Nos. 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 LTD., 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

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BRIEF OF AMICUS CURIAE ASTRAZENECA PHARMACEUTICALS LP IN SUPPORT OF NEITHER PARTY AND REVERSAL

Christopher N. Sipes
R. Jason Fowler
Michael K. Stern
Covington & Burling LLP
One CityCenter
850 Tenth Street NW
Washington, DC 20001-4956
(202) 662-6000

Counsel for Amicus Curiae AstraZeneca Pharmaceuticals LP

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF INTEREST

Case Number 24-1936

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

Filing Party/Entity AstraZeneca Pharmaceuticals LP

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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
AstraZeneca Pharmaceuticals LP		AstraZeneca PLC

☐ Additional pages attached

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INTEREST OF AMICUS CURIAE

AstraZeneca Pharmaceuticals LP is a global, science-led, patient-focused biopharmaceutical company devoted to the discovery, development, and commercialization of prescription medicines across various therapy areas including oncology, respiratory and immunology, cardiovascular and metabolic, vaccines, and rare diseases. AstraZeneca invests heavily in the research and development of these innovative new medicines, and has set a goal to deliver at least twenty new medicines before the end of the decade.

AstraZeneca supports the balance that the Hatch-Waxman Act seeks between creating incentives for innovation and enabling access to lower-cost generic drugs, and makes business decisions that rely on the application of the Hatch-Waxman Act in a predictable manner that aligns with the legislative purpose. As relevant here, AstraZeneca has a significant interest in ensuring that the patent-listing requirement is interpreted and applied consistent with the statutory framework and historical practice.[1]

INTRODUCTION

The patent-listing statute obligates the sponsor of a New Drug Application (NDA) to list in the Orange Book any patent that "claims the drug" in the NDA and

[1] AstraZeneca certifies that this brief was not authored in whole or part by any party's counsel, and that no person or entity other than AstraZeneca or its counsel contributed financially to its preparation or submission. Pursuant to Federal Rule of Appellate Procedure 29(a)(2) and the Practice Note to Federal Circuit Rule 29, all parties consented to the filing of this brief.

is a "drug product (formulation or composition) patent." In evaluating whether the patents at issue claimed the approved drug product, the district court asked whether the claims "particularly point[ed] out" or "particularly identifie[d]" the product, which the district court understood as "an albuterol sulfate HFA Inhalation Aerosol." And because the claims did not recite that product, the district court concluded that the patents had been improperly listed in the Orange Book. This was in error.

It is well-established that the term "claims" in the patent-listing statute carries its ordinary meaning from the patent law. Congress, the Food and Drug Administration (FDA), and even the district court here have recognized as much. It is equally well-established that the ordinary patent-law meaning of "claims" is "reads on." And unless closed to additional elements, a claim will read on, and thus "claim," a product if each of the limitations of the claim is found in the product, even if the product has additional elements not recited in the claim. The ordinary patent-law meaning of claim is not, as the district court appeared to believe, whether the claim particularly points out or identifies the active ingredient of the approved drug product or the approved drug product as a whole.

For the reasons discussed below, the Court should confirm that the term "claims" in the patent-listing statute has its ordinary patent-law meaning of "reads on," and, consequently, that a patent that "reads on" an approved drug product is subject to the patent-listing requirement, even if it does not mention, recite, or otherwise particularly point out the active ingredient or drug product as a whole.

ARGUMENT

I. In the context of patent listing, "claims" means "reads on."

A. The term "claims" in the Hatch-Waxman Act takes its ordinary patent-law meaning.

The Federal Food, Drug, and Cosmetic Act (FDCA) requires the sponsor of a New Drug Application (NDA) to identify patents that claim the drug for which the application was filed. Specifically, the sponsor "shall submit" to FDA:

> 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)(viii) (hereinafter, "the listing statute").[2] A central issue in this appeal is the meaning of the statutory requirement that a patent shall be submitted for listing in the Orange Book if it "claims the drug" for which the applicant submitted the NDA.

While the district court decision here erred in its application of patent law, it found "uncontroversial" that "the word 'claims' in the Listing Statute should be given its meaning under patent law." Appx37 (internal quotations omitted). Indeed, this

[2] All emphasis added unless otherwise noted.

