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 United States District Court for the District of New Jersey
Case No. 2:23-cv-20964, Judge Stanley R. Chesler

APPELLEES' RESPONSE BRIEF

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August 30, 2024

PATENT CLAIM LANGUAGE

U.S. Patent No. 9,463,289

Claim 1: An inhaler for metered dose inhalation, the inhaler comprising:

a main body having a canister housing,

a medicament canister, which is moveable relative to the canister housing and retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister, and

a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister,

wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall, and

wherein the canister housing has a longitudinal axis X which passes through the center of the central outlet port,

the inner wall canister support formation, the actuation member, and the central outlet port lying in a common plane coincident with the longitudinal axis X.

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF INTEREST

Case Number 2024-1936

Short Case Caption Teva Branded Pharmaceutical Products R&D, Inc. v. Amneal Pharmaceuticals of New York, LLC

Filing Party/Entity Amneal Pharmaceuticals of New York, LLC; Amneal Ireland Limited; Amneal Pharmaceuticals LLC; Amneal Pharmaceuticals, Inc.

Instructions:

1. Complete each section of the form and select none or N/A if appropriate.
2. Please enter only one item per box; attach additional pages as needed, and check the box to indicate such pages are attached.
3. In answering Sections 2 and 3, be specific as to which represented entities the answers apply; lack of specificity may result in non-compliance.
4. Please do not duplicate entries within Section 5.
5. Counsel must file an amended Certificate of Interest within seven days after any information on this form changes. Fed. Cir. R. 47.4(c).

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

Date: 08/30/2024

Signature: /s/ Steven A. Maddox

Name: Steven A. Maddox

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
Amneal Pharmaceuticals of New York, LLC		See attached.
Amneal Ireland Limited		See attached.
Amneal Pharmaceuticals LLC		See attached.
Amneal Pharmaceuticals, Inc.		See attached.

☑ 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).

☐ None/Not Applicable ☐ Additional pages attached

Melissa Hatch O'Donnell, Robin P. Sumner, and Andrew P. Zappia of Troutman Pepper Hamilton Sanders LLC		
Rebekah R. Conroy and Shalom D. Stone of Stone Conroy LLC		

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)

If yes, concurrently file a separate Notice of Related Case Information that complies with Fed. Cir. R. 47.5(b). **Please do not duplicate information.** This separate Notice must only be filed with the first Certificate of Interest or, subsequently, if information changes during the pendency of the appeal. Fed. Cir. R. 47.5(b).

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).

☑ None/Not Applicable ☐ Additional pages attached

3. **Parent Corporations and Stockholders.** Fed. Cir. R. 47.4(a)(3).
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.

Amneal Pharmaceuticals of New York, LLC:
Wholly owned by Amneal Pharmaceuticals LLC

Amneal Ireland Limited:
Wholly owned by Amneal Pharmaceuticals Holding GmbH, which is wholly owned by Amneal UK Holding Company Ltd., which is wholly owned by Amneal Pharmaceuticals LLC

Amneal Pharmaceuticals LLC:
Wholly owned by Amneal Pharmaceuticals, Inc.

Amneal Pharmaceuticals, Inc.:
None/Not Applicable

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STATEMENT OF RELATED CASES

No appeal in or from the same civil action was previously before this or any other appellate court. There are two pending cases that will directly affect or be directly affected by this Court's decision in the instant appeal: *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) and *Teva Branded Pharm. Prods. R&D, Inc. v. Cipla Ltd.*, No. 2023-2241 (Fed. Cir. appeal docketed August 4, 2023).

TABLE OF ABBREVIATIONS

Abbreviation	**Description**
Amneal	Defendants-Appellees
Amici	Amicus Curiae Sanofi-Aventis U.S. LLC ("Sanofi") and AstraZeneca Pharmaceuticals LP ("AstraZeneca")
ANDA	Abbreviated New Drug Application
Asserted Patents	U.S. Patent Nos. 8,132,712; 9,463,289; 9,808,587; 10,561,808; and 11,395,889
FDA	United States Food and Drug Administration
FDCA	Federal Food, Drug, and Cosmetic Act
FTC	United States Federal Trade Commission
GAO	United States Government Accountability Office
Listing Statute	21 U.S.C. § 355(b)(1)(A)(viii)
NDA	New Drug Application
OBTA	Orange Book Transparency Act of 2020
Orange Book	Approved Drug Products with Therapeutic Equivalence Evaluations
ProAir	ProAir® HFA (albuterol sulfate) Inhalation Aerosol
Teva	Plaintiffs-Appellants

INTRODUCTION

The Court should affirm the district court's injunction ordering Teva to de-list the Asserted Patents from the FDA's Orange Book. The district court properly construed the Listing Statute and applied it to the undisputed facts.

Each of the Asserted Patents fails to meet the Listing Statute's requirement of being a "drug product (formulation or composition) patent" that "claims the drug for which the applicant submitted the application." 21 U.S.C. § 355(b)(1)(A)(viii)(I). The FDA defines a "drug product" as "a finished dosage form…*that contains a drug substance*, generally, but not necessarily, in association with one or more other ingredients." 21 C.F.R. § 314.3 (emphasis added). The "drug for which [Teva] submitted the application" is ProAir® HFA (albuterol sulfate) Inhalation Aerosol ("ProAir"). As the name suggests, it is a drug product in which albuterol sulfate is the drug substance.

It is undisputed, however, that the Asserted Patent claims do not recite, identify or refer to the drug substance—albuterol sulfate—as a part of the claimed inventions. Indeed, they do not recite any specific drug substance as part of any claimed invention. Rather, all of these claims are directed solely to mechanical inhaler devices and components of such devices. Accordingly, the district court correctly determined that the Asserted Patents do not claim ProAir.

Teva and Amici seek in effect to rewrite the Listing Statute—by construing "claims" to mean "reads on any part of." Thus, Teva argues that each Asserted Patent "claims" ProAir because it "reads on" the mechanical inhaler device component of Proair. Teva's proposed construction is contrary to the meaning of "claims" taken in the context of the statutory text and contrary to black letter patent law, the legislative history, and the FDA's definition of "drug product."

Further, the Court should reject Teva's bid to remand for claim construction. Even under Teva's extraordinary constructions, the Asserted Patent claims do not recite, identify, or refer to the ProAir drug substance—albuterol sulfate—as a part of the claimed inventions. Thus, even if the claims were construed as Teva proposes, the Asserted Patents still would not qualify for listing in the Orange Book.

STATEMENT OF THE ISSUES PRESENTED FOR REVIEW

1. Whether a patent qualifies for listing in the Orange Book under the Listing Statute, when that patent has no claims requiring the NDA drug substance to be present in the claimed invention.

2. Whether remand for claim construction is required when appellant's own proposed claim constructions do not require the NDA drug substance to be present in any of the claimed inventions.

CONCISE STATEMENT OF THE CASE

I. The Listing Statute, its legislative history, and the regulatory scheme

The FDCA is part of a detailed scheme governing approval of new drugs by the FDA. The FDCA prohibits a company from introducing a new drug into commerce unless the company submits an NDA which gets approved by the FDA. 21 U.S.C. § 355(a).

The FDCA lists eight categories of information and samples that must be submitted as part of an NDA for a drug:

> (i) full reports of investigations…to show whether such drug is [safe and effective];
> (ii) a full list of the articles used as components of such drug;
> (iii) a full statement of the composition of such drug;
> (iv) a full description of the methods[,] facilities and controls used [to make and pack] such drug;
> (v) …samples of such drug and of the articles used as components [of such drug];
> (vi) [labeling] specimens to be used for such drug;
> (vii) any assessments required under [21 U.S.C. §355(c)]; and
> **(viii) the patent number and expiration date of each patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug, and that—**
>
> **(I) claims the drug for which the applicant submitted the application and is a drug substance (active ingredient) patent or a drug product (formulation or composition) patent; or**
>
> **(II) claims a method of using such drug for which approval is sought or has been granted in the application.**

21 U.S.C. § 355(b)(1)(A)(i-viii) (emphasis added). The final item in this list of NDA submission requirements, shown in bold above, is the Listing Statute. The proper interpretation of the Listing Statute is the central issue in this appeal.

An NDA must contain information on patents that meet the criteria of the Listing Statute, and applicants are prohibited from submitting information on patents that are not eligible under these criteria. 21 U.S.C. § 355(c)(2) ("Patent information that is not the type of patent information required by subsection (b)(1)(A)(viii) shall not be submitted . . . .").

A patent is only eligible for submission if it satisfies the first clause of the Listing Statute (the infringement clause). 21 U.S.C. § 355(b)(1)(A)(viii). The infringement clause requires that there be a reasonable basis to assert that the patent would be infringed by the unauthorized manufacture, use, or sale of the NDA drug. *Id*.

