53(b)(1) (2019), refuting Amneal's view that they do not "claim the drug" but only a component of it. In the OBTA, Congress did not amend the phrase "claim the drug"; rather, it added a *separate* requirement that a listable patent be either a drug product patent, a drug substance patent, or a method patent. That amendment thus did not alter the meaning of "claim the drug." *See, e.g.*, *Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc.*, 586 U.S. 123, 131-32 (2019).

Even looking just at the post-2020 statute, there is no basis for Amneal's inference that allowing a drug substance patent to be listed must forbid *any other* component patent from being listed. Drug substance patents are called out specially in the OBTA because they were called out specially in the pre-existing FDA rules,

which the OBTA codified. *See, e.g.*, 21 C.F.R. § 314.53(b)(1) (2019); *infra*, pp. 16-17. That, in turn, is because of a unique requirement to list patents claiming polymorphs—the same active ingredient in a different physical form—if the patented form will perform the same way in the body as the form used in the drug product. 68 Fed. Reg. 36,676, 36,678 (June 18, 2003). Because of this requirement, not all drug substance patents will also qualify as drug product patents—though the regulations recognize that some patents *will* qualify in both categories and authorize the patent owner to choose which category to submit them under. *See* 81 Fed. Reg. 69,580, 69,596 (Oct. 6, 2016); 21 C.F.R. § 314.53(c)(2)(i)(S) (2019). That directly refutes Amneal's view that a patent on a component, including a drug substance, cannot be a "drug product patent"—Amneal insists that there is *no* overlap between the categories, whereas FDA recognizes that there is.

Nor is there any incongruity between the broad definition of "drug" and the phrase "claims the drug for which the applicant submitted the application." That phrase ensures that the applicant does not list patents that claim *a* drug, though not the one in the NDA product. *See, e.g.*, *United Food*, 11 F.4th at 132 n.14. It does not rule out patents on the components that are submitted to FDA. *See* 21 U.S.C. § 355(b)(1)(A)(ii)-(iii) (NDA must include a full description of its components and composition). The contrary reading—which would allow only a patent claiming the *entire* drug formulation to be listed, on the theory that a patent on a subset of the

ingredients does not claim the complete drug "for which the applicant submitted the application"—would prove too much: few patents claim *every* element of the entire formulation.

C. FDA approved ProAir HFA as a drug, not a device.

Amneal repeatedly complains that the metered dose inhaler should be regarded as a device, not part of the drug. Amneal's gripe is with Congress, which directed FDA to treat combination products like ProAir HFA as drugs in their entirety.

FDA must regulate combination products "under a single application, whenever appropriate." 21 U.S.C. § 353(g)(1)(B). Here FDA determined that ProAir HFA is a "single-entity combination product[]," 21 C.F.R. § 3.2(e); Teva Br. 31-32, and that the "primary mode of action" for MDIs like ProAir HFA is "attributable to the drug component." Appx1418; *see also* Appx1052. FDA therefore regulates MDIs as drugs under the FDCA. Appx1418; *see* 21 U.S.C. § 353(g)(1)(D)(i); Teva Br. 31-32. The same is true for dose counters. Appx1419; Teva Br. 33.

Amneal points to *Genus Medical Technologies LLC v. FDA*, 994 F.3d 631, 644 (D.C. Cir. 2021), to argue that the Asserted Patents cannot be treated as if they claim a "drug." Amneal misunderstands both *Genus Medical* and the statute. *Genus Medical* makes the noncontroversial observation that, "*[e]xcepting combination*

products … devices must be regulated as devices." 994 F.3d at 644 (emphasis added); *id.* at 640 ("absent any combination," FDA may not treat drugs as devices). But MDIs *are* combination products—and indisputably so.