Court has consistently held that the term "claims," as used throughout the Hatch-Waxman Act, should be given its ordinary patent-law meaning.

In *Hoechst-Roussel Pharmaceuticals v. Lehman*, 109 F.3d 756 (Fed. Cir. 1997)—which construed the statutory provision in 35 U.S.C. § 156 that a patent "which claims a product" may be eligible for extension—this Court held that "the term should be given its ordinary meaning from the patent law." *Id.* at 761. Similarly, in interpreting the statutorily created act of infringement arising from submission of an ANDA "for a drug claimed in a patent," 35 U.S.C. § 271(e)(2)(A), this Court held that "a district court's inquiry in a suit brought under § 271(e)(2) is the same as it is in any other infringement suit." *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997); *see also id.* at 1569 ("Under § 271(e)(2)(A), a court must determine whether, if the drug were approved based upon the ANDA, the manufacture, use, or sale of that drug would infringe the patent in the conventional sense."). And finally, in the context of the patent-listing requirements of 21 U.S.C. § 355(b)(1)—the very context at issue here—this Court has expressly held that "analyzing a patent in that context involves asking the question, 'what does the patent claim,' and that the answer should be derived using the tools and framework of patent law." *Jazz Pharms., Inc. v. Avadel CNS Pharms., LLC,* 60 F.4th 1373, 1379 (Fed. Cir. 2023).

That "claims" should take its ordinary patent-law meaning is compelled as well by the canons of statutory construction. "[I]t is a cardinal rule of statutory construction that, when Congress employs a term of art, it presumably knows and adopts the cluster of ideas that were attached to each borrowed word in the body of learning from which it was taken." *Fed. Aviation Admin. v. Cooper*, 566 U.S. 284, 292

(2012) (internal quotations omitted). The legislative history of the Hatch-Waxman Act shows that "Congress deliberately chose the term 'claims' because it already had a well-known meaning and usage in the patent law." *Hoechst*, 109 F.3d at 760. And whether a patent "claims the drug" for purposes of meeting the patent-listing criteria is a question of patent law; indeed, that is the basis under which this Court exercises jurisdiction over patent-listing challenges. *See Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1343–44 (Fed. Cir. 2003). The term "claims" in 21 U.S.C. § 355(b) is a term of art in patent law, and it thus should take its patent-law meaning and be interpreted and applied using the "body of learning" from patent law—i.e., this Court's long-settled caselaw concerning the meaning and application of what a patent claims.

B. The Orange Book Transparency Act confirms that the listing requirement should be given its ordinary patent-law meaning.

The listing statute reflects amendments to the FDCA made by Congress in the Orange Book Transparency Act of 2020 (OBTA). *See* Pub. L. No. 116-290, § 2, 134 Stat. 4889, 4889 (2021). As the district court recognized, the OBTA did not change the "key" listing requirement that the patent claim the drug for which the NDA was submitted. Appx35. Indeed, the OBTA incorporates essentially verbatim the relevant portions of the listing regulation, *compare* 21 U.S.C. § 355(b)(1)(A)(viii), *with* 21 C.F.R. § 314.53(b)(1), and the legislative history confirms that the OBTA was intended 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* FDA Report to Congress, *The Listing of Patent Information in the Orange Book*, at 1 (2022), *available at* https://perma.cc/H98Z-RDW7

(confirming that amendments "were generally consistent with [FDA's] existing regulations and practices").

FDA had long made clear that under its patent-listing regulations—the language of which was adopted as the statutory listing requirements of 21 U.S.C. § 355(b)(1) by the OBTA—the requirement that a patent claim the drug that is the subject of the NDA had its ordinary patent-law meaning. In promulgating the listing regulations, FDA adopted, for patent-listing purposes, this Court's holding in *Hoechst*, which as noted above had held that the term "claims" took its ordinary patent-law meaning. *See* FDA, *Proposed Rule*, 67 Fed. Reg. 65,448, 65,451 (Oct. 24, 2002). At essentially the same time, FDA explained its understanding of the statutory term "claims" governing patent listing in the context of a patent-listing challenge:

> "Claims" is a term of art grounded in patent law. The term 'claims' has been used in patent legislation since the Patent Act of 1836 to define the invention that an applicant believes is patentable. Since that time, the term has represented that portion of the specification that defines the patent owner's property rights in the invention.