The second clause of the Listing Statute identifies two types of patents potentially eligible for submission—a "drug substance (active ingredient) patent" and a "drug product (formulation or composition) patent"—and requires that any such patent also be one that "claims the drug for which the applicant submitted the application." 21 U.S.C. § 355(b)(1)(A)(viii)(I). The "application" in this context is

the NDA. As noted above, to qualify for submission, these patent types must also satisfy the separate infringement clause.[1]

The language in the Listing Statute identifying these two patent types—"a drug substance (active ingredient) patent" and "a drug product (formulation or composition) patent" was added by the OBTA in 2021. Orange Book Transparency Act of 2020, Pub. L. No. 116-290, 134 Stat. 4889 at Section (b)(1)(A)(viii) (Jan. 5, 2021). Prior to the OBTA, the Listing Statute requirement (for non-method of use patents) was merely to submit "any patent which claims the drug for which the applicant submitted the application." H.R. Rep. No. 116-47 at 9-10 (2019) (reciting then-existing law in brackets).

This language added by the OBTA was borrowed directly from the FDA regulation implementing a prior version of the Listing Statute. That regulation (which is still in force), states that patents to be submitted under the Listing Statute ". . . consist of drug substance (active ingredient) patents, drug product (formulation and composition) patents, and method-of-use patents." 21 C.F.R. § 314.53(b). Indeed, the Committee Report for the OBTA acknowledged that it was codifying existing regulations. H.R. Rep. No. 116-47 at 6 (2019) ("H.R. 1503

[1] Of less relevance to this appeal, the final clause of the Listing Statute identifies a third patent type potentially eligible for submission, namely patents claiming certain "methods of using" the NDA drug. 21 U.S.C. § 355(b)(1)(A)(viii)(II).

would codify current regulations and practice regarding the types of patent and exclusivity-related information listed in the Orange Book.").

The OBTA also restructured the Listing Statute to make the infringement requirement expressly apply to drug substance and drug product patents. It did this by nesting clauses I and II under the infringement requirement. *Compare* H.R. Rep. No. 116-47 at 9-10 (2019) *with* Orange Book Transparency Act of 2020, Pub. L. No. 116-290, 134 Stat. 4889 at Section (b)(1)(A)(viii) (Jan. 5, 2021).

The OBTA was introduced in response to a concern that brand companies were "submitting patents potentially for the purpose of blocking generic competition." H.R. Rep. No. 116-47 at 4 (2019). The Committee Report cited a paper analyzing the proliferation of device patents submitted under the auspices of the Listing Statute for drug device combination products, including, most commonly, inhalers. *Id*. at 4, n.3 (committee report); Appx1043-44 (paper cited in committee report). The paper noted that listing of delivery device patents in the Orange Book was delaying generic entry by a median of 3.4 years. (Appx.1044.)

In its implementing regulation, the FDA has interpreted the "claims the drug" and "drug product" patent requirements in tandem, and has invoked its definition of "drug product." The regulation states that "[f]or patents that claim a drug product, the applicant must submit information only on those patents that

claim the drug product, as is defined in [21 C.F.R.] § 314.3, that is described in the pending or approved NDA." 21 C.F.R. § 314.53(b).[2]

FDA's definition of "drug product" requires the presence of a drug substance: "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 (emphasis added).

The FDCA defines the term "drug" broadly as:

> (A) articles recognized in [certain compendia]; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C).

21 U.S.C. § 321(g)(1).

The FDCA similarly defines the term "device" as:

> an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is — (A) recognized in [certain compendia], (B) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (C) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not

[2] The FDA has also interpreted the "claims the drug" requirement in tandem with the "drug substance" patent requirement. *Id*.

> dependent upon being metabolized for the achievement of its primary intended purposes.

21 U.S.C. § 321(h)(1).

The interplay of these two definitions is such that as a matter of law, the FDCA prohibits the FDA from treating a device as if it were a "drug." *Genus Medical Techs. LLC v. United States*, 994 F.3d 631, 644 (D.C. Cir. 2021). This is true even though the term "drug" is so broadly defined that it linguistically could include a device. *Id*.

Patents submitted with an NDA under the auspices of the Listing Statute are published by the FDA in a public database called the "Orange Book." 21 C.F.R. § 314.53(e); *Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1338 (Fed. Cir. 2003). The FDA has adopted a purely "ministerial" role with respect to which patents get listed in the Orange Book. That is, FDA does not screen patents to ensure they satisfy the requirements of the Listing Statute, and will not remove any patents from the Orange Book unless the NDA holder requests removal. *Apotex*, 347 F.3d at 1347; 21 C.F.R. § 314.53(f).

The listing of patents in the Orange Book for a given NDA product triggers significant rights and duties under the Hatch-Waxman provisions of the FDCA. If another company seeks FDA approval of an ANDA for a generic version of an NDA product, the ANDA must address each listed patent. 21 U.S.C. § 355(j)(2)(A)(vii). If the ANDA applicant requests that the FDA approve its

ANDA prior to expiration of a listed patent, the ANDA applicant must (a) include in the ANDA a "paragraph IV" certification that the listed patent is invalid or would not be infringed, (b) timely notify the NDA holder of its submission, and (c) timely provide the NDA holder with a detailed statement of the factual and legal basis for its opinion that the patent is invalid or would not be infringed. 21 U.S.C. § 355(j)(2)(A)(vii)(IV), -(B)(iv)(II).

The submission of an ANDA containing a paragraph IV certification triggers the ability of the NDA holder to sue for patent infringement. 35 U.S.C. § 271(e)(2)(A). If that lawsuit is timely brought, it triggers an automatic 30-month stay of final FDA approval of the ANDA. 21 U.S.C. § 355(j)(5)(B)(iii). If the NDA holder prevails on the listed patent in the lawsuit, it is entitled by statute to an injunction that prevents the FDA from approving the ANDA product until after the listed patent expires. 35 U.S.C. § 271(e)(4)(A).

In a lawsuit brought under these Hatch-Waxman provisions, the ANDA applicant can counterclaim for an order requiring the NDA holder to correct or delete the patent information in the Orange Book. 21 U.S.C. § 355(j)(5)(C)(ii)(I).

II. District court proceedings

Teva submitted the Asserted Patents for listing in the Orange Book in connection with ProAir, and they are currently listed there. (Appx67-69.) Amneal submitted an ANDA for a generic version of ProAir, and Teva sued, asserting

claims for infringement under the Hatch-Waxman Act (35 U.S.C. § 271(e)) and claims for a declaratory judgment of infringement under 35 U.S.C. § 271(a). (Appx72-90.) Teva's claims under the Hatch-Waxman Act triggered a stay of FDA approval of Amneal's ANDA that is set to expire in February 2026.

Shortly after Teva sued, the FTC asked Teva to remove the Asserted Patents (among others) from the Orange Book. (Appx813-14.) Teva has not done so. (Appx810.)

Amneal counterclaimed seeking an order compelling Teva to remove the Asserted Patents from the Orange Book listing for ProAir. (Appx-320-35.) Teva moved to dismiss those counterclaims, and Amneal moved for judgment on the pleadings in its favor on those same counterclaims. (Appx32.) The FTC filed an amicus brief in support of delisting the Asserted Patents. (Appx1274-1320.)

The district court denied Teva's motion to dismiss and granted Amneal's motion for judgment on the pleadings. (Appx24-40.) The district court found that none of the Asserted Patents qualified for listing in the Orange Book because none "claim[s] the drug for which the applicant submitted the application." (Appx33.) Guided by the Second Circuit's decision in *United Food v. Takeda Pharm. Co. Ltd.*, 11 F.4th 118, 134 (2d Cir. 2021) the district court construed the term "claims" in the Listing Statute as having its established meaning in patent law, concluding

that "a patent claims *only* that subject matter that it has particularly pointed out as the invention, and no more." (Appx36-37.)

The district court rejected Teva's reliance on the broad definition of "drug" in the FDCA, because the Listing Statute required a drug product patent to claim not just any "drug," but specifically "the drug for which the applicant submitted the application." (Appx38.) The district court noted that Teva had failed to get around the restrictiveness of this requirement. (Appx38.)

Based upon similar reasoning, the district court also rejected Teva's contention that the Asserted Patents are "drug product" patents as required by the Listing Statute. (Appx38-39.) The district court relied on the FDA definition of "drug product" as a "finished dosage form" and the FDA regulation indicating that the only listable drug product patents are those that claim the specific drug product "described in the…NDA." (*Id*.) The district court concluded that the Asserted Patents do not claim the "finished dosage form" that is the subject of the NDA. (Appx39.)

