

No. 24-1936

In the
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

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

**BRIEF OF 52 PROFESSORS OF LAW, ECONOMICS, AND MEDICINE
AS AMICI CURIAE IN SUPPORT OF DEFENDANTS-APPELLEES AND AFFIRMANCE**

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**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 52 Professors of Law, Economics, and Medicine

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Date: 08/30/2024

Signature: /s/ Mark A. Lemley

Name: Professor Mark A. Lemley

<p>1. Represented Entities. Fed. Cir. R. 47.4(a)(1).</p>	<p>2. Real Party in Interest. Fed. Cir. R. 47.4(a)(2).</p>	<p>3. Parent Corporations and Stockholders. Fed. Cir. R. 47.4(a)(3).</p>
<p>Provide the full names of all entities represented by undersigned counsel in this case.</p>	<p>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.</p> <p><input checked="" type="checkbox"/> None/Not Applicable</p>	<p>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.</p> <p><input checked="" type="checkbox"/> None/Not Applicable</p>
<p>See Appendix A (attached)</p>		

Additional pages attached

4. Legal Representatives. List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

None/Not Applicable Additional pages attached

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5. Related Cases. Other than the originating case(s) for this case, are there related or prior cases that meet the criteria under Fed. Cir. R. 47.5(a)?

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6. Organizational Victims and Bankruptcy Cases. Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

None/Not Applicable Additional pages attached

Appendix A
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INTEREST OF AMICI

Amici are professors of law, economics, and medicine. We have no personal or financial interest in the outcome of this case, but have a professional interest in seeing that the law develops in a reasonable and consistent way. A full list of amici is attached as Appendix A.¹

SUMMARY OF ARGUMENT

This is a classic case of “evergreening.” Teva seeks to extend its exclusivity beyond the expiration of its core patents by improperly listing patents in the Orange Book. In its effort to do so, it mischaracterizes basic principles of patent law. It also fails to show that its inhaler patents, which do not mention any drug at all, claim the specific drug it submitted to the FDA: “albuterol sulfate HFA Inhalation Aerosol.” Obviously an inhaler is not an active ingredient. And even if it were considered to be a “formulation or composition” patent, it still would not satisfy the requirement of covering the drug submitted to the FDA because the patents in no way claim or even mention albuterol sulfate.

¹ Pursuant to Federal Rule of Appellate Procedure 29(a)(2), all parties consented to the filing of this brief. Pursuant to Rule 29(a)(4)(E), no counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of the brief. No person or entity, other than amicus, its members, or its counsel, made a monetary contribution to the preparation or submission of this brief.

Unfortunately, the practice of false listings in the Orange Book has become widespread, extending to a wide variety of things (including software) the Hatch-Waxman Act never meant to include. The result has been to delay generic entry, raising the cost of healthcare and threatening public health in violation of both the language and the spirit of the Hatch-Waxman Act and industry regulations. This Court should make clear that these false listings are impermissible, paving the way for both the U.S. Food and Drug Administration (FDA) and the antitrust laws to stop the practice.

ARGUMENT

I. The Patents Do Not “Claim the Drug” the FDA Approved

A. Teva Misstates Patent Doctrine

Teva’s appeal proceeds from a fundamentally mistaken premise of patent law. A patent may be listed in the Orange Book only if it “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).²

² The full context of the statute reads:

(b) Filing application; contents.

(1)

Teva says that a patent “claims the drug” if “the claim limitations ‘read on’—*i.e.*, are ‘found in’—the invention at issue.” Opening Br. at 13. But a patent has never been thought to “read on” a product merely because *one of* the claim limitations appears in the product. Quite the contrary. A patent claims a product only if each and every element of the patent claims appears in the product. That is elementary patent law. *See, e.g., Disc Disease Solutions Inc. v. VGH Solutions, Inc.*, 888 F.3d 1256, 1260 (Fed. Cir. 2018).

Teva continues by saying “[c]ritically, a patent need not read on the entirety of a product to “claim[]” the product.” Opening Br. at 13. That is a true statement, but it has no relevance here. In *SunTiger, Inc. v. Scientific Res. Funding*

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

...