Brief for Federal Appellees, *Apotex, Inc. v. Thompson*, No. 02-1295 (Fed. Cir.) (Sept. 23, 2002) at 5 n.3, 2002 WL 32941938 (quoting *Hoechst*, 109 F.3d at 759).

In codifying FDA's listing regulations in the OBTA, Congress is understood to have adopted the construction implemented by FDA. *See Commodity Futures Trading Comm'n v. Schor*, 478 U.S. 833, 846 (1986) ("Where, as here, 'Congress has not just kept its silence by refusing to overturn the administrative construction, but has ratified it with positive legislation,' we cannot but deem that construction virtually conclusive." (citing *Red Lion Broadcasting Co., Inc. v. FCC*, 395 U.S. 367,

380–91 (1969)); *see also Nat'l Cable Television Ass'n, v. FCC*, 914 F.2d 285, 289 (D.C. Cir. 1990) ("[I]n adopting the FCC's waiver rule, Congress codified the rule as it was interpreted by the Commission at the time of adoption."). Hence, Congress' codification of FDA's listing regulations in the OBTA further confirms that the term "claims" should be given its ordinary patent-law meaning, as FDA indicated in promulgating those regulations. Had Congress intended to depart from the patent-law meaning of "claims," it would have used different language or otherwise expressed an intention to depart from FDA's long-standing interpretation.

C. The ordinary patent-law meaning of "claims" is "reads on."

The ordinary meaning of "claims" from the patent law is well-established. Under this Court's precedent, it is black-letter law that a patent "claims" a product if the product falls within the express bounds of the patent claim—i.e., if "each of the claim limitations 'reads on,' or in other words is found in," the product. *Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1345 (Fed. Cir. 2002) (quoting *Baxter Healthcare Corp. v. Spectramed, Inc.*, 49 F.3d 1575, 1583 (Fed. Cir. 1995); *Amhil Enters. Ltd. v. Wawa, Inc.*, 81 F.3d 1554, 1562 (Fed. Cir. 1996)). Critically, the inclusion in the product of additional elements not specified in the patent claim does not place it outside the patent's claims (unless the claim itself is so limited). *See A.B. Dick Co. v. Burroughs Corp.*, 713 F.2d 700, 703 (Fed. Cir. 1983) ("It is fundamental that one cannot avoid infringement merely by adding elements if each element recited in the claims is found in the accused device.") (citing *Temco Elec. Motor Co. v. Apco Mfg. Co.*, 275 U.S. 319, 328 (1928)); *Stiftung v. Renishaw PLC*, 945 F.2d 1173,

1178 (Fed. Cir. 1991) (an open claim "will read on devices which add additional elements").

In patent law, to "claim" has no other meaning. Indeed, as this Court has previously stated in the context of a patent-listing dispute, "[u]nder [21 U.S.C. § 355], a patent must be listed if it contains a product claim ***that reads on the drug*** that is the subject of the NDA." *Apotex*, 347 F.3d at 1344. The Court went on to observe that "[t]he 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.* This too confirms that the listing analysis requires an ordinary "reads on" analysis under patent law, since it is well established that "[l]iteral infringement exists if each of the limitations of the asserted claim(s) read on, that is, are found in, the accused device." *Baxter Healthcare*, 49 F.3d at 1583.

D. The district court recognized that "claims" has its ordinary meaning but did not apply it.

The district court agreed that "the word 'claims' in the Listing Statute 'should be given its meaning under patent law.'" Appx37 (internal quotations omitted). Rather than determine whether the challenged claims read on the approved drug product, however, its analysis focused on whether the claims "particularly point out" or "particularly identif[y]" that product. *See, e.g.*, Appx37; Appx38. Specifically, the court asserted that "a patent claims ***only*** that subject matter that it has particularly pointed out as the invention, and no more," and it found the patents at issue failed to claim the drug because the NDA holder (Teva) had failed to identify "any claim in any of the Inhaler Patents [that] particularly identifies the subject of the NDA

application, an albuterol sulfate HFA Inhalation Aerosol, as the invention." Appx37-Appx38 (emphasis in original); *see also* Appx38 ("The Inhaler Patents do not contain any claims which claim 'albuterol sulfate HFA Inhalation Aerosol.'").