Amneal attempts to avoid FDA's treatment of ProAir as a drug by describing the claims in the Asserted Patents as "directed to the device part of a drug-device combination product." Amneal Br. 37; *see also id.* at 43 n.15 (attempting to distinguish FDA's treatment of dose counters on this basis). But FDA does not regulate "the device part" of a combination product as a device on its own. Rather, a combination product in its entirety is regulated *either* as a drug *or* as a device, and the statutory scheme expressly contemplates that the device parts will sometimes be regulated as drugs. 21 U.S.C. § 353(g)(1). *Genus* reflects as much. The decision describes Congress's 1990 decision to amend the statutory definition of "drug" by *removing* the exclusion of devices and their counterparts to "facilitate the regulation of combination products," as drugs. *Genus*, 994 F.3d at 640.; *see also* Safe Medical Devices Act of 1990, Pub. L. No. 101-629, § 16(b), 104 Stat. 4511, 4526 (Nov. 28, 1990) (amending "paragraph (g)(1), by striking out '; but does not include devices or their components, parts or accessories'"). To the extent Amneal objects to this scheme, its dispute is with Congress. And to the extent Amneal objects to FDA's classification of MDIs as single-entity combination products that are regulated as

drugs, rather than as devices, then Amneal's dispute is with FDA—not with the proper interpretation of the Listing Statute.

D. Amneal's surplusage objections are not persuasive.

Amneal offers two reasons why Teva's interpretation purportedly contradicts the Listing Statute. Amneal Br. 30-33. Neither is persuasive.

1. Amneal's own brief contradicts its assertion that Teva's approach would render the "claims the drug" requirement superfluous. *Id.* at 27, 30. Under the doctrine of equivalents, an accused product might infringe by equivalents, such that "a claim of patent infringement could reasonably be asserted." 21 U.S.C. § 355(b)(1)(A)(viii). As Amneal recognizes, however, that does not mean the claims would necessarily read on the product. Amneal Br. 26-27.

Patents claiming packaging, patents claiming metabolites, and patents claiming intermediates provide three more examples. As FDA has explained, "these patents fail to meet the two prong criteria for listing *because they do not claim the approved drug product*," where FDA has identified the other "prong" as whether "a claim of patent infringement could reasonably be made if a person not licensed by the patent owner engaged in the manufacture, use, or sale of the drug." 67 Fed. Reg. 65,448, 65,452 (Oct. 24, 2002) (emphasis added); *see also* 21 C.F.R. § 314.53(b)(1) (specifying that "patents claiming packaging, patents claiming metabolites, and patents claiming intermediates" are not listable). Thus, while these patents might be

listable under the infringement clause, they are *not* listable under the "claims the drug" clause. *Hoechst* demonstrates as much for patents claiming metabolites: The patent claiming the metabolite at issue there did not "claim[] the drug," even though it might have "entitled [the patentee] to exclude others from administering" the drug. 109 F.3d at 759.

2. Amneal relies heavily on the OBTA, but both the text and the legislative history refute the notion that Congress sought to change listing practices in the significant way Amneal hypothesizes. Congress codified requirements that FDA was already applying, using the same language in FDA's regulations.[5]

As Amneal highlights, Congress directed GAO to submit data on two types of patents: those "that claim the active ingredient or formulation of a drug in combination with a device that is used for delivery of the drug" *and* those "that claim a device that is used for the delivery of the drug, but do not claim such device in combination with an active ingredient or formulation of a drug." Orange Book Transparency Act of 2020, Pub. L. No. 116-290, § 2(f), 134 Stat. 4889, 4892 (Jan. 5, 2021). This language makes clear that Congress was trying to determine, of listed patents claiming a device, how many *also* claim the active ingredient—meaning

[5] Amneal insists (at 39) that instead of *expressly* codifying FDA practice, Congress "*tacit[ly]*" codified the flawed decision in *In re Lantus Direct Purchaser Antitrust Litigation*, 950 F.3d 1 (1st Cir. 2020), but cites nothing in the legislative history to support that inference.

Congress recognized that some number of listed patents do *not* claim the active ingredient. Yet Congress did not use the OBTA to prohibit the listing of these patents. Instead it directed GAO to study their prevalence. That would make no sense if these patents could not be listed.

The legislative history confirms Congress's decision to "codify current regulations and practice regarding the types of patent and exclusivity-related information listed in the Orange Book." H.R. Rep. No. 116-47 at 6 (2019); *see also* Amneal Br. 5-6 (explaining that the OBTA codified existing FDA regulations). Current regulation and practice *is* to list precisely the types of patents Amneal complains are at issue here. *See* FTC Br. 19 (noting that listing of similar component patents "appears to be widespread"); Br. of 14 Professors of Law and Medicine 28 (similar). Until recently, Amneal itself recognized as much with respect to its patents on epinephrine injection products—which likewise did not mention the active ingredient. Appx1403-1404; Teva Br. 48-49.

