United States Court of Appeals for the Federal Circuit

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

v.

AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, AMNEAL IRELAND LTD., AMNEAL PHARMACEUTICALS LLC, AMNEAL PHARMACEUTICALS, INC.,
Defendants-Appellees

2024-1936

Appeal from the United States District Court for the District of New Jersey in No. 2:23-cv-20964-SRC-MAH, Judge Stanley R. Chesler.

Decided: December 20, 2024

WILLIAM M. JAY, Goodwin Procter LLP, Washington, DC, argued for plaintiffs-appellants. Also represented by JORDAN BOCK, CHRISTOPHER T. HOLDING, LOUIS LOBEL, THOMAS MCTIGUE, DARYL L. WIESEN, Boston, MA; NATASHA ELISE DAUGHTREY, Los Angeles, CA.

STEVEN ARTHUR MADDOX, Procopio, Washington, DC,

argued for defendants-appellees. Also represented by JEREMY JON EDWARDS, BRETT M. GARRISON.

Before PROST, TARANTO, and HUGHES, *Circuit Judges*.

PROST, *Circuit Judge*.

When a generic drugmaker applies to market a drug using the same active ingredient as a branded drug, the Food and Drug Administration ("FDA") cannot approve the generic company's application if the generic company's drug would infringe the brand-name manufacturer's patent. The FDA checks for whether the generic company's drug would infringe by looking at which patents the brand-name manufacturer listed in a publication called the Orange Book. If the brand-name manufacturer lists a non-expired patent that the brand-name manufacturer purports claims its drug, the FDA will not approve the generic company's application. Instead, simply by listing a patent as claiming a drug, the brand-name manufacturer can make the FDA withhold approval of the generic company's application for thirty months. The brand-name manufacturer's decision on which patents to list, then, can make the difference between the FDA granting the generic company's application and the FDA withholding approval.

In this case, Amneal[1] alleges that Teva[2] improperly listed patents in the Orange Book and delayed the entry of generic products onto the market. The district court agreed with Amneal and ordered Teva to delist its patents from

---

[1] Amneal Pharmaceuticals of New York, LLC, Amneal Ireland Limited, Amneal Pharmaceuticals LLC, and Amneal Pharmaceuticals, Inc.

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

the Orange Book on the ground "that the Inhaler Patents contain no claim for the active ingredient at issue, albuterol sulfate," but instead "are directed to components of a metered inhaler device." *Teva Branded Pharm. Prods. R&D, Inc. v. Amneal Pharms. of N.Y., LLC*, No. 23-20964, -- F. Supp. 3d --, 2024 WL 2923018, at *6, *7 (D.N.J. June 10, 2024) ("*Delisting Order*"). Teva appealed, and we stayed the district court's order pending our resolution of this case. We now lift the stay and affirm the district court's delisting order.

BACKGROUND

Congress has set up a complicated scheme regulating how the FDA approves applications to market drugs. Understanding whether Teva properly listed its patents in the Orange Book, a question presented by this appeal, requires an appreciation of where the Orange Book fits into this regime. We thus lay out the statutory and regulatory background before turning to the specifics of this case.

I

The Federal Food, Drug, and Cosmetic Act ("FDCA") governs the FDA's regulation of medical products. Before a company can market a drug, it must submit a new drug application ("NDA"). *See* 21 U.S.C. § 355(a), (b).[3] The NDA must include, among other things, full reports on investigations showing that the drug is safe and effective, a full description of the components and manufacturing process for the drug, the proposed labeling for the drug, and information on patents claiming the drug. *Id.* § 355(b)(1)(A). If the applicant shows that the drug described in the NDA is safe and effective, the FDA

[3] Although the parties refer to brands and generics, for precision we refer to the brand as the NDA holder/patent owner and the generic as the generic company or applicant.

approves the drug. *Id.* § 355(d). The applicant typically demonstrates safety and efficacy through time-consuming and expensive clinical trials.

This NDA process is the typical one for a new name drug containing a new active ingredient. Before 1984, a company seeking approval for a generic drug "that contains the same active ingredient[]" as the brand-name drug manufacturer had to file its own NDA with its own clinical trials, even though the FDA already determined that the active ingredient is safe and effective. *See United States v. Generix Drug Corp.*, 460 U.S. 453, 454, 461 (1983). Another aspect of the NDA process made approval of a generic drug costly and time-intensive before 1984: conducting experiments to prepare the materials for a generic-drug NDA often constituted infringement of one or more patents on the NDA holder's drug. *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 863 (Fed. Cir. 1984), *superseded by statute*, *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1358 (Fed. Cir. 2003).

In 1984, Congress enacted the Hatch-Waxman Act, which changed the landscape for generic approval in order to bring generic products to market faster. *See* Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585.

One major innovation in the Hatch-Waxman Act was the introduction of an abbreviated new drug application ("ANDA"). *See* 21 U.S.C. § 355(j). If a generic company wants to market a drug using the same active ingredient and label as a drug subject to an approved NDA, it no longer has to conduct separate clinical trials showing safety and efficacy; rather, if it submits an ANDA, the generic applicant only has to make a showing of bioequivalence. *Id.* § 355(j)(2)(A)(ii), (iv). Congress also created a safe harbor granting immunity from patent infringement "solely for uses reasonably related to the development and submission" of information to the FDA.

35 U.S.C. § 271(e)(1). This provision overturned our decision in *Roche*. In tandem, the ANDA and the safe harbor provisions helped "speed the introduction of low-cost generic drugs to market." *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405 (2012).

Clinical testing by NDA holders as well as FDA review time also resulted in the NDA holder's patent being issued well before the FDA approves an NDA, thus depriving the NDA holder of anything close to the statutory period of marketing exclusivity. The FDA often took longer to approve an NDA than the PTO took to approve a patent on the drug. Thus, Congress also included in the Hatch-Waxman Act a patent-term extension ("PTE") for patents claiming an FDA-approved product. *See* 35 U.S.C. § 156(a).

While these changes sped up the process for generic market entry, they did not deal with the litigation risk that could come from a generic company marketing a drug arguably covered by an NDA holder's patent. Congress thus decided to create "a new (and somewhat artificial) act of infringement" that would resolve patent disputes pre-approval. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990). Under this new provision, it is an act of infringement to submit an ANDA. 35 U.S.C. § 271(e)(2)(A). Upon a finding of infringement, one remedy is to set the effective date of approval no earlier than the date the brand's patent would expire. *Id.* § 271(e)(4)(A).

Congress did not just leave the approval timeline to the courts, though; it also prohibited the FDA from approving an ANDA that would infringe a patent. The FDA decides whether a generic drug would infringe a patent by looking at the Orange Book,[4] the linchpin of this entire scheme.

---

[4] The full name of this publication is Approved Drug Products with Therapeutic Equivalence Evaluations.

When an NDA holder that owns a patent submits an NDA, it must submit information on "the patent number and expiration date of each patent" meeting several requirements. 21 U.S.C. § 355(b)(1)(A)(viii). When the Hatch-Waxman Act was enacted, this listing provision required that "[t]he applicant shall file with the application the patent number and the expiration date of any patent which *claims the drug for which the applicant submitted the application* or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." Hatch-Waxman Act, sec. 102(a)(1), § 505(b), 98 Stat. at 1592 (emphasis added).