The district court's reasoning confuses the words of a claim, which serve to define the boundaries of the claimed subject matter (its "metes and bounds"), with the claimed subject matter itself. It has never been the case that the subject matter claimed in a patent is limited to just those embodiments expressly identified in the claim. A claim is not a laundry list, and "it is not necessary to embrace in the claims … all possible forms in which the claimed principle may be reduced to practice." *Smith v. Snow*, 294 U.S. 1, 11 (1935). Instead, subject matter falls within the claim if the claim reads on it, and it is enough "[i]f a claim reads merely on a part of an accused device." *SunTiger v. Sci. Rsch. Funding Grp.*, 189 F.3d 1327, 1336 (Fed. Cir. 1999); *see also A.B. Dick*, 713 F.2d at 703 ("[A] pencil structurally infringing a patent claim would not become noninfringing when incorporated into a complex machine that limits or controls what the pencil can write.").

The district court's reasoning—limiting claimed subject matter to embodiments "particularly identified" in the claim—would turn the fundamental principles of patent law upside down. Under that reasoning, a dependent patent claim that is expressly limited to aerosol inhalers containing albuterol sulfate would "claim the drug," whereas an independent claim directed to aerosol inhalers without limitation to any specific medicament (or to a broader category of medicaments) would not, since the independent claim would not expressly identify albuterol sulfate. However, it is settled law that a dependent claim cannot claim subject matter

outside the independent claim from which it depends. *See* 35 U.S.C. § 112(d) ("[A] claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed."); *see also Pfizer, Inc. v. Ranbaxy Laboratories Ltd.*, 457 F.3d 1284, 1292 (Fed. Cir. 2006). The principle that a dependent claim must not encompass subject matter outside the claim from which it depends is a threshold issue in the examination of patent applications by the Patent Office. *See* Manual of Patent Examining Procedure § 608.01(n). The district court's reasoning—which defines the claimed subject matter to be only that expressly recited in the claim—does violence to this principle by deeming a narrow dependent claim reciting the active ingredient or drug product as a whole to "claim" the drug, but not the broader independent claim from which it depends. Such a result cannot be squared with established patent law and the meaning of "claims."

The district court quoted at length from *César Castillo, Inc. v. Sanofi-Aventis U.S., LLC (In re Lantus Direct Purchaser Antitrust Litig.*), 950 F.3d 1 (1st Cir. 2020). In *Lantus*, which sounded in antitrust and not patent law, the First Circuit construed the statutory requirement that a patent claim the drug that is the subject of the NDA to mean that the patent claim must "mention" the drug: "It therefore follows that because the claims of the '864 patent do not mention the drug for which the sNDA was submitted, the patent does not 'claim the drug.'" *Id.* at 8. The court in *Lantus* provided no basis for departing from the ordinary patent-law meaning of "claims"; to the contrary, the court appeared unaware that that term had a well-established patent-law meaning. Tellingly, the *Lantus* court cited not a single decision of this Court. The *Lantus* court's reasoning is erroneous for the same reason as the district

court's decision here—it does not apply the ordinary ***patent-law*** meaning of "claims." A requirement that a patent claim "mention" an embodiment in order to claim it is no more consistent with patent law than a requirement that the claim "particularly identify" it.

II. If a drug-device combination product is the approved drug product, a patent that "reads on" that product is subject to the patent-listing requirement.