Amneal gets no mileage from a committee report's assertion that "some branded drug manufacturers … are submitting patents potentially for the purpose of blocking generic competition." Amneal Br. 40 (quoting H.R. Rep. No. 116-47 at 4 (2019)). This passage says nothing about which patents do (or do not) meet the listing requirements—which, as noted, Congress was codifying rather than

changing. The provision calling for the GAO study suggests that Congress had not yet decided on any change.

III. The Asserted Patents Are Drug Product Patents.

Amneal's primary argument on appeal was an afterthought in its argument below. Amneal now foregrounds its belief that the Asserted Patents are not properly understood as "drug product" patents, but the district court did not reach that issue below, Appx33; FTC Br. 22, and it was not the focus of the parties' briefing. Amneal's argument cannot be reconciled with the text of either the Delisting Statute *or* the Listing Statute, or with well-established principles of patent law.

A. Congress did not provide for delisting a patent on the basis that it does not claim a "drug product."

To start, as Teva pointed out, the "drug product" patent provision does not provide a proper basis for delisting a patent. Teva Br. 50. The statute provides only one "ground" for a delisting counterclaim: "that the patent does not claim either (aa) the drug for which the application was approved; or (bb) an approved method of using the drug." 21 U.S.C. § 355(j)(5)(C)(ii)(I). Amneal's theory is that *even if* the Asserted Patents claim "the drug for which the application was approved," they should still be delisted. Yet it makes absolutely no attempt to square that theory with the statutory text; it does not address the statutory text at all. And all the FTC can muster is a naked, citation-free appeal to "Congress's intent" in a statute (the OBTA)

that *did not amend* the Delisting Statute.[6] This Court can reject Amneal's "drug product" argument on this basis alone; at a minimum the Court should not affirm the injunction on this alternative ground without confirming its statutory authority.

B. The Asserted Patents claim a drug product.

The parties agree that a "drug product" patent is a patent that claims a drug product. Amneal Br. 20 n.3; *accord* 21 C.F.R. § 314.53(b)(1) (requiring submission of information on "patents that claim the [NDA] drug product"). The parties likewise agree that a "drug product" is a "finished dosage form, e.g., tablet, capsule, or solution, that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients." 21 C.F.R. § 314.3; Amneal Br. 20-21. And they agree again that the "key" question for the listing analysis is "whether the patent being submitted claims the finished dosage form of the approved drug product." 68 Fed. Reg. 36,676 at 36,680; Amneal Br. 20 n.4. They part ways only

[6] The FTC argues that Teva has forfeited the ability to *oppose* this alternative ground for affirmance. FTC Br. 23 n.17. But, of course, Amneal has not made any such forfeiture argument—nor any merits argument, either. *See Amoco Oil Co. v. United States*, 234 F.3d 1374, 1377-78 (Fed. Cir. 2000) (refusing to consider argument raised solely in amicus brief). The district court did not rule on this basis, and Teva had not even submitted its answer to the counterclaim at the time the district court ruled, making claims of forfeiture premature. Regardless, this issue raises a pure question of law; this Court has discretion to reach it, or to conclude that it should not exercise discretion to consider Amneal's alternative ground without this question being resolved. *See Harris Corp. v. Ericsson Inc.*, 417 F.3d 1241, 1251 (Fed. Cir. 2005) ("An appellate court retains case-by-case discretion over whether to apply waiver.").

on what it means for a patent to "claim[] the finished dosage form." 68 Fed. Reg. at 36,680.

As Teva explained, a patent claims a "drug product" if it reads on one or more components of a drug. *See supra*, pp. 6-10. So here the Asserted Patents must read on one or more components of ProAir HFA, whether albuterol sulfate, the propellant, the inhaler device, or the entire inhaler, with its constituent parts. Teva Br. 51-52; *see supra*, pp. 6-10. Amneal disagrees, maintaining that a patent must claim the entirety of the finished dosage form, with only one exception—a drug substance patent. Amneal Br. 31-34 (arguing drug component patents are not listable). And because a drug product contains a drug substance, it insists that every drug product patent must expressly *recite* a drug substance (*i.e.*, active ingredient). That interpretation cannot be squared with the meaning of "claims," which, as explained at length above, is not synonymous with "recites." *See supra*, pp. 2-6.