The district entered an injunction ordering Teva to request removal of the Asserted Patents from the Orange Book. (Appx40.) This Court expedited the briefing and stayed the district court order until further notice. The case is otherwise proceeding in the district court with the 30-month stay still in effect.

SUMMARY OF THE ARGUMENT

I. A. The Asserted Patents do not satisfy the requirements of the Listing Statute, and should be removed from the Orange Book listing for ProAir. The Listing Statute identifies specific kinds of patents as eligible for listing. One such type is a "drug product" patent. To qualify for listing, "drug product" patent must satisfy three criteria. First, it must be a "patent for which a claim of infringement could reasonably be asserted [against unauthorized] manufacture, use or sale" of the NDA product. 21 U.S.C. § 355(b)(1)(A)(viii). In other words, it must be infringed by the NDA product. Second, the patent must be a "drug product" patent, which simply means that it must claim a drug product. 21 U.S.C. § 355(b)(1)(A)(viii)(I). Third, the patent must "claim[] the drug for which the applicant submitted the application." *Id*.

The second and third requirements work in tandem to require a drug product patent to claim not just any "drug product," but the specific NDA "drug product," as that term is defined by the FDA. 21 C.F.R. § 314.53(b). Importantly, the FDA defines "drug product" such that it must contain a drug substance, which is also known as an "active ingredient." 21 C.F.R. § 314.3.

In view of these requirements, the Listing Statute is properly construed to permit listing a "drug product" patent in the Orange Book only if it has at least one claim requiring the active ingredient of the NDA to be present in the claimed

invention. This construction harmonizes (a) the restrictive, product-specific language of the Listing Statute, (b) the FDA definition of "drug product" requiring the presence of the active ingredient, and (c) the plain meaning of "claims" under black letter patent law as "particularly pointing out and distinctly claiming that which the applicant regards as its invention." *Hoechst-Roussel Pharms., Inc. v. Lehman*, 109 F.3d 756, 758-59 (Fed. Cir. 1997); 35 U.S.C. § 112.

Teva's and Amici's contrary interpretation of the Listing Statute is erroneous. According to Teva and Amici, the term "claims the drug" means "reads on the drug." Under Teva's interpretation, if the NDA product would infringe a claim in the patent, then the patent "claims" the NDA product. This interpretation is incorrect for several reasons. First, it departs from the meaning of "claims" under black letter patent law, ignoring both the statutory meaning of "claims," and the well-established distinction between what a patent "claims" and what infringes a patent. 35 U.S.C. §112; *Hoechst*, 109 F.3d at 758-59; *Graver Tank & Mfg. Co., Inc. v. Linde Air Prods. Co.*, 339 U.S. 605 (1950).

Second, Teva's interpretation is presumptively incorrect because it would render the "claims the drug" requirement superfluous. *Facebook, Inc. v. Windy City Innovations, LLC*, 973 F.3d 1321, 1336 (Fed. Cir. 2020); *Arlington Cent. Sch. Dist. Bd. of Educ. v. Murphy*, 548 U.S. 291, 299 n.1 (2006). Specifically, the first clause of the Listing Statute requires that the NDA product infringe the patent. 21

U.S.C. § 355(b)(1)(A)(viii). In view of this separate infringement requirement, the "claims the drug" requirement in the second clause must require more than merely infringement by the NDA product.

Third, Teva's interpretation is more permissive than a fair reading of the Listing Statute when it comes to the listing of component patents (i.e., patents that require only a component of the drug product). Specifically, Teva's interpretation would open the Orange Book up to any type of component patent, regardless of its nature. But the Listing Statute is far more restrictive about authorizing listing of component patents. Even though the adjacent NDA submission provisions broadly require NDA applicants to submit information and samples of *all* components of the NDA drug, the Listing Statute does not broadly permit listing of any kind component patents. Instead, it specifically and narrowly permits listing of only *one* kind: "a drug substance (active ingredient) patent." 21 U.S.C. § 355(b)(1)(A)(viii)(I). Under standard principles of statutory construction, this implies that patents on other kinds of drug components are not authorized. *Syngenta Crop Protection, LLC v. Willowood, LLC*, 944 F.3d 1344, 1361 (Fed. Cir. 2019).

Fourth, Teva's interpretation of the Listing Statute is especially problematic as applied to device patents, like the Asserted Patents. Teva relies on the FDCA's general definition of "drug" because it is broad enough on its face to include

device components. Thus, Teva argues that a patent claiming a device component of a drug-device combination product can satisfy the "claims the drug" requirement of the Listing Statute.

But it does not make sense to plug the "component" aspect of the definition of "drug" into the Listing Statute. The Listing Statute requires that the patent claim not just *any* drug, but specifically "the drug for which the applicant submitted the application." Here, Teva submitted its application for the entirety of the ProAir product, not just for the inhaler device component of that product. This incongruity shows that the general definition of "drug" cannot be applied in the manner suggested by Teva. *Lawson v. Suwannee Fruit & S.S. Co.*, 336 U.S. 198, 206 (1949).

Moreover, purely as a matter of law, the FDCA prohibits the FDA from treating a device as if it were a drug *Genus Medical Techs. LLC v. FDA*, 994 F.3d 631, 644 (D.C. Cir. 2021). By extension, the FDCA must prohibit FDA from treating patents claiming only a device as if they claimed a drug. Listing device patents, which do not require the presence of an active ingredient, would violate this prohibition.

B. The Asserted Patents do not qualify under the Listing Statute for inclusion in the Orange Book. The "drug for which [Teva] submitted the application" is ProAir. The active ingredient of ProAir is albuterol sulfate. Yet

none of the Asserted Patents has any claim that requires the presence of albuterol sulfate in the claimed invention. Thus, none qualify for listing as a "drug product" patent that "claims the drug for which [Teva] submitted the application." The Asserted Patents should be removed from the Orange Book.

II. The Court should not remand for claim construction because it would not change the result. Teva's proposed claim constructions merely posit the presence of some unidentified, non-specific "active drug." But none of Teva's proposed claim constructions would require albuterol sulfate to be present in any claim of any Asserted Patent. Accordingly, even under Teva's proposed claim constructions, the Asserted Patents would not qualify for listing in the Orange Book.

ARGUMENT

Properly construed, the Listing Statute requires a "drug product" patent to have at least one claim requiring the NDA drug substance to be present in the claimed invention. This construction best harmonizes the restrictive, product-specific language of the Listing Statute, the meaning of "claims" under black letter patent law, and the FDA's definition of "drug product" requiring the presence of the drug substance.

The plain language of the Listing Statute points to this construction. The Listing Statute does not broadly authorize listing of *any* "drug product" patent.

Instead, it authorizes listing a "drug product" patent only if that patent "claims the [NDA] drug." 21 U.S.C. § 355(b)(1)(A)(viii)(I). Further, the Listing Statute does not authorize listing a patent claiming *any* kind of component found in the NDA product. Instead, it conspicuously authorizes listing of only one kind of component patent, a "drug substance (active ingredient) patent." *Id*.

The legislative history of the Listing Statute also supports this interpretation of the Listing Statute. It shows congressional intent to curtail the listing of device component patents specifically. (*Infra* at 40-42.)

Requiring the presence of the NDA drug substance in the claimed invention of a "drug product" patent also squares with FDA's definition of "drug product." The FDA's definition of a "drug product" requires the presence of a drug substance in a drug product. Applying this definition to the Listing Statute, a patent does not claim a "drug product" if none of its claims require the drug substance to be present in the claimed invention.

None of the Asserted Patents qualify for the Orange Book under this proper interpretation of the Listing Statute. Teva offers the Asserted Patents as "drug product" patents, but none claims an invention that requires the presence of albuterol sulfate. Accordingly, none is a "drug product" patent that "claims the [NDA] drug" for which Teva submitted its NDA. None of the Asserted Patents even mentions albuterol sulfate.

Teva's contrary and expansive interpretation of the Listing Statute—that a patent "claims the drug" if any part of the NDA product would infringe the patent—is both erroneous and problematic. ***First***, Teva's interpretation strays from the controlling black letter patent law, which is that a patent "claims" an invention by "particularly pointing out and distinctly claiming what the applicant regards as its invention." 35 U.S.C. § 112. Along the way, Teva departs from this Court's precedent to erroneously equate *claiming* with *being infringed*. ***Second***, Teva's interpretation would render the "claims the drug" requirement superfluous in view of the separate "infringement" requirement in the Listing Statute, which already requires the NDA product to infringe the patent. ***Third***, Teva's interpretation ignores the FDA's definition of a "drug product," which requires the presence of a drug substance in a drug product. ***Fourth***, Teva's interpretation would open up the Orange Book to patents on *any aspect* of the NDA product *or any component* that happens to be found in the NDA product. This result contravenes the specific and restrictive authorization to list only one kind of drug component patent: a drug substance patent.

