No. 24-1936

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.

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

BRIEF OF *AMICUS CURIAE* SANOFI-AVENTIS U.S. LLC IN SUPPORT OF PETITION FOR REHEARING EN BANC

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CERTIFICATE OF INTEREST

Pursuant to Fed. Cir. R. 47.4, counsel for *Amicus Curiae* Sanofi-Aventis U.S. LLC certifies the following:

1. Provide the full names of all entities represented by undersigned counsel in this case.

Sanofi-Aventis U.S. LLC

2. 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.

N/A

3. Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities.

Sanofi

4. 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.

N/A

5. 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)?

N/A

6. 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).

N/A

Dated: February 4, 2025

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INTEREST OF *AMICUS CURIAE*

Sanofi-Aventis U.S. LLC is the principal U.S. subsidiary of Sanofi, a leading global healthcare company engaged in researching, developing, and manufacturing therapeutic solutions to patient needs. Researching and developing new drugs is a costly, lengthy, and uncertain process, and Sanofi invests billions of dollars annually in its R&D pipeline, including many products that never make it to market. Sanofi relies on patents to protect its innovative products, recoup its investments, and fund future innovations. Moreover, Sanofi is obligated under Hatch-Waxman to list patents in FDA's "Orange Book." Sanofi thus has a significant interest in ensuring that the listing requirement is interpreted correctly and consistently.[1]

INTRODUCTION

The panel's decision strikes at the heart of the Hatch-Waxman framework for efficiently resolving patent disputes between innovative pharmaceutical companies and generic follow-on companies. In construing the listing provision to require Teva to delist patents on the device component of its ProAir HFA metered-dose inhaler product, the panel concluded that those patents do not "claim the drug for which the applicant submitted the application," 21 U.S.C. § 355(b)(1)(A)(viii)(I). The panel construed this phrase to mean something like "recite the active pharmaceutical

[1] No counsel for a party authored this brief in whole or in part. No person other than *amicus* or its counsel contributed money to fund its preparation or submission.

ingredient," but that interpretation is wrong. It conflicts with precedent, disregards the controlling definition of "drug," ignores FDA's long-held views, and unsettles the industry's understanding of the statutory framework.

Nor is the panel's decision clearly limited to device patents. It may very well be interpreted to prohibit the listing of formulation patents not claiming the particular active ingredient, and it could even be misread as excluding genus patents. Prior to this decision, no one doubted that these types of patents were listable, regardless of whether they include claims reciting the active ingredient.

Left uncorrected, the panel's decision threatens to upset the Hatch-Waxman regime on which innovative and generic manufacturers have come to rely for over 40 years, and which promotes early and efficient resolution of patent disputes related to innovative therapeutics. Sanofi thus urges the Court to grant Teva's rehearing petition.

ARGUMENT

I. The panel incorrectly interpreted the Orange Book listing provision.

The panel held that Teva could not list the patents at issue because they do not "claim the drug for which the applicant submitted the application," 21 U.S.C. § 355(b)(1)(A)(viii)(I). In doing so, the panel never clearly spelled out what this phrase means. On the contrary, the panel offered only adverbs and synonyms, explaining that a patent "'claims the drug for which the applicant submitted the application' … when it particularly points out and distinctly claims the drug." Op. 27. At bottom, the panel seems to read the key phrase to mean "recites the active pharmaceutical ingredient."

See Op. 27, 38. That is wrong. Teva explains some of the reasons why. Sanofi wishes to emphasize two particular problems.