Nor has Amneal solved its surplusage problem. As Teva explained (at 37, 53), if a drug product patent must recite the active ingredient, there would be no reason for the statute to separately require the listing of "drug substance" patents. Amneal responds that "a drug product patent requires both the drug substance and some further aspect(s) of the drug product." Amneal Br. 34. That is not correct: the relevant regulation defines a "drug product" as "contain[ing] a drug substance, generally, *but not necessarily*, in association with one or more other ingredients."

21 C.F.R. § 314.3(b) (emphasis added). As a result, under Amneal's definition all "drug substance" patents are also "drug product" patents.

C. The Asserted Patents are composition patents.

Amneal and the FTC both insist that the Asserted Patents are not "formulation or composition" patents, terms added to the statute by the OBTA in 2020 but long used by FDA to implement the Listing Statute. And under its rules, FDA expressly recognized that patents on a "finished dosage form" (including metered aerosols) can be listed. Teva Br. 50-51; Appx974. Amneal's interpretation of "formulation or composition" would evidently exclude many of these patents, contrary to the OBTA's stated purpose to codify rather than modify FDA's listing practices. *See supra*, pp. 16-17.

"Composition" is not a defined term in FDA law, though in patent law a "composition of matter" encompasses "all compositions of two or more substances and all composite articles, whether they be the results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders, or solids." *In re Nuijten*, 500 F.3d 1346, 1357 (Fed. Cir. 2007) (quoting *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980)); *see also Jazz*, 60 F.4th at 1379-80 (construing patent-law terms in the Listing Statute using patent-law principles). Thus, "composition patents" include patents on composite articles—a standard the Asserted Patents easily satisfy here through the combination of multiple physical components (*e.g.*,

the inhaler and medicament canister). *See id.*; *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 591 (2013) (referring to a patent on a "composition of matter" as a "composition patent"). That is certainly consistent with how the FDCA and FDA regulations use the term: an NDA must list all of the drug product's "components," "regardless of whether they appear in the drug product," as well as its "composition," which appears to simply refer to what components *do* appear in the drug product. 21 U.S.C. § 355(b)(1)(B)-(C); 21 C.F.R. § 314.50(d)(1)(ii)(a).

Amneal and the FTC attempt to narrow "composition" by claiming that it is a chemistry term of art limited to a mixture of active and inactive ingredients. *See* FTC Br. 24; Amneal Br. 38-39. That better describes a *formulation* patent. *See HZNP Meds. LLC v. Actavis Lab'ys UT, Inc.*, 940 F.3d 680, 683 (Fed. Cir. 2019) (listing "formulation patents" consisting of a mixture of the active and inactive ingredients making up a drug). And "composition" must be distinct from "formulation"; "Congress is presumed to have intended a disjunctive meaning by using the disjunctive word 'or.'" *Markovich v. Sec'y of HHS*, 477 F.3d 1353, 1357 (Fed. Cir. 2007).[7] In any event, nothing in "composition" excludes the dosage form

[7] Notably, the 1986 Hatch-Waxman Letter that Amneal cites (at 26) treats a formulation patent as a subcategory of composition patents, consistent with Teva's position. *See* Letter from Harry M. Meyer, Jr., Director, Center for Drugs and Biologics, to Pharmaceutical Manufacturers Association (Mar. 26, 1985) (repeatedly referring to "drug composition patents, including formulation patents"), *available at*

itself—whether that is a capsule or an MDI. There is no established distinction between "inactive ingredients" and other components; to the contrary, an inactive ingredient is simply "any component other than an active ingredient." 21 C.F.R. § 314.3. Nor would such a distinction make sense—here, for example, the propellant contained in an inhaler is part of the dosage form as well as (as Amneal concedes) an inactive ingredient.

IV. At A Minimum, Claim Construction Is Required.

If the Court nevertheless concludes that the Asserted Patents must claim an active ingredient, the case must be remanded to the district court to conduct claim construction. Teva Br. 45-48, 53-54. As Teva has explained in extensive claim construction briefing (filed after this interlocutory appeal), the claims, specification, and prosecution history demonstrate that each of the Asserted Patents has a claim term that requires incorporation of an active ingredient.