In 2003, FDA revised the listing regulation "to ensure that if the patent claims the ***drug product*** as defined in § 314.3, the patent must be submitted for listing." FDA, *Final Rule*, 68 Fed. Reg. 36,676, 36,680 (June 18, 2003). *See also* 21 C.F.R. § 314.53(b)(1).[3] The regulation defines "drug product," in relevant part, as "a finished ***dosage form***." 21 C.F.R. § 314.3(b). In turn, the regulation defines "dosage form" as "the physical manifestation containing the active and inactive ingredients that delivers a dose of the drug product[,]" which "includes such factors as: (1) [t]he physical appearance of the drug product; (2) [t]he physical form of the drug product prior to dispensing to the patient; (3) [t]he way the product is administered; and (4) [t]he design features that affect frequency of dosing." *Id.*

[3] FDA had long made clear that patents claiming the approved drug product should be submitted for listing in the Orange Book. In promulgating its first listing regulations in 1994, FDA stated "both the statute and its legislative history reveal that Congress intended the term 'drug' to mean 'drug product' rather than 'active ingredient' because NDA's are granted only for drug products and not for active ingredients." FDA, *Abbreviated New Drug Application Regulations; Patent and Exclusivity Provisions*, 59 Fed. Reg. 50,338, 50,346 (Oct. 3, 1994).

As FDA explained in the preamble to the final regulation, "dosage forms" include, among others, "metered aerosols, capsules, metered sprays, gels, and pre-filled drug delivery systems." 68 Fed. Reg. at 36,680. Notably, FDA contrasted patents claiming these dosage forms with "patents claiming a package or container," stating that "[p]atents must not be submitted for bottles or containers and other packaging, as these are not 'dosage forms.'" *Id.* "The key factor is whether the patent being submitted claims the finished dosage form of the approved drug product." *Id.*

The list of dosage forms that FDA described in the preamble includes items that FDA classifies as "combination products," such as pre-filled drug delivery systems and metered sprays. *See* FDA, Frequently Asked Questions about Combination Products, *available at* https://perma.cc/7ZWB-XXQF. A combination product may include, for example, a drug and device "that are physically, chemically, or otherwise combined or mixed and produced as a single entity[.]" 21 C.F.R. § 3.2(e)(1). A drug-device combination product may be approved in an NDA if FDA determines that the drug is "expected to make the greatest contribution to the overall intended therapeutic effects of the combination product." 21 U.S.C. § 353(g)(1)(C); *see generally* 21 U.S.C. § 353(g)(1); 21 C.F.R. part 3.

A drug-device combination product that is a "dosage form" is a "drug product" under FDA's regulations. Accordingly, a patent that "reads on" such a drug-device combination product that is approved in an NDA claims the approved drug product and must be submitted for listing in the Orange Book.

This conclusion is confirmed by the OBTA. In codifying FDA's listing regulations, Congress adopted FDA's determination that the category of patents

eligible for listing includes "a drug substance (active ingredient) patent or a drug product (formulation or composition) patent." 21 U.S.C. § 355(b)(1)(A)(viii)(I). The statutory language thus makes express that patents directed to the drug product (its formulation or composition), rather than the active ingredient, are eligible for listing in the Orange Book. In the case of a drug-device combination product, the approved drug product includes the device component. Moreover, as FDA explained, the category of "drug product (formulation or composition)" serves to distinguish patents covering the approved drug product from those covering packaging, emphasizing that "if the patent claims the drug product as defined in § 314.3, the patent must be submitted for listing." 68 Fed. Reg. at 36,680. Congress' adoption in the listing statute of FDA's regulatory language thus further confirms that patents claiming the approved drug product must be submitted for listing in the Orange Book.

III. Arbitrarily excluding device patents from the Orange Book would frustrate the purpose of the Hatch-Waxman Act.

"[T]he Hatch-Waxman Act creates a mechanism that allows for prompt judicial determination" before the approval and launch of a generic product "of whether the ANDA applicant's drug or method of using the drug infringes a valid patent." *Bayer Schering Pharma AG v. Lupin, Ltd.*, 676 F.3d 1316, 1318 (Fed. Cir. 2012). It does this, in part, by "requir[ing] an NDA applicant seeking FDA approval for a drug that enjoys patent protection to identify [in the Orange Book] every patent that claims the drug or a use of the drug that could reasonably be asserted in an infringement action." *Id.* The listing of patents in the Orange Book that claim the