When a generic company submits an ANDA, it must make certifications about the patents that the patent owner listed on its NDA drug product. For patents that the NDA holder asserts claim the drug, the generic applicant makes one of four certifications. *See* 21 U.S.C. § 355(j)(2)(A)(vii).[5] The first, called a paragraph I certification, is when "such patent information has not been filed." *Id.* § 355(j)(2)(A)(vii)(I). The second, called a paragraph II certification, is when "such patent has expired." *Id.* § 355(j)(2)(A)(vii)(II). The third, called a paragraph III certification, contains "the date on which such patent will expire." *Id.* § 355(j)(2)(A)(vii)(III). And the fourth, called a paragraph IV certification, certifies "that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." *Id.* § 355(j)(2)(A)(vii)(IV).

---

[5] There are other statements a generic applicant can make about patents claiming methods of using the drug, called section viii statements. *See* 21 U.S.C. § 355(j)(2)(A)(viii); *Caraco*, 566 U.S. at 406. We do not discuss them here.

Which certification a generic applicant makes determines when the FDA may approve the generic applicant's ANDA. If a generic applicant makes a paragraph I or II certification, "the approval may be made effective immediately," assuming the FDA is otherwise ready to approve the generic's ANDA. *Id.* § 355(j)(5)(B)(i). For a paragraph III certification, the FDA will not approve the ANDA until the relevant patent expires. *Id.* § 355(j)(5)(B)(ii).

A paragraph IV certification leads to a much more complicated path. After the generic applicant sends the patent owner a paragraph IV notice, the patent owner has forty-five days to decide whether to file an infringement suit. *Id.* § 355(j)(5)(B)(iii). If the patent owner sues the generic company for patent infringement within forty-five days of receiving the notice, "the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice" (subject to various exceptions). *Id.* If the patent owner does not sue within forty-five days, "the approval shall be made effective immediately." *Id.*

As the foregoing suggests, whether the FDA approves an ANDA immediately or in thirty months depends on which, if any, patents the NDA holder lists. If the NDA holder does not list a patent, the generic applicant can file a paragraph I certification, and approval can be effective immediately. If, however, the NDA holder lists a patent that has not expired and that the NDA holder purports claims the drug, the generic applicant has to file a paragraph IV certification, which delays approval for thirty months if the patent owner sues for infringement. This regime works as intended only if the NDA holder lists those patents required by the listing provision and no more.

The attractiveness of the thirty-month stay might arguably provide an NDA holder significant incentives to improperly list patents in the Orange Book as purporting

to claim the drug, even if they do not actually claim the drug. And this concern is not illusory. "In the late 1990's, evidence mounted that some brands were exploiting this statutory scheme to prevent or delay the marketing of generic drugs" with the "submission of inaccurate patent information to the FDA." *Caraco*, 566 U.S. at 408.

So what happens if the NDA holder does submit inaccurate patent information? The FDA does not police this process, as it has long taken the position that it lacks patent-law expertise and thus cannot determine whether the patents that a patent owner lists in the Orange Book are properly included. Abbreviated New Drug Application Regulations; Patent and Exclusivity Provisions, 59 Fed. Reg. 50,338, 50,345 (Oct. 3, 1994) ("FDA does not have the resources or the expertise to review patent information for its accuracy and relevance to an NDA."). Thus, it effectively plays only a "ministerial" role and does not substantively review patents before publishing them in the Orange Book. Applications for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug Is Invalid or Will Not Be Infringed, 68 Fed. Reg. 36,676, 36,683 (June 18, 2003). Several courts have concluded that the FDA's position is a reasonable understanding of the statutory framework. *See Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1347–50 (Fed. Cir. 2003); *aaiPharma Inc. v. Thompson*, 296 F.3d 227, 238–43 (4th Cir. 2002). Certain generic companies, in the face of no help from the FDA, tried another argument—that the FDCA provides an implied cause of action to delist an improperly listed patent. We threw cold water on that position and rejected it in *Mylan Pharmaceuticals, Inc. v. Thompson*, 268 F.3d 1323, 1332 (Fed. Cir. 2001), *superseded by statute*, *Caraco*, 566 U.S. at 408. The state of play was thus that there was no way to force an NDA holder to remove inappropriately listed patents.

In 2003, Congress provided a partial fix regarding this matter. If the generic company provides the NDA holder notice of a paragraph IV certification, and if the NDA holder sues for infringement within forty-five days, Congress has authorized the generic company to bring a counterclaim that can require the NDA holder to fix its listed patent information in the Orange Book. *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, sec. 1101(a), § 505(j), 117 Stat. 2066, 2452. The counterclaim provision states:

> 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 U.S.C. § 355(j)(5)(C)(ii)(I) (emphasis added). A generic company cannot seek a delisting order "other than [with] a counterclaim described in subclause (I)." *Id.* § 355(j)(5)(C)(ii)(II). This counterclaim is a limited but potent tool. If the NDA holder lists patents, if the generic company files a paragraph IV certification, and if the NDA holder sues for infringement, the counterclaim can make

the difference between a thirty-month stay in approval or immediate approval.[6]

Adding the counterclaim was not, however, Congress's last word addressing which patents should be listed in the Orange Book. In 2021, Congress amended the listing provision in the Orange Book Transparency Act ("OBTA"), Pub. L. No. 116-290, 134 Stat. 4889 (2021). In so doing, Congress observed that "some branded drug manufacturers may choose not to submit every patent on a product to the FDA, and others are submitting patents potentially for the purpose of blocking generic competition." H.R. Rep. No. 116-47, at 4 (2019).

Before the OBTA, the Hatch-Waxman Act required an NDA holder to file "the patent number and the expiration date of any patent which *claims the drug for which the applicant submitted the application* or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." Hatch-Waxman Act, sec. 102(a)(1), § 505(b), 98 Stat. at 1592 (emphasis added). In the OBTA, among other changes, Congress amended the listing provision to further specify the class of patents that an NDA holder must list. The amended listing provision, with emphasis indicating the language Congress added in the OBTA, requires that the NDA holder list:

> the patent number and expiration date of each patent for which a claim of patent infringement could reasonably be asserted if a person not

---

[6] As described above, this immediate approval happens either if the generic company makes a paragraph I or paragraph II certification or if the NDA holder does not sue after the generic company makes a paragraph IV certification.

> 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) (emphasis added). The OBTA also added language specifying that patent information on patents other than the ones specified above "shall not be submitted." *Id.* § 355(c)(2). In other words, the amended language sets both a floor and a ceiling for what patents an NDA holder must list.

Congress adopted this language to "codify current [FDA] 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. The regulatory provisions that Congress referenced reflect that, since 2003, the FDA has interpreted the class of patents that claim the drug for which the applicant submitted the application to "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)(1). The FDA defines "drug substance" to mean "an active ingredient," and it defines "drug product" to mean "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(b).