Amneal argues that claim construction would be relevant only if Teva's proposed constructions expressly required the presence of albuterol sulfate; claiming an "active drug" is, in its view, insufficient. Amneal Br. 48-49. This argument fails on the same grounds as Amneal's interpretation of the statute: a patent can *claim* the active ingredient without *naming* it, as genus claims do. *See supra*, pp. 5-6.

---

https://www.fda.gov/media/149035/download?attachment.

The FTC does not adopt Amneal's position that claiming an "active drug" is insufficient. FTC Br. 31 n.21. Instead, it maintains that Teva's claims cannot be read to claim an "active drug" because "the Asserted Patents recite only structural elements and do not mention any chemical or biological substances whatsoever." *Id.* Again, as Teva explained in detail in its claim construction briefing, each of the Asserted Patents has at least one claim that requires the presence of an active ingredient. The FTC—an agency with no specialized patent knowledge—dismisses this position in a footnote invoking the principle that limitations cannot be *imported* into the claims. *Id.* But the purpose of claim construction is to determine whether a limitation is *present* in a claim, without importation; that is precisely why claim construction is necessary here. The FTC's cited authority itself makes clear that merely scanning the claims for particular terms (*e.g.*, active ingredient) is insufficient. *See Phillips*, 415 F.3d at 1313. Claim construction is far from over merely because the patent does not recite a "chemical or biological substance[]." FTC Br. 31.

The FTC, like Amneal, has no answer to this Court's decision in *Jazz*. Notwithstanding this Court's express directive to use claim construction to determine what a patent "claims," the FTC's sole response is that the Court there "did not conduct a detailed claim construction analysis." FTC Br. 31-32. That is incorrect; the district court issued a highly detailed 22-page decision on the six

claims at issue, which this Court affirmed on appeal. *See Jazz Pharms., Inc. v. Avadel Pharms.*, No. 1:21-cv-00691 (D. Del. Nov. 18, 2022), ECF No. 229; 60 F.4th at 1380. Regardless, the FTC's suggestion that the level of "detail[]" matters is unsupported. This Court squarely held that determining what a patent "claims" involves claim construction.[8]

V. Amneal's Approach Will Destabilize The Hatch-Waxman Regime.

The Hatch-Waxman Act is Congress's effort to "balance competing interests in the pharmaceutical industry: (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market." *Janssen Pharm., N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1355 (Fed. Cir. 2008) (citation omitted). Different stakeholders might do the balancing differently; the current FTC, for one, plainly has a different view of the proper balance than the 2021 FTC. Teva Br. 48. But it is up to Congress to draw that line, and here Congress drew the line to require listing patents that claim a component of the NDA drug product. *See supra*, pp. 10-13; *PDS Consultants, Inc. v. United*

[8] The FTC also asserts that claim construction was unnecessary in *United Food* because, "on their face," the patents "claimed a combination of two active ingredients, but the NDA drug contained only one of them." 11 F.4th at 124, 132. The Second Circuit's decision says nothing one way or the other about claim construction. Regardless of what role claim construction may have played in determining that the patents claimed a combination of two active ingredients, the decision has no bearing on whether claim construction is required here, nor does it in any way undercut this Court's binding decision in *Jazz*.

States, 907 F.3d 1345, 1360 (Fed. Cir. 2018) (recognizing that the Court "must give effect to the policy choices made by Congress"); Deva Br. 18-22 (Congress is proper body to "fix any policy" issues surrounding the Listing Statute). The extensive amicus arguments critiquing the effects of that choice are both wrong and irrelevant to the legal analysis.

Amneal and amici base their policy arguments on the premise that listing patents like Teva's stifles generic competition. *See, e.g.*, Br. of 52 Professors 16; Br. of 14 Professors of Medicine and Law 13-14. That assumption is deeply flawed. To start, it is not the case that "[e]very one of the days making up the 30 months from improperly listed patents is a day that consumers are robbed of lower-cost generic medicines." *Id.* at 15. FDA typically takes more than 30 months to review an ANDA, meaning that the stay does not actually delay approval. *See* Appx1428-1431 (mean time for tentative approval of an ANDA in October-December 2023 was 41 months); Appx1436 (explaining that "30-month stays are unlikely to delay the timing of generic entry"). And the stay terminates as soon as a generic wins, even pretrial. 21 U.S.C. § 355(j)(5)(B)(iii)(I).