(viii) the patent number and expiration date of each patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug, and that—

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

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

21 U.S.C. § 355. This case does not present an issue regarding methods of use of the drug.

Grp., 189 F.3d 1327, 1336 (Fed. Cir. 1999), the authority on which Teva relies for this proposition, the question was the opposite of the one posed here. There, each and every element of the patent claim was present in the accused device, but the accused device also had lots of other features beyond the patent. The Court held, again consistent with basic principles of patent law, that “one cannot avoid infringement merely by adding elements *if each element recited in the claims is found in the accused device.*” *Id.* (quoting *Stiftung v. Renishaw PLC*, 945 F.2d 1173, 1178 (Fed. Cir. 1991)).

That situation would be presented if a drug patent covering the active ingredient were asserted against a product that included that drug. If the accused infringer included *each and every* element of the patented claim in its product, it could not avoid infringement by adding new elements outside the scope of the patent claims.

But that principle of patent law in no way proves the opposite – that the presence of *just one* claim element in an accused device somehow means the patent “reads on” the accused device. That has never been the law. And it would radically upend patent doctrine. Imagine the consequences of saying, for instance, that a patent for a specific encryption algorithm that operated within a computer “reads on” any computer at all, whether or not it runs the algorithm, simply because the existence of a computer is one element of the patent claim.

Under patent law, a patent “claims” something only if each and every element of the patent claim is present in that thing.

B. Teva’s Patents Do Not Cover a Drug Product for Which It Received FDA Approval

In this case, Teva’s claims would fail even if its radical reinterpretation of patent law were correct, because the patents cannot plausibly be understood to claim the drug for which Teva received FDA approval.

To be listable in the Orange Book under the provisions at issue in this case,³ a patent must meet two requirements. First, it must “claim[] the drug for which the applicant submitted the application.” 21 U.S.C. §355(b)(1)(A)(viii)(I). Second, it must be a “drug substance (active ingredient) patent or a drug product (formulation or composition) patent.” *Id.*

The district court properly concluded that patent claims to (as Teva states in its brief) “an inhaler for metered dose inhalation,” a “medicament canister,” “an inhaler,” “a metered dose inhaler,” and a “canister” do not meet the first requirement. Opening Br. at 45-46. Those patents make no mention of any drug at all, much less “the drug for which the applicant submitted the application”: albuterol sulfate HFA Inhalation Aerosol.⁴ The products they cover could include

³ The patent also must be one “for which a claim of patent infringement could reasonably be asserted.” 21 U.S.C. §355(b)(1)(A)(viii).

⁴ This is not uncommon in the industry. See Brandon J. Demkowicz et al., *Patenting Strategies on Inhaler Delivery Devices*, 164 CHEST 450, 458 (Aug.

any drug at all or even something other than an FDA-approved drug.⁵ As the First Circuit has explained: “Under the plain wording of the statute, proper filing of the . . . patent would require not only that it be a patent that claims a drug; it must be a patent that claims the drug . . . ‘for which the applicant submitted’” the application. *In re Lantus Direct Purchaser Antitrust Litig.*, 950 F.3d 1, 8 (1st Cir. 2020) (emphases in original). Teva’s patent claim is not a claim to “the drug for which the applicant submitted the application” any more than a patent on a spoon would be listable in the Orange Book because it is possible to take some medicines

2023) (“The bulk of inhaler device patents listed over the past 3 decades have failed to claim any particular active ingredients, and almost half have claimed components of delivery devices (e.g., dose counters and nozzles), rather than delivery devices as a whole.”).

⁵ For example, Teva cites U.S. Patent No. 9,463,289. Claim 1 reads:

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.

with a spoon. *See also id.* (“We see nothing in the statute or regulations that welcomes such a further expansion of the already stretched statutory terms, whereby an integral part of an injector pen becomes the pen itself, and in turn is a drug. One would not think, for example, that a patent claiming only a transmission system must be read as also claiming any car in which it is used.”).