The restrictive nature of the Listing Statute makes sense in view of the powerful exclusionary rights bestowed on Orange Book patents, including *automatic* preliminary injunction just for asserting them, and *automatic* permanent injunction if patentee prevails. These powerful rights—which no other patents

carry—should not be bestowed liberally. This is especially so because FDA does not gatekeep or police the Orange Book. It only makes sense, then, that the Listing Statute was written and amended—and should be construed—to permit listing of drug product patents only if they are specific to the NDA product.

Requiring that a product patent be listable only if it requires the presence of the NDA drug substance in the invention is consistent with the language and purpose of the Listing Statute, and better serves the goals of Hatch-Waxman. It also provides a clear rule that will allow stakeholders to more confidently order their affairs when it comes to the listing of patents in the Orange Book.

Finally, no remand for claim construction is required to affirm. None of Teva's proposed constructions would require albuterol sulfate to be part of the claimed invention. Thus, even if adopted, Teva's proposed constructions would not qualify the Asserted Patents for listing in the Orange Book. The Court should affirm.

I. The Asserted Patents do not qualify for listing in the Orange Book.

A. To qualify for Orange Book listing, a "drug product" patent must require the NDA drug substance to be present in the claimed invention.

The correct interpretation of the Listing Statute is that a "drug product" patent must require the NDA drug substance to be present in the claimed invention. This inclusion in the claimed invention can be articulated as "particularly pointing

out and distinctly claiming," "mentioning," "reciting," "explicitly including," or the like. Such a requirement harmonizes the black letter meaning of "claims" in patent law, its usage in the OBTA itself, the specificity of the Listing Statute, the relevant legislative history, and FDA's express definition of "drug product," which requires the presence of the active ingredient.

The Listing Statute permits listing of a "drug product" patent[3] only if it "claims the drug for which the applicant submitted the application." 21 U.S.C. § 355(b)(1)(A)(viii)(I). Read in tandem, the "claims the drug" requirement and the "drug product" patent requirement impose a highly specific requirement, that a drug product patent must claim the specific NDA drug product at issue. This is precisely how the FDA has interpreted the Listing Statute. 21 C.F.R. § 314.53 ("[f]or patents that claim a drug product, the applicant must submit information *only on those patents that claim the drug product, as is defined in § 314.3, that is described in the pending or approved NDA*.") (emphasis added).[4]

Importantly, in its regulation implementing the Listing Statute, the FDA has invoked its definition of "drug product," which is "a finished dosage form . . . *that*

[3] The parties agree that a "drug product" patent is one that *claims* a "drug product." (Teva Br. at 50.)

[4] The FDA echoed this regulation in its comments on the listing requirements, explaining that in making a listing determination, "[t]he key factor is whether the patent being submitted *claims the finished dosage form of the approved drug product*." 68 Fed. Reg. 36,676, 36,680 (June 18, 2003) (emphasis added).

contains a drug substance, generally, but not necessarily, in association with one or more other ingredients." 21 C.F.R. § 314.3 (emphasis added).[5] This definition underscores in several ways the commonsense notion that a drug substance is a required part of a "drug product." First, according to the definition, a drug product "*contains a drug substance*." *Id*. (emphasis added). Second, the definition contrasts the mandatory nature of the drug substance requirement with the optional nature of "other ingredients," as the latter are "not necessarily" included in a drug product. *Id*. Third, the definition notes that a "drug product" is not just any dosage form, but a "*finished* dosage form." *Id*. (emphasis added). Finally, the definition indicates that a "drug product" is a kind of "dosage form," which the FDA also defines as containing the "active ingredient." 21 C.F.R. § 314.3 ("Dosage form is the physical manifestation *containing the active and inactive ingredients* that delivers a dose of the drug product.").[6]

The FDA definition of "drug product" is especially informative here, because the corresponding statutory language "drug product (formulation or composition) patents" came directly from the FDA's implementing regulation. That regulation—21 C.F.R. §314.53—has been in effect since at least 2003, and, as noted above, expressly invokes the FDA definition of "drug product." 68 Fed.

[5] The FDCA does not provide a definition of "drug product."
[6] The Listing Statute also equates the terms "drug substance" and "active ingredient." 21 U.S.C. § 355(b)(1)(A)(viii)(I).

Reg. 36,676, 36,703 (June 18, 2003). And indeed, the OBTA, which was enacted in 2021, was intended to "codify current regulations and practice regarding the types of patent . . . information listed in the Orange Book." H.R. Rep. No. 116-47 at 6 (2019). This suggests that in the Listing Statute, Congress used the phrase "drug product" as defined by FDA: to refer to a product that necessarily contains a drug substance.

Notably, *Teva itself* has argued that drug product patents must require the presence of the active ingredient to qualify for listing in the Orange Book, even under the less restrictive pre-OBTA Listing Statute:

> patents relating solely to 'physical manifestations,' such as delivery systems that do not contain the active ingredient, are *not* patents relating to finished dosage forms of the drug product described in the NDA. In other words, patents reciting such physical manifestations do not 'claim' 'the drug' and therefore should not be listed in the Orange Book.

Warner Chilcott (US), LLC v. Teva Pharms. USA, Inc., No. 18-1241 (Fed. Cir. May 15, 2018), ECF No. 50, Corrected Non-Confidential Joint Appendix at Appx5183-5204 (emphasis in original).

In short, because a "drug product" requires the presence of a drug substance in the product, a "drug product" *patent* must likewise require the presence of a drug substance in the claimed product. Further, because a drug product patent must

also claim the specific NDA drug, such a patent must, at a minimum, require the presence of the particular drug substance in the NDA product.[7]

This interpretation of the Listing Statute harmonizes the specific meaning of "claims" under black letter patent law, the specific and restrictive language of the Listing Statute, and its legislative history. Teva, by contrast, seeks a highly permissive interpretation of the Listing Statute that is contrary to the meaning of "claims," the Listing Statute, and its legislative history. As explained below, Teva's various arguments are misplaced.

1. The correct meaning of "claims" requires particularly pointing out and distinctly claiming the invention, not merely being infringed.

Under settled statutory patent law, a patent "claims" something by "particularly pointing out and distinctly claiming the subject matter which the inventor . . . regards as the invention." 35 U.S.C. § 112(b). This Court has already acknowledged and applied this as the "settled ordinary meaning of the term 'claims'…". *Hoechst-Roussel Pharms., Inc. v. Lehman*, 109 F.3d 756, 758-59 (Fed. Cir. 1997). Thus, a patent "claims" something by *particularly pointing out* and *distinctly* claiming it.

[7] To resolve the present dispute, the Court need not determine what other aspects of the NDA product (if any) a patent must require to qualify for listing as a drug product patent. It need only determine that at a minimum, such a patent must require the NDA drug substance to be present in the claimed invention.

As this Court has also explained, the *words of the claim* do the claiming. *Corning Glass Works v. Sumimoto Elec. U.S.A., Inc.*, 868 F.2d 1251, 1258 (Fed. Cir. 1989) (explaining that the "wordings of a claim describe and point out the invention by a series of limiting words or phrases," known as "limitations") (cleaned up). Thus, when determining what a patent "claims," the focus should be on what words are present in (or absent from) the claims.

Congress employed this usage in the OBTA itself. In the OBTA, Congress directed the GAO to submit data on claims in listed patents "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, 134 Stat. 4889, 4892 (Jan. 5, 2021). Clearly, Congress was using "claim" the same way it is defined in the patent statute: to refer to the affirmative limitations expressly recited in the claims.

The FDA, too, has embraced this patent law meaning of "claims." In 2002, FDA proposed a rule expressly requiring listing of "product by process" patents. 67 Fed. Reg. 65,448, 65,452 (Oct. 24, 2002). In support, the FDA explained that such patents "claim" a drug product precisely because their claims "must *particularly point out and distinctly claim* the product or genus of products for which patent protection is sought . . . ." *Id*. (emphasis added). The FDA later characterized this as follows: "a product-by-process patent *claims a product by*

describing or listing process steps to wholly or partially define the claimed product." 68 Fed. Reg. 36,676, 36,679 (June 18, 2003) (emphasis added).

This plain meaning of "claims" is also intuitive. Consider, for example, a patent with a single claim reciting "a brake assembly comprising a brake pad mounted to a metal disk." It would make sense to say that such a patent "claims" a particular kind of brake assembly. But it would not make sense to say that such a patent "claims" a 2024 Ford Bronco, even though the Bronco uses the claimed brake assembly.