II

We now turn to the facts of this case. In order, we discuss Teva's NDA for its drug, Amneal's ANDA and paragraph IV notice, and the district court's delisting order.

A

The NDA product for which Teva listed the patents Amneal sought to delist is the ProAir® HFA Inhalation Aerosol, described in NDA No. 021457, which was approved on October 29, 2004. It "provides for the use of albuterol sulfate HFA Inhalation Aerosol for the treatment or prevention of bronchospasm with reversible obstructive airway disease in adults and children 12 years of age or older." J.A. 352. The ProAir® HFA combines albuterol sulfate (the active ingredient) with a propellant, ethanol, and an inhaler device to administer the drug. J.A. 649.[7] Per the approved label, each actuation (or press) of the inhaler "delivers 108 mcg of albuterol sulfate from the actuator mouthpiece (equivalent to 90 mcg of albuterol base)." J.A. 642. The albuterol sulfate is supplied in a canister containing 200 doses. J.A. 642. In the approved form, the ProAir® HFA "contains a microcrystalline suspension of albuterol sulfate in propellant HFA-134a (1,1,1,2-tetrafluoroethane) and ethanol." J.A. 649. "The pharmacologic effects of albuterol sulfate are attributable to activation of beta$_2$-adrenergic receptors on airway smooth muscle." J.A. 649.

Although the FDA approved Teva's ProAir® HFA as a drug, the ProAir® HFA contains both drug and device components (the device components being the physical machinery of the inhaler). The FDA approved the ProAir® HFA as a drug, as it does for all metered-dose inhalers, because the primary mode of therapeutic action comes from the active ingredient—here, albuterol sulfate. *See* J.A. 1052 (FDA guidance stating that "Metered Dose Inhalers and Actuators are reviewed in the Center for Drug Evaluation and Research (CDER)").

---

[7] Albuterol sulfate is called salbutamol sulfate in other countries. J.A. 649.

Teva lists nine non-expired patents in the Orange Book for its ProAir® HFA. Five are relevant here: U.S. Patent Nos. 8,132,712 ("the '712 patent"), 9,463,289 ("the '289 patent"), 9,808,587 ("the '587 patent"), 10,561,808 ("the '808 patent"), and 11,395,889 ("the '889 patent"). They expire in 2028, 2031, or 2032. J.A. 810.

These patents are similar but not identical in claimed subject matter. The '712 patent relates to "[a] metered dose inhaler dose counter." '712 patent Abstract. A dose counter lets a user know "how many doses remain" in the inhaler's canister. *Id.* at col. 2 l. 34. The '712 patent discusses problems with existing dose counters, including that existing ones undercount doses used, which "can lead to a patient believing that there are more doses left within the inhaler than there actually are." *Id.* at col. 5 ll. 8–9. The other patents also relate to dose counters. The '289 patent discusses solutions to the problem opposite of the one addressed in the '712 patent—of the dose counter "count[ing] a dose when the canister has not fired." '289 patent col. 2 ll. 20–21. The '289 patent discloses dose-counter configurations and methods of assembly that purport to solve this problem. The '587, '808, and '889 patents have substantially the same specification as the '289 patent.

These patents relate to improvements in the device parts of inhalers—specifically, the dose counter—although their specifications make some reference to active ingredients being used alongside the dose counter. The '289 patent, for example, discusses "a medicament-containing pressurised canister containing a mixture of active drug and propellant," but only in the background section of the patent. *Id.* at col. 1 ll. 27–29. The '712 patent has more specific references to active drugs. In the detailed description of the invention, it discusses the presence of "a medicament in the form of an aerosol" in its inhaler. '712 patent col. 8 ll. 49–50. The specification mentions several classes of medicaments, including anti-allergic agents,

anti-inflammatory steroids, bronchodilators, and anticholinergic agents. *Id.* at col. 8 ll. 57–67. One specifically mentioned is a beta$_2$-agonist by the name of salbutamol, the international name for albuterol. *Id.* at col. 8 l. 62.

The claims in these patents focus on the device components of the inhaler—specifically, the dose counter and the inhaler canister. One example of the claims in these patents is claim 1 of the '289 patent. It recites:

> 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.

'289 patent claim 1. Claim 1 of the '712 patent similarly recites a collection of physical components that are part of an inhaler. Claim 16, which depends from claim 1, recites "[a] metered dose inhaler comprising a medicament canister, an actuator body for receiving the canister and having a medicament delivery outlet, and the dose counter as claimed in claim 1." '712 patent claim 16. None of the claims in the five asserted patents explicitly require the presence of an active drug, let alone any specific active drug.

B

Amneal filed an ANDA seeking approval to market a generic version of Teva's ProAir® HFA that uses the same active ingredient. Because Teva listed a number of patents in the Orange Book as claiming its ProAir® HFA, Amneal filed a paragraph IV certification asserting that it did not infringe the nine patents listed for Teva's ProAir® HFA. Amneal sent notice of its paragraph IV certification to Teva on August 24, 2023. Teva sued for infringement of six of those patents, and it subsequently amended its complaint to sue for infringement of only the five patents identified above. J.A. 56.

Amneal filed antitrust counterclaims, counterclaims for declaratory judgment of noninfringement and invalidity, and counterclaims seeking an order requiring Teva to delist the five patents that it asserted against Amneal. Amneal alleges that Teva's infringement suit "triggered a 30-month stay of final FDA approval of Amneal's ANDA." J.A. 298 ¶ 23. Further, it alleges that, had Teva not listed the five asserted patents in the Orange Book, Amneal would have filed a paragraph I certification and no 30-month stay would be imposed. J.A. 313 ¶ 102.

C

Teva moved to dismiss Amneal's antitrust and delisting counterclaims. Amneal cross-moved for a motion for

judgment on the pleadings on the ground that Teva improperly listed the asserted patents. The district court denied Teva's motion, granted Amneal's motion, and ordered Teva to delist the five asserted patents. The other counterclaims and Teva's infringement claims remain pending before the district court.

The district court concluded that Teva's patents "do not claim the drug for which the applicant submitted the application" and thus ordered Teva to delist its patents from the Orange Book. *Delisting Order*, 2024 WL 2923018, at *6, *9. The district court based its conclusion on the fact that Teva's patents "contain no claim for the active ingredient at issue, albuterol sulfate." *Id.* Rather, the district court concluded that the patents "are directed to components of a metered inhaler device, but do not claim or even mention albuterol sulfate or the ProAir® HFA." *Id.* at *7.

In reaching its conclusion, the district court rejected two arguments from Teva. The first was Teva's argument that "a patent 'claims' a product if the patent would be infringed by the product." *Id.* Rather, the district court concluded that "a patent claims *only* that subject matter that it has particularly pointed out as the invention, and no more"—which "is inconsistent with Teva's contention that a patent claims all products that are infringing." *Id.* (emphasis in original). The second was Teva's argument that, because the five patents "claim articles intended for use as a component of the ProAir® HFA (albuterol sulfate) Inhalation Aerosol," the patents were properly listed. *Id.* at *8. The district court concluded that Teva's argument failed to account for the statutory phrase "for which the applicant submitted the application," which required the claim to include albuterol sulfate. *Id.*; 21 U.S.C. § 355(b)(1)(A)(viii)(I).