The court also correctly rejected Teva’s argument that the patents at issue are “‘drug product’ patents within the meaning of § 355.” It pointed to the regulations, which make clear that “[f]or patents that claim a drug product, the applicant must submit information only on those patents that claim the drug product, as is defined in § 314.3, *that is described in the pending or approved NDA.*” 21 C.F.R. § 314.53(b)(1) (*cited and emphasized in* 2024 WL 2923018, at *8). The district court correctly concluded that “[t]he Inhaler Patents do not claim the ‘finished dosage form’ that is the subject of NDA No. 021457.” 2024 WL 2923018, at *8. Given that the NDA covered albuterol sulfate HFA Inhalation Aerosol, it is hard to see how the court could have concluded otherwise.⁶

⁶ Teva’s reliance on *Apotex, Inc. v. Thompson*, 347 F.3d 1335 (Fed. Cir. 2003), is not persuasive: the case was decided on jurisdictional grounds, raised the very different question of whether the FDA was *required* to police the Orange Book for false listings like this one, and still referred to the “drug that is the subject of the NDA.” *Id.* at 1344. The same goes for *United Food & Com. Workers Loc. 1776 & Participating Emps. Health & Welfare Fund v. Takeda Pharm. Co. Ltd.*, where the court found that patents were not properly listed because the claims were “broader than and different from the scope” of the drug submitted to the FDA and rejected

Nor is Teva correct that all that is required is to prove that Amneal infringes its patents. That fact, if true, may give rise to a cause of action for patent infringement. And it is *one* of the requirements for patent listing. But it does not permit listing a patent in the Orange Book, with the considerable procedural and substantive advantages that brings, when the patent clearly does not claim the drug.

Indeed, the language of the statute itself disposes of Teva’s claim that proof of infringement is all that required. The statute requires that the patentee show

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;

21 U.S.C. § 355(b)(1)(A)(viii) (emphasis added). The fact that the patentee must show: (1) a reasonable case of infringement; (2) that the patent claims an active ingredient, formulation, or composition, *and* (3) that the patent claims the drug for which the applicant submitted the application belies the assertion that evidence of infringement is sufficient to relieve the patentee of the obligation to comply with subsection I. In short, “the possibility that the statute does not accommodate all

Takeda’s claim that the “risk of infringement” is “the only relevant listing factor.” 11 F.4th 118, 132–33 (2d Cir. 2021).

desired listings does not mean that [a court can] rewrite it.” *In re Lantus Direct Purchaser Antitrust Litig.*, 950 F.3d 1, 9 (1st Cir. 2020).

C. Claim Construction is Not Necessary to Resolve This Issue

Finally, Teva asserts that it should be entitled to claim construction (and a concomitant delay in the removal of its improperly listed patents from the Orange Book). There may well be circumstances in which parties could reasonably dispute the scope of a patent and which might turn on claim construction. But this is not such a case.

None of the patents mentions, much less claims, the drug in question or indeed any chemical at all. Indeed, the only reference to any medical use at all in any of the claims is in the preamble of two of the five patents, and that language merely recites the intended purpose of a physical device (“an inhaler for metered dose inhalation”). This Court has held that a preamble that merely recites the purpose or intended use of a structurally complete invention is not limiting. *See Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1118 (Fed. Cir. 2004) (finding that preamble did not add limitation to claim because it recited purpose or intended use of invention).

Instead, Teva proposes to read in limitations not found in the claims at all. Thus, it says “The term ‘an inhaler’ (found in the ’808 patent) is properly construed as ‘an inhaler containing an *active drug* capable of being dispensed via the inhaler

to the lungs.” Opening Br. at 46 (emphasis in original). And so on for each of the claims. But it is a fundamental principle of claim construction that the Court does not read in limitations not present in the claims. *See, e.g., Rambus Inc. v. Infineon Techs. Ag*, 318 F.3d 1081, 1089 (Fed. Cir. 2003) (reversing district court decision because it “reads into the claim two new limitations not required by the claim language”); *K-2 Corp. v. Salomon S.A.*, 191 F.3d 1356, 1364 (Fed. Cir. 1999) (“Courts do not rewrite patent claims” but “instead . . . give effect to the terms chosen by the patentee.”). Teva’s proposed claim construction simply isn’t plausible.