Moreover, this product itself rebuts amici's premise that these patents prevent competition. Multiple generic versions of ProAir HFA are already on the market; the first was approved in 2020. Appx1422-1426. And Teva itself currently distributes an authorized generic of ProAir HFA under NDA No. 021457. Amneal

and amici also entirely ignore the unnecessarily destabilizing effects of their proposed approach—which does not avoid any litigation. Rather, it pushes disputes over these patent rights out of a highly ordered process—one specifically "designed to speed the introduction of low-cost generic drugs to market," *Caraco Pharm. Lab'ys, Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405 (2012)—into chaotic, hurried, and risky preliminary-injunction proceedings. The district court itself noted that such proceedings create "havoc" and that there "is nothing worse than having to deal with complex legal and factual issues on an expedited basis" when facing an at-risk launch. Appx1575.

Nor does Amneal and amici's approach change the scope of any party's patent rights. Rather, potential generic manufacturers will simply not have notice of the full scope of those rights when attempting to make decisions about which drugs to develop and launch—at least not without extensive research and monitoring that, at a minimum, less sophisticated generics may not have the capabilities and resources for. Teva Br. 24-26.[9] Indeed, the leading trade association for generic manufacturers itself stated in a 2020 comment to FDA that "[i]nformation on those device-related patents that 'read on' the approved drug product and that is

[9] That is particularly problematic here, as the Asserted Patents are hardly "tangential" or "*de minimis*." Sandoz Br. 6. Nor, for that matter, are the inhaler and dose counter akin to a "spoon." *See* Br. of 52 Professors 6-7. The inhaler and dose counter are integral parts of the approved NDA product—not stand alone products that can be sold separately.

subsequently listed in the Orange Book would be beneficial to the generic drug industry by allowing the normal pre-approval patent resolution to take place …. " Association for Accessible Medicines Comment at 16, Docket No. FDA-2020-N-1069-0013 (Aug. 31, 2020).[10]

* * *

The sole question on appeal is how to interpret the Listing Statute, the linchpin of a carefully calibrated scheme that balances pharmaceutical innovation with the availability of generic drugs. The answer is clear from the established meaning of statutory terms, including Congress's explicit definition. Amneal and its amici would prefer to strike a different balance, but the question is not what the statute *should* say. The Asserted Patents are drug product patents that claim ProAir HFA. They are required to be listed.

CONCLUSION

The district court's injunction ordering delisting should be reversed.

[10] Sandoz dismisses the Orange Book's notice function by arguing (at 10) that the listed patents "are not the only patents that a brand company may assert." *Id.* at 10. But patents that "claim the drug," as opposed to its manufacture or packaging, are highly likely to read on an ANDA product that is required to be bioequivalent and bear the same labeling; such patents are crucial to adjudicate while an ANDA is pending, rather than by jury trial after launch.

September 11, 2024

Respectfully submitted,

/s/ William M. Jay

William M. Jay
GOODWIN PROCTER LLP
1900 N Street, N.W.
Washington, DC 20036
(202) 346-4000

Counsel for Appellants

Daryl L. Wiesen
Christopher T. Holding
Louis L. Lobel
Jordan Bock
Thomas V. McTigue IV
GOODWIN PROCTER LLP
100 Northern Ave.
Boston, MA 02210
(617) 570-1000
Fax.: 617.523.1231

Natasha E. Daughtrey
GOODWIN PROCTER LLP
601 South Figueroa Street
Los Angeles, CA 90017
(213) 426-2642

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitations of Federal Rule of Appellate Procedure 27(d)(2)(A) because it contains 6,982 words, excluding the parts of the brief 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 365 in 14-point Times New Roman font.

Dated: September 11, 2024

/s/ William M. Jay
William M. Jay

CERTIFICATE OF SERVICE

I hereby certify that on September 11, 2024, I electronically filed the foregoing using the Court's CM/ECF system, which will send notifications to all counsel registered to receive electronic notices.

/s/ William M. Jay
William M. Jay