Teva timely appealed the district court's interlocutory delisting order, and we have jurisdiction under 28 U.S.C.

§ 1292(a)(1) and (c)(1). Shortly after Teva filed its appeal, we issued a stay of the district court's order pending our review. ECF No. 29.

DISCUSSION

Statutory interpretation is an issue of law that we review de novo. *Cal. Institute of Tech. v. Broadcom Ltd.*, 25 F.4th 976, 985 (Fed. Cir. 2022). "In statutory construction, we begin 'with the language of the statute.'" *Kingdomware Techs., Inc. v. United States*, 579 U.S. 162, 171 (2016) (quoting *Barnhart v. Sigmon Coal Co.*, 534 U.S. 438, 450 (2002)). In doing so, we focus on "the language itself, the specific context in which that language is used, and the broader context of the statute as a whole." *Caraco*, 566 U.S. at 412 (2012) (quoting *Robinson v. Shell Oil Co.*, 519 U.S. 337, 341 (1997)). And we remain mindful that, in resolving disputes about the meaning of the text, "[u]ltimately, context determines meaning." *Johnson v. United States*, 559 U.S. 133, 139 (2010). To this end, we evaluate the meaning of the words in a statute "with a view to their place in the overall statutory scheme." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000) (quoting *Davis v. Mich. Dep't of Treasury*, 489 U.S. 803, 809 (1989)).

In sum, as described in more detail below, Teva argues that the district court erred by interpreting the listing provision to permit the listing of only a small class of patents claiming at least the active ingredient. Rather, Teva argues on appeal, as it did before the district court, that a patent can (and indeed must) be listed in the Orange Book if the claimed invention is found in any part of its NDA product. On these facts, Teva's argument goes as follows: Teva's ProAir® HFA metered-dose inhaler, the approved NDA product in this case, has various features including an active ingredient, a dose counter, and a canister (which Amneal does not dispute). Teva's patents at issue here have claims to the dose-counter and canister

parts of a metered-dose inhaler. Since Teva's ProAir® HFA has features claimed by these patents—the dose counter and canister—Teva's argument is that it properly listed its patents in the Orange Book.

To support this position, Teva makes two key interpretive moves. First, in the bulk of its argument on appeal, Teva asserts that a patent "claims the drug" if the claim reads on the approved drug—in other words, if the NDA drug product infringes that claim. If claims means infringes, as Teva contends, then it properly listed its patents for a simple reason: its claims for a dose counter and for a canister read on the ProAir® HFA. Second, Teva relies on the FDCA's broad definition of the word "drug" to argue that any component of an article that can treat disease meets the statutory definition of a "drug." If Teva is right about its interpretation of "drug," then Teva's patents "claim the drug," as they claim components of the ProAir® HFA—the dose counter and canister.

As we explain below, we reject Teva's interpretation as allowing for the listing of far more patents than Congress has indicated. In doing so, we first reject Teva's argument that a patent claims the drug if it reads on the approved drug. Instead, a patent claims the drug when it particularly points out and distinctly claims the drug as the invention. We then reject Teva's argument that a patent claiming any component of a drug is listable. Instead, to qualify for listing, a patent must claim at least what made the product approvable as a drug in the first place—its active ingredient. In other words, Teva cannot list its patents just because they claim the dose-counter and canister parts of the ProAir® HFA.

Teva also argues that, even if we reject its statutory arguments, we must remand for the district court to construe the claims. We also reject this argument. Adopting Teva's proposed construction, we still conclude

that Teva's patents do not qualify for listing because they do not claim the active ingredient.

We address each issue in turn—first, rejecting Teva's argument that "claims" means "reads on"; second, explaining why a listable patent is one that claims at least the active ingredient in the approved drug; and third, explaining why the district court properly ordered these specific patents to be delisted.

I

We start by rejecting Teva's interpretation of the word "claims" in the listing and counterclaim/delisting provisions.[8] Teva argues that "[t]he scope of what a patent 'claims' is effectively coterminous with the products that infringe a patent." Appellants' Br. 21. This argument, which comprises the bulk of Teva's briefing on appeal, is defective.

The most identifiable problem with Teva's position is that the listing provision identifies infringing and claiming as two distinct requirements. Teva must list "the patent number and expiration date of each patent for which a claim of patent infringement could reasonably be asserted" *and* that "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." 21 U.S.C. § 355(b)(1)(A)(viii), (I). When interpreting a statute, we are "obliged to give effect, if possible, to every word Congress used." *Reiter v. Sonotone Corp.*, 442 U.S. 330, 339 (1979). Accepting Teva's

---

[8] Although the counterclaim provides a mechanism to "correct or delete the patent information" in the Orange Book, 21 U.S.C. § 355(j)(5)(C)(ii)(I), this appeal addresses only the "delete" portion of the counterclaim. We refer to this portion of the counterclaim as the delisting provision in the remainder of our analysis.

interpretation would create a stunning example of statutory redundancy. If we read claiming to be "effectively coterminous" with infringing, Congress would have, in effect, added a separate requirement to the listing provision that would have essentially no meaning. The more natural reading is that, in order to be listed, a patent must both claim the drug and be infringed by the NDA product. We "reject[] an interpretation of the statute that would render an entire subparagraph meaningless." *Nat'l Assn of Mfs. v. Dep't of Defense*, 583 U.S. 109, 128 (2018).

Still, Teva insists that the specialized patent-law meanings of claiming and infringement compel us to adopt its interpretation. We disagree and view the Patent Act and our cases as supporting the opposite interpretation. While Teva is correct that the words claim and infringe have a meaning "peculiar to patent law," *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 374 (1996), the "substantial body of law" illuminating these two terms confirms that they have distinct meanings, *Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc.*, 586 U.S. 123, 130 (2019).

We begin with the statutory text. A claim is a numbered paragraph at the end of the patent document that "particularly point[s] out and distinctly claim[s] the subject matter which the inventor or a joint inventor regards as the invention." 35 U.S.C. § 112(b); *see also Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1258 (Fed. Cir. 1989). And that invention is what is described in the specification, which "contain[s] a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same." 35 U.S.C. § 112(a). When the claims and specification are read together, then, the claims "define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415

F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (cleaned up). This is why the claims are "of primary importance, in the effort to ascertain precisely what it is that is patented." *Merrill v. Yeomans*, 94 U.S. 568, 570 (1876). In short, the claims identify the invention. Infringement is a distinct concept with a different statutory basis. Inventors claim what they invent, but infringement occurs when others make, use, or sell the invention without authorization. The relevant provision states that "whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent." 35 U.S.C. § 271(a). With its reference to "patented invention," § 271(a) is referring to what is claimed. But infringing the claimed invention has several distinct features that differentiate it from claiming the invention.