But even if it was, it wouldn’t matter. Teva does not suggest that the patent claims albuterol sulfate. Even Teva can’t imagine reading that much into a claim that makes no mention of it. Instead, it says the inhaler and canister patents should be read to have “an active drug.” But the presence of *some* chemical in the inhaler does not mean that the patent claims “the drug for which the applicant submitted the application.” 21 U.S.C. §355. So even the improper claim construction for which Teva advocates wouldn’t justify its listing the patents in the Orange Book.

Courts regularly grant judgment on the pleadings in patentable subject matter cases despite protestations that they should wait for claim construction. *See, e.g., Bancorp Servs. LLC v. Sun Life Assurance Co. of Can.*, 687 F.3d 1266, 1273 (Fed. Cir. 2012) (“claim construction is not an inviolable prerequisite to a

validity determination under § 101”). “In aid of determining whether a particular motion requires claim construction before disposition of the motion, a district court is free to require the party asking for construction to provide an actual proposed construction, to demonstrate that its construction is not frivolous, and to articulate how adoption of the construction would materially impact the analysis” *Sanderling Mgmt. Ltd. v. Snap Inc.*, 65 F.4th 698, 704 (Fed. Cir. 2023). Here, Teva’s proposed claim construction is both frivolous *and* could not possibly help it. There is no reason to delay the proceedings further, particularly since, as we discuss in the next Part, unreasonable delay is the entire point of the strategy of baselessly listing Orange Book patents.

II. The Baseless Listing of Orange Book Patents Like Teva’s Causes Significant Harm

Teva’s listing threatens to undermine the careful balance at the core of the Hatch Waxman Act, reducing competition and harming consumers.

A. The Hatch Waxman Act Created a Balance between Competition and Innovation

Congress enacted the complex regulatory regime known as the Hatch-Waxman Act to foster innovation and competition. The pharmaceutical marketplace in the early 1980s suffered from sparse generic entry and stifled brand-drug firm innovation.

The Act enhanced innovation incentives through extensions of the patent term, periods of nonpatent regulatory exclusivity for new chemical entities and new clinical investigations, and an automatic 30-month stay for brands that sued generics that had challenged the patent’s validity or claimed noninfringement.

Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 Mich. L. Rev. 37, 43–45 (2009).

In addition, the Act fostered competition by allowing generics to experiment on brand drugs during the patent term, by permitting generics to avoid the lengthy process for new-drug approval by showing equivalence to the brand’s product, and by granting a valuable 180-day exclusivity period to the first generic to certify that the patent is invalid or not infringed. 35 U.S.C. § 271(e)(1); 21 U.S.C. § 355(j)(2)(A); 21 U.S.C. § 355(j)(5)(B)(iv). The drafters explained the significance of providing “low-cost, generic drugs for millions of Americans.” 130 Cong. Rec. 24427 (1984) (statement of Rep. Waxman). Generic competition would save consumers and the government millions of dollars each year. And it would “do more to contain the cost of elderly care than perhaps anything else this Congress has passed.” *Id.*

The Act’s drafters emphasized the equilibrium between competition and innovation. Representative Henry Waxman underscored the “fundamental balance of the bill.” 130 Cong. Rec. 24425 (Sept. 6, 1984). And the Energy and

Commerce Committee Report explained that allowing early generic challenges “fairly balances” the exclusionary rights of patent owners with the “rights of third parties” to contest validity and market products not covered by the patent. H. R. Rep. No. 98-857, pt. 1, at 28.

B. The Orange Book Is Central to the Hatch Waxman Regime

The Orange Book plays a critical role in the Hatch Waxman regime. It is at the center of the carefully choreographed system by which brands and generics litigate patents. Upon filing an NDA, a brand firm lists relevant patents in the Orange Book. The 30-month stay is limited to the subset of patents that could be listed in the Orange Book. The generic company then can file its application only by making one of four certifications for each of the listed patents: “no patent information appears in the Orange Book” (Paragraph I); “the patent has expired” (Paragraph II); “it will not seek approval until the patent expires” (Paragraph III); or “the patent is invalid or will not be infringed by the generic drug” (Paragraph IV). 21 U.S.C. § 355(j)(2)(A)(vii).⁷