The First and Second Circuits have also properly embraced this approach to determining what a patent "claims" under the Listing Statute. In *In re Lantus*, the First Circuit held that a patent claiming a device intended for use in an injector pen was not properly listed in the Orange Book for an insulin glargine injector pen, because the claims of the patent "do not mention the drug." *In re Lantus Direct Purchaser Antitrust Litig.*, 950 F.3d 1, 7-8 (1st Cir. 2020). Citing *In re Lantus*, the Second Circuit explained in *United Food* that under the Listing Statute, "a patent claim that fails to *explicitly include* the drug" does not "claim the drug." *United Food v. Takeda Pharm. Co. Ltd.*, 11 F.4th 118, 134-35 (2d Cir. 2021).

FDA commentary on the Listing Statute is also consistent with requiring a specific reference to the NDA drug substance in the claims of a drug product for it to be listable. In 1997, the FDA published Guidance for Industry in the form of

"Hatch-Waxman Letters" from 1985 and 1986, in which FDA twice explained that a drug product patent must explicitly "refer to" the NDA product. *See* 1985 Hatch-Waxman Letter at PDF p.4 of 4 (noting that "[a] patent that claims a drug, unlike a patent that claims a use, must **refer to** an approved drug product.") (emphasis added);[8] *see also* 1986 Hatch-Waxman Letter at PDF p.3 of 8 (noting that "NDA applicants should only file information on those patents that **refer to** an approved drug product.") (emphasis added).[9]

At its core, Teva's contrary interpretation is that if the NDA product would infringe a claim in the patent, then the patent necessarily "claims" the NDA product. (Teva Br. at 13-14, 21-25.) Amici have the same general interpretation. (Sanofi Br. at 12-21; AstraZeneca Br. at 3-11.) But this Court has already rejected such an approach, because conflating "claiming" with "being infringed" is contrary to patent law.

In *Hoechst*, this Court interpreted the phrase "a patent which claims a product," which appears in the patent term extension provision of the Hatch-Waxman Act. *Hoechst*, 109 F.3d at 758-60 (interpreting 35 U.S.C. § 156). There, the patentee offered essentially the same argument Teva does here, "that a patent 'claims' an FDA-approved product . . . if the FDA-approved product would

[8] Available at https://www.fda.gov/media/149035/download?attachment.
[9] Available at https://www.fda.gov/media/149030/download?attachment.

infringe a claim of that patent." *Id*. at 758. This Court rejected that argument. Citing the patent statute and the doctrine of equivalents, this Court explained that "the concept of a claim is different from the concept of infringement, and, as a result, the plain meaning of 'claims' is not the same as the plain meaning of infringement." *Id*. at 759. As the FDA itself has acknowledged, the reasoning in *Hoechst* also applies to the Listing Statute. 67 Fed. Reg. 65,448, 65,451 (Oct. 24, 2002) (discussing *Hoechst*, then noting that "[t]he court's reasoning and conclusion are equally applicable to patent listings.") Likewise, under the "reverse" doctrine of equivalents, even if a product falls within the literal scope of a claim, it does necessarily infringe that claim. *Graver Tank & Mfg. Co., Inc. v. Linde Air Prods. Co.*, 339 U.S. 605 (1950); *SRI Int'l v. Matsushita Electrical Corp. of America*, 775 F.2d 1107, 1118 (Fed. Cir. 1985).

Accordingly, under long-established doctrines of patent law, that which a patent "claims" is not defined merely by what infringes that patent. Teva's interpretation and suggestion—that what a patent "claims" is "effectively coterminous" with whatever products infringe that patent (Teva Br. at 21-22, n.7)—contradicts settled distinctions between what a patent "claims," on the one hand, and what might infringe that patent, on the other hand.

Teva also leans heavily on this Court's decision in *Apotex, Inc. v. Thompson*, 347 F.3d 1335 (Fed. Cir. 2003), but that decision did not change the plain meaning

of "claims" under the patent statute. Nor is *Apotex* controlling here, as Teva contends. (Teva Br. at 24-25.)

In *Apotex*, Apotex sued the FDA seeking to require FDA to de-list certain patents. *Apotex*, 347 F.3d at 1340. The district court dismissed, finding no cause of action existed against FDA to require de-listing. *Id*. at 1341. On appeal, this Court determined that the Federal Circuit (as opposed to a regional circuit) had jurisdiction because the question of whether a patent qualified for listing arose under an Act of Congress relating to patents. *Id*. at 1342-44. In doing so, this Court reasoned that the listing decision implicates an issue of patent law because it "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*. at 1343-44.

As an initial matter, this statement does not prove Teva's point. At most, this statement acknowledges the unremarkable proposition that—consistent with the infringement clause of the Listing Statute—one precondition for listing a patent in the Orange Book is that the NDA product must infringe that patent. But *Apotex* only states that such infringement is *necessary* for listing, not that it is *sufficient*.

In any event, the statements from *Apotex* on which Teva relies are dicta. The *Apotex* panel was not resolving a dispute over the proper interpretation of the Listing Statute, let alone the particular dispute presented in this appeal; it was merely explaining that the case arose under patent law, such that the Federal

Circuit, and not a regional circuit, had jurisdiction. *Id*. Second, having found jurisdiction, *id*. at 1344, the Court did not even evaluate (let alone decide) whether any given patent or category of patents qualified for listing. Instead, the Court merely held that the FDA was not required to adjudicate patent listing disputes. *Id*. at 1352.

Teva cites *Envirotech Corp. v. Al George, Inc.*, 730 F.2d 753, 759 (Fed. Cir. 1984) for the proposition that "a patent 'claims' a product if making, using, or selling that product would infringe the patent." (Teva Br. at 13.) But *Envirotech* says nothing of the sort. It does not address what it means for a patent to "claim" something. Instead, it merely notes that "[i]f the accused matter falls clearly within the terms of the claim, infringement is normally made out." *Envirotech*, 730 F.2d at 759.

Nor does *United Food* support Teva's interpretation of the Listing Statute. (Teva Br. at 16, 38-39.) There, the patent did not qualify for listing because it required a drug substance not present in the NDA product, and therefore the NDA product did not infringe the patent. *United Food*, 11 F.4th at 132. As explained above regarding *Apotex*, this only demonstrates that infringement by the NDA product is *necessary* to qualify for listing, not that infringement alone is *sufficient* for a "drug product" patent to satisfy the "claims the drug" requirement.

2. Teva's interpretation of "claims" contradicts the Listing Statute.

Teva's interpretation does not square with the structure and context of the Listing Statute. ***First***, Teva's interpretation cannot be correct because it would render the "claims the drug" requirement superfluous. There is a strong presumption against such an interpretation. *See, e.g., Facebook, Inc. v. Windy City Innovations, LLC*, 973 F.3d 1321, 1336 (Fed. Cir. 2020). Specifically, the first clause of the Listing Statute requires that each listed patent be one "for which a claim of patent infringement could reasonably be asserted if [an unauthorized] person…engaged in the manufacture, use, or sale of the [NDA] drug." 21 U.S.C. § 355(b)(1)(A)(viii). This "infringement" clause *already requires* a patent to read on the NDA product. Indeed, a claim of patent infringement could not "reasonably be asserted" against the manufacture of the NDA product unless the asserted patent "reads on" that product.[10]

Accordingly, the independent requirement that a listable product patent also "claims the [NDA] drug" must require more than merely showing that the NDA drug "reads on" the patent. This is also consistent with the plain meaning of "claims" discussed above, further indicating that a product patent only "claims the

[10] Teva does not address this problem, arguing against only the reverse proposition—that its interpretation of "claims the drug" does not render the infringement clause superfluous. (Teva Br. at 41-42; *see also* Sanofi Br. at 20.)

[NDA] drug" if at least one of its claims "particularly point[s] out and distinctly claim[s]" that NDA drug.

Second, Teva's interpretation is far more expansive than afforded by a fair reading of the Listing Statute. Under Teva's interpretation, a patent is listable if it claims *any component* found in the NDA product. (Teva Br. 43-44.) But the Listing Statute contains no provision authorizing the listing of patents claiming any or all kinds component found in the NDA product. To the contrary, the Listing Statute authorizes listing of only one type of component patent: a "drug substance (active ingredient) patent." 21 U.S.C. § 355(b)(1)(A)(viii)(I); 59 Fed. Reg. 50,338 at 50,347, 50,350, 50,361 (Oct. 3, 1994) (FDA identifying the drug substance as a "component" of the drug product).

Viewed in the context of the subsection in which the Listing Statute appears, it is clear that Congress did not intend the listing of any other kinds of drug component patents, let alone *all* other kinds, as Teva's interpretation would permit. The Listing Statute is part of a subsection of the FDCA listing eight categories of information and things that an applicant must submit with its NDA. 21 U.S.C. § 355(b)(1)(A)(i)-(viii). That list includes both "a full list of the articles used as components of [the NDA] drug," and "samples . . . of the articles used as components" of the NDA drug. 21 U.S.C. § 355(b)(1)(A)(ii) and (v).