First, claims and infringement have different analytical focal points. Infringement is assessed by examining a particular thing or series of acts that exists out in the world. Thus, "[l]iteral infringement of a claim exists when each of the claim limitations 'reads on,' or in other words is found in, the accused device." *Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1345 (Fed. Cir. 2002). Determining what is claimed, in contrast, requires examining the intrinsic meaning of the written patent document, informed by extrinsic evidence about how a person of ordinary skill in the art would understand the words of the written instrument. *See Phillips*, 415 F.3d at 1312–14 (analyzing claim meaning in light of the claims themselves, the specification, prosecution history, and extrinsic evidence illuminating the meaning of the words of a claim).

Second, one can infringe a patent without literally meeting all of the claim elements. For example, infringement occurs when, even though "a product or process . . . does not literally infringe upon the express

terms of a patent claim," "there is 'equivalence' between the elements of the accused product or process and the claimed elements of the patented invention"—what we call infringement under the doctrine of equivalents. *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 21 (1997). "The doctrine of equivalents, by definition, involves going beyond any permissible interpretation of the claim language; i.e., it involves determining whether the accused product is 'equivalent' to what is described by the claim language." *Wilson Sporting Goods Co. v. David Geoffrey & Assocs.*, 904 F.2d 677, 684 (Fed. Cir. 1990). Thus, "[t]he doctrine of equivalents provides a limited exception to the principle that claim meaning defines the scope of the exclusivity right in our patent system." *See VLSI Tech. LLC v. Intel Corp.*, 87 F.4th 1332, 1341 (Fed. Cir. 2023).

Third, a product whose making, using, offering, sale, or importation is infringing under 35 U.S.C. § 271—an "infringing product" in the common shorthand—can, and often does, contain additional features beyond what the patent claims. For one thing, the potential presence of additional features is the bedrock understanding of a "comprising" claim, which "[i]n the patent claim context" means "including but not limited to." *CIAS Inc. v. Alliance Gaming Corp.*, 504 F.3d 1356, 1360 (Fed. Cir. 2007) (internal quotations omitted). "For example, 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." *Stiftung v. Renishaw PLC*, 945 F.2d 1173, 1178 (Fed. Cir. 1991) (citation omitted). The Supreme Court long ago confirmed this fundamental point about infringement embodied in § 271. The Court explained that it "could" not be "controverted" that a "patent covering a top-structure for automobile 'convertibles'" was infringed "by making and selling cars embodying the patented top-structures." *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 478, 483 (1964). Simply put, a claim to a product is

infringed by making or selling (or using, offering, or importing) an article that contains the claimed product, even though the larger article contains additional unclaimed features.

Fourth, the requirement that "[t]he specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same" does not apply to the entirety of an infringing product. 35 U.S.C. § 112(a). Rather, it applies to what the patent discloses and claims as "the invention." *Id.* § 112(a), (b). A hypothetical raised at oral argument illustrates why Teva's position equating claiming with infringement is incorrect in view of their different meanings and requirements. We asked Teva about a claim to an improved steering wheel, even though the steering wheel clearly is intended for use in a car. As all agree, a car incorporating the steering wheel would infringe the claim. But when asked about whether a patent claiming the improved steering wheel would need to describe and enable the car, Teva could not and did not argue that it must. Oral Arg. at 22:57–25:52.[9]

The interpretation is consistent with how we have interpreted the word "claims" in the PTE provisions of the Hatch-Waxman Act, which provide for extending the term of a patent that, among other things, "claims a product" that "has been subject to a regulatory review period before its commercial marketing or use." 35 U.S.C. § 156(a)(4). In *Hoechst-Roussel Pharmaceuticals, Inc. v. Lehman*, 109 F.3d 756 (Fed. Cir. 1997), we addressed and rejected the argument "that a patent 'claims' an FDA-approved product, within the meaning of that term as employed in the

---

[9] Available at https://oralarguments.cafc.uscourts.gov/default.aspx?fl=24-1936_11082024.mp3.

statute, if the FDA-approved product would infringe a claim of that patent." *Id.* at 758. We noted that "[t]he term 'claims' has been used in patent legislation since the Patent Act of 1836 to define the invention that an applicant believes is patentable." *Id.* We concluded that "[t]his concept of a claim is related to, but distinct from, the concept of infringement." *Id.* at 759. Applying this reasoning, we concluded that Hoechst's patent, which claimed 1-hydroxy-tacrine, did not claim the chemically distinct compound tacrine hydrochloride. *Id.* This was so *even though* "Hoechst may be entitled to exclude others from administering tacrine hydrochloride to patients" because, "when administered, tacrine hydrochloride metabolizes into another product, 1-hydroxy-tacrine, which Hoechst has claimed." *Id.*

Accordingly, both the relevant statutory provisions and our case law clearly establish that what a patent claims and what infringes a claim are distinct concepts. A patent claims something by "particularly pointing out and distinctly claiming" it as the invention. 35 U.S.C. § 112(b). A product infringes a claim if each element (or an insubstantially different version of each element) of the claim is found in the accused product—in other words, if the patent claim "reads on" the accused product. *Allen Eng'g*, 299 F.3d at 1345. Whether Teva's NDA infringes Teva's patents is separate from the issue of whether those patents actually claim the drug for which Teva submitted the application.

Teva's counterarguments are unpersuasive. Teva's first argument is that our precedent has already conclusively established that the patents that claim the drug are the same as the patents that the approved drug would infringe. In support, Teva cites *Apotex, Inc. v. Thompson*, where we stated 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 and the 'accused method' is a method

that is reasonably likely to be used by a hypothetical infringer." 347 F.3d at 1344.[10] To Teva, reaching a different conclusion would require overturning *Apotex*, which we cannot do as a three-judge panel.

Teva both takes the quotation from *Apotex* out of context and misreads it. First, as to context, the specific language Teva cites comes from the section of *Apotex* concluding that the Federal Circuit has appellate jurisdiction over a listing dispute. To exercise jurisdiction, we had to identify an issue that "necessarily depends on resolution of a substantial question of federal patent law, in that patent law is a necessary element of one of the well-pleaded claims." *Id.* at 1342 (quoting *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 808–09 (1988)). We concluded that the listing provision in effect at the time, which referenced both claiming the drug *and* reasonably asserting infringement, required answering at least a question of patent infringement, which is a question of patent law. *Id.* at 1344. Beyond making that point, which established this court's jurisdiction, we did not need to, and did not, interpret the listing provision because we rejected Apotex's argument that the FDA had to police the Orange Book. *Id.* at 1349.