The first certification does not involve patents. But each of the other three shows the harm from improper listings. Certifications that the patent has expired,

⁷ We do not discuss the other route by which a generic can reach the market: a section viii statement filed against a method-of-use patent that avoids the patented indication. 21 U.S.C. § 355(j)(2)(A)(viii).

that the generic will wait until the patent expires, or that the generic certifies that the patent is invalid or not infringed only make sense if they address the drug for which the brand firm seeks approval. Allowing brand firms to list patents and obtain 30-month stays on drugs for which they did *not* seek approval would upset the carefully calibrated regulatory regime by delinking the patent listing process from the approval process. The drafters never envisioned giving brand holders such a second bite at the apple.

Obtaining such airtight protection in most cases would be slowed by agency review of the activity to prevent abuse. But that is not the case here. The FDA famously takes a hands-off approach to the question, stating that it “has no expertise or resources with which to resolve complex questions of patent coverage” and thus has only a “ministerial” role “in the patent-listing process.” FDA, *Small Business Assistance: 180-Day Generic Drug Exclusivity*, <https://www.fda.gov/drugs/cder-small-business-industry-assistance-sbia/small-business-assistance-180-day-generic-drug-exclusivity> (last visited Aug. 2, 2024).

That creates a loophole that permits brand firms to improperly list patents and then justify the conduct by offering convoluted arguments that muddy the patent listing waters, all while avoiding scrutiny. That is just what happened here. Congress enacted the delisting counterclaim procedure precisely to address the problem of such abusive listings. 21 U.S.C. § 355(j)(5)(C)(ii).

C. Harms to Competition and Consumers

Listing patents in the Orange Book is not a victimless action. It results in a powerful 30-month stay. Every one of the days making up the 30 months from improperly listed patents is a day that consumers are robbed of lower-cost generic medicines. Given the difficulty many consumers face in their ability to afford critical medicines, this is a real problem. For the ProAir HFA in particular, commentators have estimated that Medicare Part D and Medicaid paid an extra \$214 million in a single year from improper Orange Book listings. American Economic Liberties Project & Initiative for Medicines, Access, & Knowledge (I-MAK), *The Costs of Pharma Cheating*, at 12, 13, 18 (May 2023) (assuming generic prices 60% lower than brand prices).

The American Thoracic Society has found “[m]ounting evidence” that “out-of-pocket costs for prescription medications, particularly among low- and middle-income patients with chronic diseases, are imposing financial burden, reducing medication adherence, and worsening health outcomes.” Minal R. Patel et al., *Improving the Affordability of Prescription Medications for People with Chronic Respiratory Disease. An Official American Thoracic Society Policy Statement*, 198(11) *Am. J. Respir. Crit. Care Med.* 1367 (2018). This leading respiratory health group has concluded that “[t]his problem is exacerbated by a paucity of generic alternatives for prevalent lung diseases, such as asthma and chronic

obstructive pulmonary disease.” *Id.* Improper Orange Book listings contribute to “burdensome . . . pharmaceutical costs of common therapies . . . for many patients” that are “a major barrier to medication adherence.” *Id.*; *see also* Demkowicz et al., *Patenting Strategies on Inhaler Delivery Devices, supra*, at 459 (“Financial toxicity leading to medication nonadherence and poor outcomes is only exacerbated by patent thickets extending periods of market exclusivity on brand-name inhalers.”).

That is a particular problem in cases such as this one, where the patent on the active ingredient expired decades ago, in 1989. Despite that fact, Teva has prevented effective generic competition by falsely listing on the Orange Book patents on devices that do not plausibly claim any drug, delaying generic entry until 2026.

False listing of patents in the Orange Book causes real harm to consumers, competitors, and competition. The law can and does permit courts to do what the FDA will not – delist patents that have no business being in the Orange Book in the first place. And it should permit those injured by anticompetitive gaming of the FDA regulatory process to invoke the antitrust laws to redress that injury.

CONCLUSION

The district court's rulings on false patent listing should be affirmed.

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Federal Circuit Rules 29(a) and 32(b)(1). It contains 3,929 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f) and Federal Circuit Rule 32(b)(2).

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

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