First, the term "claims" is best read as having its ordinary patent-law meaning, which is "reads on" (not "recites"). Construing "claims" as "reads on" tracks a longstanding PTO regulation using the terms interchangeably. 37 C.F.R. § 1.740(a)(9). It also tracks precedent. In *Apotex, Inc. v. Thompson*, this Court interpreted "claims" to mean "reads on" when interpreting the listing provision. 347 F.3d 1335, 1343-44 (Fed. Cir. 2003). The Second Circuit later "agree[d]" with that reading. *United Food & Com. Workers Loc. 1776 & Participating Emps. Health & Welfare Fund v. Takeda Pharm. Co. Ltd.*, 11 F.4th 118, 132 (2d Cir. 2021).[2]

The panel rejected this view, but its analysis proceeded from a mistaken premise. The panel believed that to construe "claims" as "reads on" would create "a stunning example of statutory redundancy," because "claiming [would] be 'effectively coterminous' with infringing," and yet the statute requires someone making a listing decision to assess separately whether the patent claims the drug and whether the patent-

[2] The panel seems not to have considered how its understanding of "claims" as "recites" could square with the basic patent-law principle that merely reciting something as part of a patent's claim is not enough to claim that thing as patented subject matter. *See Gen. Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d 1272, 1274 (Fed. Cir. 1992) ("It cannot be said—though it often is, incorrectly, by the uninitiated—that a part of a claim is 'claimed' subject matter.").

holder could reasonably assert infringement. Op. 19-20. The panel thus went searching for other meanings of "claims." Op. 20-27.

There is no "statutory redundancy" to avoid. Both the infringement clause and the "claims the drug" clause are fully operational even when "claims" means "reads on." On one hand, infringement of many types of patents could be asserted even though the patent does not literally read on the drug product. This includes patents on packaging, manufacturing processes, and metabolites. *See* 21 C.F.R. § 314.53(b)(1). Only the "claims the drug" clause excludes those patents from listing. On the other hand, there are reasons infringement could *not* be asserted even if a patent reads on another product. For example, certain conduct in the course of prosecuting the patent will preclude later assertions of infringement. *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 734 (2002) (discussing "prosecution history estoppel.").[3] Only the infringement clause excludes those patents from listing. In truth, then, it is the panel's decision that creates a stunning example of statutory superfluity, by rendering meaningless the phrase "could reasonably be asserted."

Second, the panel improperly discarded the statutory definition of "drug" in interpreting "claims the drug." For purposes of that provision, Congress chose not to

[3] *See also Takeda*, 11 F.4th at 134 ("[T]here are a handful of situations in which a patent may literally 'claim' an invention and yet a cause of action for patent infringement could *not* be reasonably asserted. Two examples are where 'the patentee had learned that the patent was invalid or had been procured by fraud.'").

define "drug" as the active ingredient. It instead defined "drug" as an "article" used to treat disease, or a "component" of an "article" used to treat disease. 21 U.S.C. § 321(g)(1). In contrast, Congress elsewhere defined "drug" as "the active ingredient." 35 U.S.C. § 156(a), (f)(2). The panel disregarded Congress's choice to use different definitions in different places, reasoning that to follow the applicable definition would create tension with the panel's perception of the "statutory context." Op. 28.

The problem here is obvious: Statutory definitions *are* context—and they are binding. *See Van Buren v. United States*, 593 U.S. 374, 387 (2021) ("When a statute includes an explicit definition of a term, we must follow that definition, even if it varies from a term's ordinary meaning." (internal citation omitted)). The panel ignored that interpretive rule. Rather than following the controlling definition—which represents Congress's policy choice—the panel substituted its own preference about what patents should be listed and construed the listing provision accordingly.

II. Rehearing en banc is warranted.

Properly construing the listing provision is exceptionally important—to the Hatch-Waxman regime, to the healthcare and pharmaceutical industry, and to the development and manufacture of innovative therapeutics to meet patient needs. Indeed, Amneal's *amici* at the merits stage emphasized this case's importance, representing that it "could have far-reaching impact." Br. of 14 Professors of Medicine and Law as *Amicus Curiae* 28 (Doc. 60); *see also* Br. of FTC as *Amicus Curiae* 19-20 (Doc.

62) (discussing consequences for various types of patents). That was true then, and it is especially true now that the panel has issued its surprising decision.