Second, as to meaning, contrary to Teva's contention, we did not say in *Apotex* that, if something infringes a

---

[10] *Apotex* analyzed the listing provision before it was amended by the OBTA. When *Apotex* was decided, 21 U.S.C. § 355(b)(1) required that a patent must be listed if it "claims the drug for which the applicant submitted the application or . . . claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." Hatch-Waxman Act, sec. 102(a)(1), § 505(b), 98 Stat. at 1592.

patent, then the patent claims it—i.e., that, to meet the requirement that a patent claims something, it suffices to show that thing infringes the patent. Instead, we identified one necessary condition for listing—that determining whether a patent is properly listed "*requires* what amounts to a finding of patent infringement." *Id.* at 1344 (emphasis added). Even putting aside the "infringement reasonably could be asserted" language in the listing provision, this necessary condition of infringement is met by something that the patent claims. That is because determining whether a patent claims something amounts to determining literal infringement, in that both require the presence of every limitation of a patent claim. But that does not mean that nothing else counts as infringement, contrary to what Teva contends.[11] The statement in *Apotex* that Teva cites—that being claimed can establish infringement—is essentially a converse of what Teva contends—that infringement can establish being claimed. Thus, this statement in *Apotex*, even aside from its limited context, does not support Teva's position.

Teva also seeks refuge in the Second Circuit's decision in *United Food & Commercial Workers Local 1776 v. Takeda Pharmaceutical Co.*, 11 F.4th 118 (2d Cir. 2021). In Teva's view, the Second Circuit adopted its interpretation of the listing provision in *United Food* by citing the same language from *Apotex* that Teva invokes. As it does with *Apotex*, Teva misreads *United Food*. First, although *United Food* cites *Apotex*, the Second Circuit concluded that, "although the concepts are closely related, 'the plain meaning of "claims" is not the same as the plain meaning of infringement.'" 11 F.4th at 134 (quoting *Hoechst-Roussel Pharms.*, 109 F.3d at 759). Second, the facts of *United Food*

---

[11] One example, as we discussed above, is infringement under the doctrine of equivalents.

involved the listing of a patent claiming two active ingredients when the approved drug used only one of the two. *Id.* at 127. As the Second Circuit correctly noted, "[a] long line of Supreme Court case law confirms that a combination patent, in general, does not 'claim' its constituent parts." *Id.* at 131; *see also id.* (citing *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 337–39, 339–40 (1961)). Those facts do not address the dispute here about whether patents that claim some, but not all, of the features in an approved drug product may be listed.

Teva's second argument is that what a patent claims is what literally infringes the patent. Appellants' Br. 21–22; Appellants' Reply Br. 7. To Teva, this interpretation eliminates any redundancy between the requirements of claiming and infringing because the infringement requirement still references the doctrine of equivalents. We find this argument unpersuasive for several reasons. First, literal infringement and infringement under the doctrine of equivalents are better understood as separate "theor[ies] of infringement" that are alternative ways of satisfying "the statutory basis for direct infringement." *Wis. Alumni Rsch. Found. v. Apple Inc.*, 112 F.4th 1364, 1382 (Fed. Cir. 2024). Second, as we explained above, *Hoechst-Roussel* rejected the argument that claiming and literal infringement are coextensive. 109 F.3d at 759. Third, Teva's argument does not acknowledge that claiming and infringement have separate statutory bases and that the listing provision identifies both as separate requirements.

In sum, we conclude that a patent "claims the drug for which the applicant submitted the application," 21 U.S.C. § 355(b)(1)(A)(viii)(I), when it particularly points out and distinctly claims the drug—not simply when the claim could somehow be interpreted to read on the drug. In other words, the fact that an NDA could infringe a patent does not mean that the patent "claims" the underlying drug within the meaning of the listing provision. Reaching this

conclusion, though, does not answer the second question raised by Teva's argument—how much of the drug for which the applicant submitted the application a patent must claim to be listed. We now turn to that issue.

II

Teva also argues on appeal that a patent is listable if it claims any part of its NDA product. One requirement for listing a patent in the Orange Book is that the patent "claims the drug for which the applicant submitted the application." 21 U.S.C. § 355(b)(1)(A)(viii)(I). Teva's argument about what it means to "claim[] the drug for which the applicant submitted the application" rests on combining the FDCA's statutory definition of "drug" with the listing provision. The FDCA provides two definitions of the word "drug" relevant here. The first is "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals." 21 U.S.C. § 321(g)(1)(B). The second is "articles intended for use as a *component* of any article specified in clause . . . (B)." *Id.* § 321(g)(1)(D) (emphasis added). Putting these definitions together, Teva asserts that the FDCA defines any part of something used to treat a disease as a drug. Then, turning to the listing and delisting provisions, Teva focuses on the common requirement that listable patents claim *the* drug in the NDA. *Id.* § 355(b)(1)(A)(viii)(I), (j)(5)(C)(ii)(I)(aa). Thus, so long as a patent claims any part of the NDA product, even if it only claims device parts, Teva's conclusion is that such patents belong in the Orange Book.

We reject this contention. While Teva's argument may have some superficial appeal, its reliance on the FDCA's definition of drug fails to account for how the FDCA's other provisions inform and limit what kind of medical products within the FDA's purview are drugs. Instead, the FDCA's broader statutory context leads us to conclude that, for a patent to "claim[] the drug for which the applicant

submitted the application," such a patent must claim at least the active ingredient identified in the application.

Especially when interpreting a regulatory regime with as many interlocking parts as the FDCA, we do not "confine [ourselves] to examining a particular statutory provision in isolation." *Brown & Williamson*, 529 U.S. at 132. Rather, we "interpret the statute 'as a symmetrical and coherent regulatory scheme' and 'fit, if possible, all parts into a harmonious whole.'" *Id.* at 133 (first quoting *Gustafson v. Alloyd Co.*, 513 U.S. 561, 569 (1995), then quoting *FTC v. Mandel Bros., Inc.*, 359 U.S. 385, 389 (1959)). When looking at *how* the FDA approves the many different medical products it regulates, it is apparent that a product regulatable and approvable as a drug contains an active ingredient.

In answering the question of what makes something eligible for approval as a drug by the FDA, it helps to compare the approval pathway for drugs and devices. Every new drug must receive premarket approval from the FDA before it can come to market. 21 U.S.C. § 355(a). An applicant seeks premarket approval for a drug by submitting an NDA or ANDA in the processes we described above. *See id.* § 355(b), (j).

Devices have a distinct approval pathway. The FDCA defines a device as, among other things, an instrument that treats disease or affects the structure of the body and "which does not achieve its primary intended purposes through chemical action . . . and which is not dependent upon being metabolized for the achievement of its primary intended purposes." 21 U.S.C. § 321(h)(1). Before 1976, devices, unlike drugs, did not require premarket approval. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 315 (2008).

Following what many viewed as "the inability of the common-law tort system to manage the risks associated with dangerous devices," Congress established FDA premarket regulation for devices with the Medical Device

Amendments of 1976. *Riegel*, 552 U.S. at 315–16. Devices have three levels of oversight with different premarket approval requirements, depending on the level of risk associated with using the device. Class I devices are "subject to the lowest level of oversight: 'general controls,' such as labeling requirements." *Id.* at 316 (quoting 21 U.S.C. § 360c(a)(1)(A)). Class II devices are "subject in addition to 'special controls' such as performance standards and postmarket surveillance measures." *Id.* at 317 (quoting 21 U.S.C. § 360c(a)(1)(B)). Class III devices require premarket approval "if it cannot be established that a less stringent classification would provide reasonable assurance of safety and effectiveness." *Id.* (citing 21 U.S.C. § 360c(a)(1)(C)(ii)). But even Class III devices do not necessarily require thorough premarket review. "A new device need not undergo premarket approval if the FDA finds it is 'substantially equivalent' to another device exempt from premarket approval" through what is called the § 510(k) process. *Id.* (quoting 21 U.S.C. § 360c(f)(1)(A)).