Congress thus required NDA applicants to submit a full list and samples of *all* its NDA drug components, yet when it came to the final item in this same list—the Listing Statute itself—Congress did *not* authorize submission of *all kinds* of component patents. Instead, Congress authorized listing of only *one specific kind* of component patent: the "drug substance (active ingredient) patent." 21 U.S.C. § 355(b)(1)(A)(viii)(I).

This is doubly significant for purposes of construing the Listing Statute. It indicates that Congress purposefully excluded other kinds of component patents from listing in the Orange Book. *Syngenta Crop Protection, LLC*, 944 F.3d at 1361 ("Where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.") (quoting *Rodriguez v. U.S.*, 480 U.S. 522, 525 (1987)).

It also shows that Teva's interpretation would render the "drug substance" category superfluous. Indeed, if patents claiming any type of component found in the NDA product were listable as "drug product" patents, there would have been no need for the Listing Statute to specify "drug substance" patents as a listable category of patents. There is a strong presumption against interpretations that render statutory language superfluous. *See, e.g., Facebook, Inc. v. Windy City Innovations, LLC*, 973 F.3d 1321, 1336 (Fed. Cir. 2020); *Arlington Cent. Sch. Dist.*

Bd. of Educ. v. Murphy, 548 U.S. 291, 299 n.1 (2006). Teva has not overcome this presumption.

Third, the fallacy of Teva's interpretation is exposed by the text of the OBTA itself. As noted above, in the OBTA, Congress directed the GAO to submit data on claims in Orange Book patents "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." (*Supra* at 24-25; Orange Book Transparency Act of 2020, Pub. L. No. 116-290, 134 Stat. 4889, 4892 (Jan 5, 2021).) This directive would make no sense under Teva's proposed interpretation of "claims." Under Teva's interpretation, <u>all</u> "patents that 'claim' a device that is used for the delivery of the drug" would *necessarily* also "claim such device in combination with an active ingredient or formulation of that drug." Under Teva's interpretation, Congress nonsensically directed the GAO to provide data on a set of patents that (axiomatically, under Teva's interpretation) could not exist. Clearly, Congress did not use "claim" according to Teva's interpretation.

3. <u>Teva's remaining arguments lack merit.</u>

Teva first counters by arguing that if a drug product patent had to require the presence of the NDA drug substance, this would render "drug substance" patent category superfluous, because the drug product patent listing requirement would alone require the listing of all drug substance patents. (Teva Br. at 37, 53.) This is

incorrect, because the two categories of patents are distinct. A drug substance patent requires only the drug substance per se, whereas a drug product patent requires both the drug substance and some further aspect(s) of the drug product. Thus, authorizing listing of one type of patent does not expressly authorize listing of the other, even if both types of patents must require the presence of the drug substance.

Teva further counters by pointing to the broad general definition of "drug" as including components of a drug. (Teva Br. at 29-30; *see also* Sanofi Br. at 19-20.) But this general definition does not open up the Orange Book to patents on any kind of "component" that might be found in the NDA product. First, as discussed above, the Listing Statute conspicuously authorizes only *one* kind of component patent for listing: a drug substance patent. (*Supra* at 31-33.)

Second, as also discussed above, the Listing Statute does not merely require that a product patent claim *a* "drug." (*Supra* at 7, 11-13, 15.) It is far more specific than that, requiring a product patent to claim one specific drug, namely "the drug for which the applicant submitted the application." 21 U.S.C. § 355(b)(1)(A)(viii)(I). The general definition of "drug" cannot be divorced from this highly specific contextual language to loosen the Listing Requirements. As the FDA has acknowledged, the meaning of the term "drug" in the Listing Statute

"cannot be determined apart from its context." 68 Fed. Reg. 36,676, 36,681 (June 18, 2003).

Indeed, mechanically plugging the "component" aspect of the definition of "drug" into the statutory phrase "claims the drug for which the applicant submitted the application" creates a clear incongruity, because applicants do not submit their NDAs for approval of only a *component* of their proposed drug, but rather for approval of the *entirety* of their proposed drug product. This incongruity suggests that the "component" aspect of the general definition of "drug" does not apply. *See, e.g., Lawson v. Suwannee Fruit & S.S. Co.*, 336 U.S. 198, 206 (1949) (rejecting mechanical application of statutory definition because doing so would have created an incongruity). At a minimum, it shows that it cannot be used to open up the Listing Statute in the way Teva advocates.

Similarly, although the definition of "drug" ostensibly includes the entirety of a drug product, simply plugging that meaning of "drug" into the "claims the drug" requirement of the Listing Statute is both paradoxical as applied to a drug substance patent and redundant as applied to a drug product patent.

In view of these incongruities that arise from simply plugging any aspect of the definition of "drug" into the Listing Statute, its meaning in the Listing Statute must be determined according to its context. The simplest way to harmonize the "claims the drug" requirement with the rest of the Listing Statute is to construe the

term as requiring *specificity to the NDA product*. Thus, in the context of a drug substance patent, "claims the drug" requires claiming the specific NDA drug substance per se. And in the context of a drug product patent, "claims the drug" requires claiming the specific NDA product. Because a "drug product" must contain a drug substance, a claim to a specific NDA drug product must require, at a minimum, that the NDA drug substance be present in the claimed product.

* * * * *

Teva points to the FDA's prohibition against listing of intermediate and metabolite patents, arguing that "FDA needed to distinguish" those kinds of patents "because patents otherwise claiming components of an [NDA] product *are* listable in the Orange Book. (Teva Br. at 30 (emphasis in original).) This is a pure non-sequitur. As Teva itself points out, per FDA, intermediates and metabolites are not present in the NDA product, and thus are not components of the NDA product. (*Id*.) Excluding patents on non-components does not imply anything about what types of component patents should be included in the Orange Book. In any event, as noted above, the Listing Statute answers that question more directly by authorizing the listing of only one kind of component patent: a drug substance patent.[11]

[11] Nor does FDA's exclusion of certain types of patents imply that all component patents are listable. In declining to add to its list of excluded patents, the FDA has expressly cautioned against making such inferences. 68 Fed. Reg. 36,676, 36687

In any event, Teva's interpretation is especially problematic in the context of claims like those in the Asserted Patents that are directed to the device part of a drug-device combination product. As a matter of law under the FDCA, the FDA is prohibited from regulating as a "drug" anything that meets the statutory definition of a "device," even if that item also meets the definition of a "drug." *Genus Medical Techs. LLC v. FDA*, 994 F.3d 631, 644 (D.C. Cir. 2021). As is evident from *Genus Medical*, based on the interplay of these statutory definitions of "drug" and "device," it is the presence of an active ingredient in a "drug" that distinguishes a "drug" from a "device." *Id.* at 641.

Teva has studiously ignored this central holding of *Genus Medical* in every round of briefing below, and yet again in its opening brief on appeal. Sanofi's amicus brief ignores it, too. (Sanofi Br. at 3, 8, 15.) But the holding in *Genus Medical* cannot be ignored. Applying the logic of *Genus Medical* to the Listing Statute, if a patent claims only a "device," in part by not requiring the presence of an active ingredient, the FDA is *prohibited* by the FDCA from treating that patent as if it claims a "drug." Teva's interpretation cannot be correct, because it would permit precisely what the FDCA prohibits.

(June 18, 2003) ("We decline to revise the proposed rule to list every excluded type of patent as requested by some comments. Based on our experience, we believe that if we attempted to…specifically list all exclusions in the final rule, there would be disagreements over whether the examples are all-inclusive or whether other types of patents were excluded as well.).

To be sure, the FDA can and does regulate some drug-device combination products as drugs. Critically, however, it is the presence and activity of a drug substance in such products that leads the FDA to regulate a combination product as a drug rather than as a device. 21 U.S.C. § 353(g)(1)(C), (D). Regardless, a device retains its character and function as a device, even when incorporated into a drug-device combination product. 21 U.S.C. § 353(g)(4) (distinguishing between "drug constituent part" and "device constituent part" of a drug-device combination product); 21 C.F.R. § 3.2(k) (recognizing that drug-device combination products can have both a drug mode of action and a device mode of action).