approved drug product helps to ensure early, efficient, and orderly resolution of patent issues in a single litigation, before the generic drug manufacturer faces potential liability for an injunction and/or damages for marketing an infringing product. *See, e.g., Janssen Pharms., Inc. v. Tolmar, Inc.,* No. 21-cv-1784-WCB, 2024 WL 2972832, at *4 (D. Del. Jun. 13, 2024) ("An injunction governing the entire ANDA product is the expected result of a Hatch-Waxman trial in which the plaintiff prevails."); *see also Salix Pharms., Ltd. v. Norwich Pharms., Inc.*, No. 20-cv-430-RGA, 2023 WL 3496373, *2 (D. Del. May. 17, 2023) (denying request to modify final judgment that would result in what "would essentially be a second litigation"), *aff'd* 98 F.4th 1056 (Fed. Cir. 2024). As the FDA emphasized in promulgating its final listing regulations in 2003 (which were subsequently codified in the OBTA), timely listing of patents in the Orange Book "ensures prompt public notice that the NDA holder believes the patent claims the approved drug product and permits legal issues regarding these later-issued patents to be resolved as early as possible." 68 Fed. Reg. at 36,684.

Arbitrarily excluding device patents from the Orange Book because they are not limited to (and hence do not "particularly identify") the drug substance itself is contrary to, and would frustrate the purpose of, the Hatch-Waxman Act. Such an exclusion of device-directed patents from the Orange Book would not only contradict basic principles of patent law as discussed above, but would also prevent disputes over these patents from being litigated and potentially resolved before FDA approves a generic drug-device combination product.

Instead, the parties and courts would need to devote resources to both an initial, pre-approval round of litigation over drug patents and a later, post-approval round of litigation over patents directed to the device constituent of a combination product. The second round of litigation could be expected to include motions to preliminarily enjoin the launch or ongoing sales of generic products, delayed availability of generic products if their sponsors wait for patent disputes to be resolved before launching their products, and the potential for generic applicants to be liable for damages if they choose to launch at risk. *See* Pallavi Ail, *Teva, Sun To Pay $2.15 Billion To Settle Pfizer Patent Suit*, Reuters (June 25, 2013), *available at* 2013 WL 3196960 (noting settlement resulted from generic manufacturers' at-risk launch). Accordingly, the need to conduct a second, post-approval round of litigation over device-related patents for combination products would prevent the parties and courts from receiving the intended benefits of the pre-approval litigation procedure created by the Hatch-Waxman Act.

Indeed, as the leading trade association for generic manufacturers stated in a 2020 comment to FDA: "Information on those device-related patents that 'read on' the approved drug product and that is subsequently listed in the Orange Book would be beneficial to the generic drug industry by allowing the normal pre-approval patent resolution procedure to take place …." Association for Accessible Medicines (AAM) Comment at 16, Docket No. FDA-2020-N-1069-0013 (Aug. 31, 2020), *available at* https://perma.cc/DQ4H-PDSE.

Moreover, by limiting the listing of drug-product patents to those that particularly identify the active ingredient or approved drug product in the claim, the

district court's decision distorts the incentives to innovate underlying the statutory scheme. Under that decision, innovation in the development of new drug-product technology to deliver a specific active ingredient is afforded the protections of Orange Book listings (and generics receive the incentive of 180 days of exclusivity for bringing a patent challenge) when that innovation is incorporated into an approved drug product with that active ingredient. By contrast, innovation of new drug-product technology applicable to a broader class of active ingredients would not be afforded that protection (and the generics would be denied their incentive) when that more broadly applicable innovation is incorporated into an approved drug product. Nothing in the text or logic of the Hatch-Waxman Act justifies treating innovation limited to delivering a single active ingredient differently from innovation useful for delivering a broader class of active ingredients, when that innovation is incorporated into an approved drug-device combination product.

CONCLUSION

The Court should confirm that the term "claims" as used in the patent-listing statute has its ordinary patent-law meaning of "reads on," and therefore that a patent that "reads on" an approved drug product is subject to the patent-listing requirement, even if it does not mention or particularly point out the active ingredient.

Dated: August 6, 2024

Respectfully submitted,

/s/ Christopher N. Sipes

Christopher N. Sipes
R. Jason Fowler
Michael K. Stern
Covington & Burling LLP
One CityCenter
850 Tenth Street NW
Washington, DC 20001-4956
(202) 662-6000

Counsel for Amicus Curiae
AstraZeneca Pharmaceuticals LP

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

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATIONS

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