These distinct regulatory regimes and approval pathways mean that a product's classification as a drug or device guides the life cycle for how that product comes to market. These distinct pathways mean that "a product may be regulated as a drug *or* a device, but not both, and while a single product may simultaneously satisfy the linguistic elements of two definitions [of drug and device], it is not possible for the FDA to give simultaneous *effect* to both." *Genus Med. Techs. LLC v. FDA*, 994 F.3d 631, 639 (D.C. Cir. 2021) (emphasis in original). "And no one suggests that the FDCA requires products meeting both definitions to be regulated *both* as drugs and devices, which would create a breathtaking example of statutory redundancy." *Id.* (emphasis in original). Even though the FDCA defines "drug" broadly as something that treats disease, then, the statutory context demonstrates that a drug is a narrower class of medical product.

While it is clear that there is a distinction between what qualifies as a drug and what qualifies as a device, we still must identify which features make a product approvable as a drug rather than as a device. One touchstone of the distinction between drugs and devices is that the former are "composed of complex chemical compounds or biological substances" and the latter are "characterized more by their purely mechanical nature." *United States v. Article of Drug, Bacto-Unidisk*, 394 U.S. 784, 800 (1969). Put differently, "what distinguishes a drug from a device under the FDCA is that a device excludes a product that achieves its primary intended purposes through either chemical action or metabolization." *Genus Med.*, 994 F.3d at 641.

The FDCA uses a specific term for the part of a drug that supplies the chemical action or metabolization that treats disease—the active ingredient. And it is the presence of this active ingredient that makes a product approvable as a drug. The FDCA's requirements for drug approval bear this out. "While the FDA approves [a] drug as a whole, assessment and study of the active ingredient is central to the new drug approval process." *Sandoz Inc. v. Becerra*, 57 F.4th 272, 280 (D.C. Cir. 2023). We know this because the FDA decides whether a drug is safe and effective "under the conditions prescribed, recommended, or suggested in the proposed labeling." 21 U.S.C. § 355(d)(1); *id.* § 355(d)(5) (similar). The label itself focuses on the active ingredient—it must include the "quantity or . . . proportion of each active ingredient" in the drug. *Id.* § 352(e)(1)(A)(ii). Notably, the inactive ingredients of the drug, which do not cause the chemical action or metabolization that make the drug perform its intended function, need only be put on the label; their proportion in the drug does not have to be included. *Id.* § 352(e)(1)(A)(iii).

This statutory focus on the active ingredient is also reflected in what a generic applicant must show in an

ANDA. "An ANDA may be submitted only when the 'active ingredient' of the proposed generic drug 'is the same as that of the listed drug.'" *Sandoz*, 57 F.4th at 281 (quoting 21 U.S.C. § 355(j)(2)(A)(ii)). If an applicant wishes to submit an ANDA "for a new drug which has a different active ingredient or whose route of administration, dosage form, or strength differ from that of a listed drug," the FDCA requires the applicant to conduct new investigations on the different active ingredient, route of administration, dosage form, or strength if the differences make the FDA unable to assure itself that the generic drug is still safe and effective. 21 U.S.C. § 355(j)(2)(C), (4)(C). What these provisions demonstrate is that the presence of an active ingredient that is safe and effective is what makes something approvable as a drug.

Two recent decisions from the D.C. Circuit reinforce this understanding. First, in *Sandoz*, the D.C. Circuit concluded that the FDA did not approve an impurity that was only sometimes present in the approved version of a drug. 57 F.4th at 280–81. The *Sandoz* court reached this conclusion because the FDA, when approving a new drug, evaluates the safety and efficacy of a product with a focus on the active ingredient. The FDA does not, however, evaluate safety and efficacy with respect to impurities; rather, the only analysis is whether the presence or inclusion of the impurities undermine the safety or efficacy of the drug. *Id.* at 281–82.

Second, in *Ipsen Biopharmaceuticals, Inc. v. Becerra*, the D.C. Circuit evaluated whether a particular medical product was properly classified as a drug or a biologic. 108 F.4th 836 (D.C. Cir. 2024). In answering this question, the D.C. Circuit stated that "a *drug* furnishes pharmacological activity, but a drug *product* is the 'thing' that is ingested or administered. Said another way, you must ingest the drug product to reap the drug's benefits." *Id.* at 842 (emphasis in original). In determining whether something is a drug (rather than whether the final drug product is safe and

effective), *Ipsen* concluded that such a "decision is made by looking at the drug's active ingredient. Full stop." *Id.* The ultimate conclusion was that classification as a drug or biological product depended on "the active ingredient," not the "dosage form." *Id.* at 844.

Sandoz and *Ipsen Biopharmaceuticals* support the conclusion that what makes something approvable as a drug is the presence of an active ingredient. Thus, to claim the drug for which the applicant submitted the application and for which the application was approved, a patent must claim an invention containing the active ingredient. Otherwise, a patent claims something that the FDA could not have properly regulated as a drug in the first place.

To summarize, our analysis of the numerous relevant statutory provisions and the relevant case law leads us to only one conclusion: To list a patent in the Orange Book, that patent must, among other things, claim the drug for which the applicant submitted the application and for which the application was approved. And to claim that drug, the patent must claim at least the active ingredient. Thus, patents claiming just the device components of the product approved in an NDA do not meet the listing requirement of claiming the drug for which the applicant submitted the application.

Teva pushes back on this conclusion with two arguments. We find neither persuasive. First, Teva argues that this conclusion ignores the FDCA's explicit definition of a drug as a component intended for use in an article to treat disease. We take Teva's point that a patent need not claim every aspect of the final approved NDA product and can indeed claim only parts of it. But Teva's invocation of "components," with respect to the question before us, ignores the requirement that listable patents must claim the drug for which approval is sought. That requires claiming the active ingredient. "And we think that is so because Congress meant (as it usually does) for the

provision it enacted to fit within the statutory scheme." *Caraco*, 566 U.S. at 416–17.

Second, Teva disputes our interpretation of the phrases "for which the applicant submitted the application" in the listing provision and "for which the application was approved" in the delisting provision. Since the FDA permissibly approved the ProAir® HFA as a drug, Teva argues that even the device components of an inhaler are statutorily a drug. For this position, Teva relies on the FDA's designation of its ProAir® HFA as a combination product that should be approved in an NDA. We reject this argument as well.