Finally, the language of the Listing Statute itself suggests that a patent claiming only a device component of a drug-device combination product is not a "drug product (formulation or composition) patent." 21 U.S.C. § 355(b)(1)(A)(viii)(I). Although the FDCA and FDA regulations do not define "formulation" or "composition," they consistently use those terms to refer to the types and amounts of the *ingredients* of a drug product.[12] *See, e.g.*, 21 U.S.C. § 355(j)(4)(H) (providing that the FDA will approve an ANDA unless, among other things, "the *composition* of the drug is unsafe [to use] because of *the type or*

[12] Citing multiple pages of the Federal Register, Sanofi proposes that "compositions" "encompasses any patent that reads on a finished dosage form." (Sanofi Br. at 21 & n.13 (citing 59 Fed. Reg. 50,338, 50,339, 50,343-45, and 50361).) It is not clear what statements Sanofi is referring to. In any event, Sanofi's proposition does not appear to be supported by that citation.

quantity of inactive ingredients included or the manner in which the *inactive ingredients* are included") (emphases added); 21 C.F.R. § 314.127(a)(8)(i)(B) (same language); 21 C.F.R. § 314.127(a)(8)(ii)(A)(2)-(6) (referring to various changes relating to "inactive *ingredients*" as changes to the "*composition*" of a drug product) (emphases added); 21 C.F.R. § 314.70(b)(2)(i) (identifying changes to an approved NDA, including "changes in the qualitative or quantitative *formulation* of the drug product, *including inactive ingredients*…") (emphases added); 21 C.F.R. § 314.200(e)(2) (requiring certain submissions to include documentation "to establish the exact quantitative *formulation* of the drug (both active and inactive *ingredients*)…") (emphases added).[13] By contrast, as noted above, the FDCA refers a device component of a drug-device as a "device constituent part."

4. The Listing Statute should be narrowly construed in view of its legislative history.

The legislative history of the OBTA shows that the Listing Statute should be construed narrowly, especially with respect to device patents, and even specifically with respect to the Asserted Patents. It also reflects tacit congressional approval of the *In re Lantus* decision. The OBTA added the "drug substance" and "drug

[13] As noted below, the Senate Amendment of the OBTA shows that the "formulation or composition" parenthetical delimits what qualifies as a "drug product" patent, and is not merely illustrative. (*Infra* at 41.)

product" patent requirements, which did not appear in the prior version of the Listing Statute. (*Compare* H.R. Rep. No. 116-47 at 9-10 (2019) *with* Orange Book Transparency Act of 2020, Pub. L. No. 116-290, 134 Stat. 4889 at Section (b)(1)(A)(viii) (Jan. 5, 2021).)

As the Committee Report for the OBTA demonstrates, these requirements were introduced expressly to preclude Orange Book listing of the very type of device patents at issue here. Committee reports are a particularly authoritative source for interpreting a statute. *Garcia v. U.S.*, 469 U.S. 70, 76 (1984). Here, when the Committee Report set forth the "Background and Need for Legislation," it explained that:

> **some branded drug manufacturers. . . are submitting patents potentially for the purpose of blocking generic competition.**[3] . . . This legislation would help to ensure that the Orange Book is accurate and up-to-date, by specifying what information must be submitted to FDA and what information should be listed . . . .

H.R. Rep. No. 116-47 at 4 (2019) (emphasis added) (footnote in original).

To support the observation that some branded drug manufacturers may be submitting patents "for the purpose of blocking competition," in footnote 3, the Committee Report cited a 2018 article published in Nature Biotechnology. *Id*. That article analyzed the proliferation of device patents in the Orange Book for drug device combination products, including, most commonly, inhalers. (Appx1043-44 (reporting that "[t]he most common such products were inhalers . . ." and that

"market exclusivity extensions" from drug delivery device patents listed with the FDA were "particularly common among pens and inhalers.").) The supporting data for this article expressly included the Orange Book listing for ProAir.[14]

Further, in the wake of *In re Lantus*, the Senate not only passed on an opportunity to legislatively overrule that decision, it further tightened the "drug substance" and "drug product" requirements as illustrated here with strike through and underlining: "…claims the drug for which the applicant submitted the application and is a drug substance (~~including~~ active ingredient) patent or a drug product (~~including~~ formulation ~~and~~ or composition) patent." (*Compare* Appx1117 *with* Appx1179.) This amendment implies that the drug product patent requirement should be narrowly construed. It also suggests that in Congress's view, *In re Lantus* correctly held that patents claiming only device components of a drug-device combination product do not belong in the Orange Book. After all, Congress is presumed to be aware of the existing legal landscape when it passes legislation. *Miles v. Apex Marine Corp.*, 498 U.S. 19, 32 (1990).

[14] Appx1224 (citing row 7 of supporting data available at https://static-content.springer.com/esm/art%3A10.1038%2Fnbt.4078/MediaObjects/41587_2018_BFnbt4078_MOESM2_ESM.xlsx) (last accessed Aug. 29, 2024).

B. The Asserted Patents do not require the presence of albuterol sulfate in the claimed inventions.

It is undisputed that none of the Asserted Patents even mention albuterol sulfate. And it is undisputed that none of the Asserted Patents have any claim that requires the presence of albuterol sulfate in the claimed invention. Because the Asserted Patents do not require the NDA drug substance to be present in the claimed invention, they do not "claim" the NDA drug product, under the proper interpretation of the Listing Statute. Thus, none of the Asserted Patents qualify for listing as "drug product" patents, and they should be removed from the Orange Book.

In its argument, Teva tries to decouple the "claims the drug" requirement from the "drug product" patent requirement. (Teva Br. at 19-20, 49; compare sections I and II.) This deconstruction contravenes the plain text of the Listing Statute, under which a "drug product" patent must be one that "claims the [NDA] drug." It also contravenes the FDA implementing regulation that couples these requirements, stating that "[f]or patents that claim a drug product, the applicant must submit information *only on those patents that claim the drug product, as is defined in § 314.3, that is described in the pending or approved NDA"*. 21 C.F.R. § 314.53.

Teva argues that three of the Asserted Patents "expressly claim the *full* finished dosage form," because those patents have claims directed to an inhaler,

not just a dose counter. (Teva Br. at 52.) This argument misses the mark. FDA's own definitions require the active ingredient to be present in a "drug product" and a "dosage form." 21 C.F.R. § 314.3.[15] None of the claims in any of the Asserted Patents require the presence of albuterol sulfate, so none can particularly point out or distinctly claim the NDA "drug product" or the "finished dosage form" of the NDA.

C. Amneal's interpretation of the Listing Statute best aligns with the goals of the Hatch-Waxman Act.

Amneal's interpretation of the Listing Statute preserves the intended balance struck under the Hatch-Waxman Act. Listing a patent in the Orange Book immediately attaches to that patent at least two extraordinary rights that unlisted patents do not carry. First, it allows the NDA holder to trigger an *automatic* 30-month stay of final FDA approval of any would-be competitor products—effectively an automatic preliminary injunction during the first two and half years of the patent litigation. 21 U.S.C. § 355(j)(5)(B)(iii). Second, if the NDA holder prevails in the litigation on the listed patent, the remedy is an *automatic* injunction

[15] Pointing to an FDA guidance document, Teva asserts that the FDA has long classified metered dose inhalers (MDIs) and their dose counters as drugs. (Teva Br. at 15.) As to MDIs, Teva overlooks that, consistent with the FDA definition of "drug product" and "dosage form," the cited guidance document refers to MDIs as "containing a drug substance." (Appx1418.) As to dose counters, the cited document says essentially the opposite of what Teva asserts, that "dose counters frequently have been determined to be *device components* of combination products." (Appx1419 (emphasis added).)

preventing final FDA approval until the listed patent expires. 35 U.S.C. § 271(e)(4)(A).

The ability to get automatic preliminary and permanent injunctive relief is a powerful right unique to Orange Book patents. In normal patent litigation, a complete injunction barring a competitor from the market is neither guaranteed nor the norm. Rather, the patentee can only obtain injunctive relief if it makes the requisite showing under the *eBay* factors, a very high bar in many situations. *eBay Inc. v. MercExchange, LLC*, 547 U.S. 388 (2006).

Because Orange Book patents carry these powerful special rights, it makes sense for the Listing Statute to be restrictive, permitting listing of patents in the Orange Book only if they arose from the development efforts specific to *a given new drug*. As the FDA has recognized, "All of the benefits afforded NDA holders under the Hatch-Waxman Amendments, such as the 30-month stay, derive from obtaining our approval of a particular drug product." 68 Fed. Reg. 36,676, 36,681 (June 18, 2003). Requiring at least one claim of a listable drug product patent to require the presence of the NDA drug substance ensures that patents only acquire the special Orange Book rights if they actually relate to the development efforts that Hatch-Waxman actually sought to incentivize—those undertaken to develop the specific NDA product for which the patents are listed.

By contrast, automatically blocking competing medicines from market, based on a patent to *any* component found in the drug product, skews the Hatch-Waxman scales against one of its animating purposes: speeding access to affordable medicines. Under Teva's highly permissive reading of the Listing Statute, patents having nothing to do with the drug development efforts for a given product could be listed in the Orange Book, as long as the claimed invention, no matter how inconsequential, was found in some part of the NDA product. The OBTA was enacted specifically to curb the proliferation of such patent listings.