Combination products are yet another innovation in the FDA's regulation of medical products. Before 1990, the definition of "drug" in the FDCA excluded "devices or their components, parts, or accessories." FDCA, Pub. L. No. 75-717, § 201(g), 52 Stat. 1040, 1041 (1938). Recognizing that certain products regulated by the FDA could have both drug parts and device parts, like Teva's ProAir® HFA, Congress added provisions in the Same Medical Devices Act of 1990 ("SMDA") creating a new class of products—combination products. Pub. L. No. 101-629, sec. 16, § 503, 104 Stat. 4511. They "constitute a combination of a drug, device, or biological product." 21 U.S.C. § 353(g)(1)(A). Although Congress defined a new kind of product, it did not create a new approval pathway. Instead, the FDA must "conduct the premarket review of any combination product under a single application, whenever appropriate." *Id.* § 353(g)(1)(B). The FDA determines the appropriate approval pathway—as a drug, device, or biological product—by looking at the "primary mode of action of the combination product." *Id.* § 353(g)(1)(D). The primary mode of action is "the single mode of action of a combination product expected to make the greatest contribution to the overall intended therapeutic effects of the combination product." *Id.* § 353(g)(1)(C). If the primary mode of action is that of a drug, the FDA must approve the product as a

drug. The FDA considers metered-dose inhalers like Teva's ProAir® HFA to have a primary mode of action of a drug. J.A. 1052. Thus, the FDA approved Teva's ProAir® HFA with an NDA.

But the fact that the FDA approved Teva's ProAir® HFA combination product as a drug does not make the inhaler's device parts a drug. They are still devices, just ones present in the product that was approved, in a single application, under the NDA pathway. The statutory structure bears this out. First, the definition itself states that these products are "a combination of a drug, device, or biological product." 21 U.S.C. § 353(g)(1)(A). This language reflects that the combination product is not a drug—rather, the drug and device subparts still retain their identify as drugs and devices, respectively.

Second, the way the FDCA addresses combination products that use, as subparts, products that the FDA has already approved reveals that the subparts retain their separate identity. Combination products can contain "an approved constituent part." *Id.* § 353(g)(3). An approved constituent part includes a drug that has already been approved or a device that is available on the market. *Id.* § 353(g)(4)(A), (B). For an approved constituent part that is a drug, it must be an "approved drug." *Id.* § 353(g)(4)(A). An "approved drug" is "an active ingredient" that meets several requirements, including that it was identified in an NDA and that the FDA considered whether the active ingredient is safe and effective. *Id.* § 353(g)(5)(B).

Once again, the statutory focus on an active ingredient reveals that what makes a product a drug is the presence of an active ingredient giving rise to chemical action. And including a drug in a combination product does not transform each and every component of that combination product into a drug. Instead, each subpart retains its separate identity. The ultimate approval pathway depends

on whether the drug part or device part of the combination product supplies the primary mode of action.

The Sixth Circuit reached a similar conclusion in *Miller v. Mylan Inc.*, 741 F.3d 674 (6th Cir. 2014). In *Miller*, the Sixth Circuit explained that "[t]he effect of" the SMDA "was to create a distinction between how a product is *defined* and how that product will be *regulated*." *Id.* at 677. Thus, for "ambiguous products," it is the primary mode of action that determines whether a product will be regulated under the drug or device pathway. *Id.* In short, a combination product does not become a drug just because it is regulated as a drug.

Returning to Teva's argument, we conclude that a combination product being approved with an NDA does not necessarily make every part of the NDA a drug. That is, a drug-device combination product being approved with an NDA does not make the device parts a drug. The fact that the combination product was approved with an NDA just means that the drug mode of action predominated. On the facts of this case, the drug for which the application was submitted and approved is thus not every component of Teva's ProAir® HFA. Instead, it is the part of the drug-device combination that made it regulatable as a drug in the first place. And that is the active ingredient.

For completeness, we note, but neither adopt nor reject, Amneal's additional argument that Teva's patents are delistable on the ground that they are not drug-substance or drug-product patents. In the OBTA in 2021, Congress added language to the listing provision requiring that a patent that "claims the drug for which the applicant submitted the application" also be "a drug substance (active ingredient) patent or a drug product (formulation or composition) patent." 21 U.S.C. § 355(b)(1)(A)(viii)(I). Amneal argues that patents that are not drug-substance or drug-product patents are delistable on the ground that they do not "claim . . . the drug for which the application

was approved." *Id.* § 355(j)(5)(C)(ii)(I)(aa). Because we concluded above that a patent does not "claim[] the drug for which the applicant submitted the application" if it does not claim at least the active ingredient, we do not need to reach Amneal's additional argument regarding drug-substance and drug-product patents.

III

Finally, Teva argues that, even if a patent must claim at least the active ingredient to be listed in the Orange Book, its patents *do* claim an active ingredient. Apart from the merits of this position, Teva advances a procedural joust—that remand is needed for the district court to construe the claims. Once again, we disagree. When determining what a patent claims for the purpose of the listing inquiry, we apply the rubric of claim construction. *Jazz Pharms., Inc. v. Avadel CNS Pharms., LLC*, 60 F.4th 1373, 1379 (Fed. Cir. 2023). But a formal *Markman* hearing is not required in every case. Rather, in resolving an issue as a matter of law at the pleadings stage, we can "proceed by adopting the non-moving party's construction[]." *UTTO Inc. v. Metrotech Corp.*, 119 F.4th 984, 994 (Fed. Cir. 2024) (quoting *Aatrix Software, Inc. v. Green Shades Software, Inc.*, 882 F.3d 1121, 1125 (Fed. Cir. 2018)). We thus adopt the construction Teva proposes here, only for the purposes of resolving this appeal.

Turning to the claims themselves, Teva's proposed construction is that each patent includes one claim requiring the presence of "an active drug." Appellants' Br. 45–46 (citing J.A. 1589–91). No claim in the patent requires the presence of such an active drug in the claim language itself; rather, Teva seeks to import this limitation into the claims using implicit representations in the specifications. Teva argues that, even if its patents must claim at least the active ingredient in its ProAir® HFA, the requirement of "an active drug" in the claims means that its patents "claim[] the drug for which the applicant

submitted the application" as required by the statute. 21 U.S.C. § 355(b)(1)(A)(viii). Even accepting Teva's (somewhat dubious) construction, we conclude that the district court properly ordered Teva to delist the five asserted patents.

As we explained above, to claim something, a patent must particularly point out and distinctly claim what it purports to be the invention. *See* 35 U.S.C. § 112(b). And to qualify for listing, a patent must claim at least the active ingredient in the application and the approved drug product. Importantly, the FDA does not approve a medical product as a drug with reference to some vague active ingredient in the abstract. Rather, it approves a specific active ingredient at a specific concentration if that active ingredient, in combination with other features of the drug product, is safe and effective. *See* 21 U.S.C. § 355(b), (d).

A claim requiring the presence of "an active drug" is far too broad to particularly point out and distinctly claim the drug approved in Teva's NDA. Teva's construction permits the presence of any active ingredient in any form. As a matter of law, Teva's construction does not particularly point out and distinctly claim what was approved—the ProAir® HFA with albuterol sulfate as the active ingredient. We do not and need not decide more.

CONCLUSION

We have considered Teva's remaining arguments and find them unpersuasive. For the foregoing reasons, we lift our stay and affirm the district court's order requiring Teva to delist its patents.

AFFIRMED