The Asserted Patents illustrate that kind of unwanted proliferation. Because the Asserted Patents are so wholly untethered from any particular NDA drug, they are listed in connection with at least one NDA product beyond ProAir having different active ingredients. (Appx310-11, Appx822, Appx825, Appx828, Appx831, Appx834, Appx837-38, Appx840-41, Appx844-45, Appx848-49.) One is listed in connection with 21 different products. (Appx1282.) Listing a given patent for more than one NDA product is not necessarily problematic. But requiring at least one claim that requires the presence of the active ingredient of each product helps to ensure that the development efforts leading to the patent were actually undertaken in connection with that NDA product.

Contrary to admonitions by Teva and Amici, (Teva Br. at 54-56; AstraZeneca Br. at 14-15; Sanofi Br. at 11), excluding patents from the Orange

Book does not prevent brand companies from enforcing them, nor does it thwart the goals of the Hatch-Waxman scheme. Brand companies are still permitted to assert unlisted patents, even in the context Hatch-Waxman litigation premised on properly-listed patents.[16] Regardless, if the brand prevails in litigation only on unlisted patents, they can still forestall generic entry, if the situation meets the standards for obtaining such injunctive relief. If not, the generic product should be permitted to enter the market, subject to available damages remedies, such as a reasonable royalty. This is consistent with the Hatch-Waxman goal of promoting generic competition. And it still rewards the patentee's investment in innovation in manner and degree commensurate with the equitable circumstances.

Teva's and Amici's policy arguments to the contrary are baseless and hyperbolic. First, Teva and Amici suggest that excluding patents from the Orange Book will hurt would-be ANDA filers by obscuring the patent landscape that they may have to contend with upon launch. (Teva Br. at 17-18, 54-56; Sanofi Br. at 4, 7, 11, 17-18, 25.) But various kinds of patents (e.g., process, packaging, and metabolite) have long been excluded from the Orange Book. And would-be ANDA filers have long been able to identify unlisted patents and assess the risks of being sued and of incurring infringement liability. *See, e.g.*, 68 Fed. Reg. 36,676, 36,685

[16] *See, e.g., Merck Sharp & Dohme Corp. v. Sandoz Inc.*, No. 12-cv-3289, 2013 WL 591976 (D.N.J. Feb. 14, 2013) (permitting unlisted patents to be asserted in Hatch-Waxman litigation alongside timely-listed patents).

(June 18, 2003) (FDA relying on comments that "no 'prudent generic company' would rely solely on the Orange Book listings to evaluate patent information for litigation exposure, particularly when all patents cannot be listed in the Orange Book.") Notably, Teva and Amici present no evidence of any scourge of unlisted patents being asserted upon launch of generic products.

Teva also suggests that Amneal's interpretation would "clog the courts" by increasing the risk of jury trials and injunctive proceedings, which Teva asserts is "contrary to the express purpose of Hatch-Waxman." (Teva Br. at 54-56.) And Sanofi intimates that Hatch-Waxman litigation is "injunction-free" litigation. (Sanofi Br. at 18.) But the Hatch-Waxman scheme expressly contemplates the use of preliminary injunctions for preventing launch and setting and resetting ANDA approval dates. 21 U.S.C. § 355(j)(5)(B)(iii)(IV). Indeed, the 30-month stay often expires during Hatch-Waxman litigations, leading to jury trials and preliminary injunction proceedings. *See, e.g., Warner Chilcott Lab'ys Ireland Ltd. v. Mylan Pharms. Inc.*, 451 F. App'x 935, 936 (Fed. Cir. 2011) (vacating the district court's preliminary injunction preventing the generic company from marketing its ANDA product); *Sciele Pharma Inc. v. Lupin Ltd.*, 684 F.3d 1253, 1256 (Fed. Cir. 2012) (vacating the district court's preliminary injunction preventing the generic company from marketing its ANDA product).

II. Claim construction is not required.

The Court should not remand for claim construction. Claim construction is not required, and in any event, none of Teva's proposed constructions would qualify the Asserted Patents for listing. Teva's demand for claim construction is really just another bid to run the clock for as long as possible on the 30-month stay that Teva should not have been able to obtain in the first place.

Claim construction is not required here. As explained above, to qualify for listing as a drug product patent that "claims the drug for which the applicant submitted the application," the patent must do *more* than simply be infringed by the NDA product—it must *particularly point out and distinctly claim* that NDA product. This is not a claim construction question where, as here, the claims on their face do not particularly point out the albuterol sulfate drug substance of the NDA product or require it to be present in the claimed invention.

Moreover, not even Teva's proposed constructions could change the result of this appeal. None of Teva's proposed constructions would require the presence of albuterol sulfate. Instead, the proposed constructions posit merely that the claims require some unspecified "active drug." (Teva Br. at 45-46.) Even if Teva prevails on such claim construction arguments, the Asserted Patents still would not require the presence of albuterol sulfate in the claimed inventions. Remanding for

claim construction would serve no legitimate purpose in the resolution of the question presented in this appeal. The Court should affirm.

CONCLUSION AND STATEMENT OF RELIEF SOUGHT

The district court's injunction ordering the Asserted Patents delisted should be affirmed, and the Court should lift its stay of that injunction.

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ADDENDUM

Section 505 of the Federal Food, Drug, and Cosmetic Act
21 U.S.C. § 355(b)(1)(A):

Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a). Such persons shall submit to the Secretary as part of the application—

(i) full reports of investigations which have been made to show whether such drug is safe for use and whether such drug is effective in use;
(ii) a full list of the articles used as components of such drug;
(iii) a full statement of the composition of such drug;
(iv) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug;
(v) such samples of such drug and of the articles used as components thereof as the Secretary may require;
(vi) specimens of the labeling proposed to be used for such drug;
(vii) any assessments required under section 355c of this title; and
(viii) the patent number and expiration date of each patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug, and that—

(I) claims the drug for which the applicant submitted the application and is a drug substance (active ingredient) patent or a drug product (formulation or composition) patent; or

(II) claims a method of using such drug for which approval is sought or has been granted in the application.

21 U.S.C. § 355(c)(2) [relevant excerpt]

Patent information that is not the type of patent information required by subsection (b)(1)(A)(viii) shall not be submitted under this paragraph.

21 U.S.C. § 321 (Definitions; generally)

(g)(1) The term "drug" means (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C).

(h)(1) The term "device" (except when used in paragraph (n) of this section and in sections 331(i), 343(f), 352(c), and 362(c) of this title) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—

> (A) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
> (B) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
> (C) intended to affect the structure or any function of the body of man or other animals, and
>
> which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The term "device" does not include software functions excluded pursuant to section 360j(o) of this title.

21 U.S.C. § 355(j)(5)(C)(ii)

Counterclaim to infringement action.

(I) In general

If an owner of the patent or the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or (c) on the ground 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 C.F.R. § 314.3(b)

Definitions

* * * * *

Dosage form is the physical manifestation containing the active and inactive ingredients that delivers a dose of the drug product. This includes such factors as:

(1) The physical appearance of the drug product;
(2) The physical form of the drug product prior to dispensing to the patient;
(3) The way the product is administered; and
(4) The design features that affect frequency of dosing.

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. § 314.53(b) Patents for which information must be submitted and patent for which information must not be submitted—

(1) General requirements [relevant excerpts; breaks added for readability]

An applicant described in paragraph (a) of this section must submit to its NDA the required information, on the required FDA declaration form, set forth in paragraph (c) of this section for each patent that claims the drug or a method of using the drug that is the subject of the NDA or amendment or supplement to it and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product.

For purposes of this part, such patents consist of drug substance (active ingredient) patents, drug product (formulation and composition) patents, and method-of-use patents.

For patents that claim the drug substance, the applicant must submit information only on those patents that claim the drug substance that is the subject of the pending or approved NDA or that claim a drug substance that is the same as the active ingredient that is the subject of the approved or pending NDA.

* * * * *

For patents that claim a drug product, the applicant must submit information only on those patents that claim the drug product, as is defined in § 314.3, that is described in the pending or approved NDA.

* * * * *

Process patents, patents claiming packaging, patents claiming metabolites, and patents claiming intermediates are not covered by this section, and information on these patents must not be submitted to FDA.

CERTIFICATE OF COMPLIANCE

This filing complies with the type-volume limitation of Federal Rule of Appellate Procedure 27(d)(2). This filing contains 11,445 words.

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). This brief has been prepared in a proportionally spaced typeface, 14-point Times New Roman font, using Microsoft Word 2016.

/s/ Steven A. Maddox
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CERTIFICATE OF SERVICE

I, Steven A. Maddox, hereby certify that on August 30, 2024 the foregoing document was electronically filed with the Court using the Court's CM/ECF systems, which will send notifications to all counsel registered to receive electronic notices.

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