A. The panel's decision threatens to upend Hatch-Waxman.

The listing provision is a cornerstone of Hatch-Waxman. The provision "facilitate[s] the resolution of patent-related disputes over pharmaceutical drugs by creating a streamlined mechanism for identifying and resolving patent issues related to … proposed generic products" before the generics launch. *Apotex*, 347 F.3d at 1338. That, in turn, requires a clear and settled understanding of what patents are listable. Unfortunately, the panel's decision works as a drastic rewriting of the statute that will fundamentally alter current listing practices and undermine Congress's aims.

Consistent with statutory text, precedent, and agency guidance, companies have listed patents in the Orange Book that do not have claims that recite the active pharmaceutical ingredient. This includes not only hundreds of device patents, FTC Br. 19-20, but many non-device patents equally important to the safe and effective performance of the drugs for which they are listed. For example, Endo Operations has listed—and enforced—patents on a controlled-release formulation that do not include claims mentioning the active ingredient in the drug product that is the subject of the new drug application. *See Endo Pharm. v. Impax Labs., Inc.*, No. 09-cv-832 (D.N.J. filed Jan. 25, 2008) (asserting U.S. Patent Nos. 5,662,933 and 5,958,456). Under the panel's decision, Endo acted unlawfully—a surprising result given that nobody in the litigation (or in a subsequent FTC investigation) seems to have doubted that the patents were

properly listed. And even a cursory review of the Orange Book shows that there are likely hundreds more formulation patents that are listed but that do not have claims reciting the active ingredient in the drug product that is the subject of the new drug application.

The panel's decision arguably dictates that companies delist all these patents and refrain from listing all similar patents. That undermines Hatch-Waxman, as generic manufacturers would no longer have notice of patents relevant to their decision to develop and launch a generic product; brand manufacturers would no longer have notice of potential products whose unlawful launch could undermine their incentive to innovate; and neither brand nor generic manufacturers would have the ability to resolve patent disputes efficiently before the generic launches at risk of treble damages for willful infringement. GAO, Stakeholder Views on Improving FDA's Information on Patents 15-16 (Mar. 2023), https://www.gao.gov/assets/gao-23-105477.pdf (explaining that Orange Book listings help companies "determine how to design or innovate to avoid infringing," "decide how and when to enter the market with a generic product," and "resolve patent disputes early"). Instead, and under the panel's decision, these patent disputes would have to be litigated through a preliminary injunction, a jury trial, or both—the precise outcome Congress passed Hatch-Waxman to avoid.

B. The panel's decision conflicts with FDA's longstanding regulations and guidance.

FDA's understanding of the listing provision differs radically from the panel's. FDA requires "drug product" patents to be listed, and drug product patents include more than patents that recite the active ingredient. To illustrate, FDA regulations, which were promulgated in 1994 and codified into the statute itself in 2020, require companies to list "drug product" patents *and* "drug substance" patents—where "drug product" is defined as "the finished dosage form" and "drug substance" is defined as the "active ingredient." 21 U.S.C. § 355(b)(1)(A)(viii)(I); 21 C.F.R. § 314.3(b). FDA has repeatedly confirmed this view.[4]

The panel's opinion arguably writes "drug product" patents out of the statute. Under the panel's reasoning, the only listable patents apparently are those that recite the "drug substance" and therefore are drug substance patents. The panel's decision also comes at a time FDA is evaluating, at Congress's direction, the need to clarify how existing rules for Orange Book listings apply to drug-device combination products. FDA, Report to Congress: The Listing of Patent Information in the Orange Book (Dec.

[4] *E.g.*, Letter from FDA to Donald Beers et al., Re: Dkt. No. 2004P-0386/CP1 & RC1, at 4-5 (Nov. 30, 2004) ("Because applications are submitted and approved for drug products, not active ingredients or active moieties, FDA interprets the phrases 'patent which claims the *drug for which the applicant submitted the application*' and 'a patent which claims *such drug*' as meaning patents claiming the *drug product*.").

2021), https://www.fda.gov/media/155200/download. The panel's decision fails to grapple with FDA's view and ongoing effort to study the issue.

Even in a world without *Chevron*, the agency's view matters. *See Loper Bright Enterprises v. Raimondo*, 603 U.S. 369, 403 (2024) ("[Agency] expertise has always been one of the factors which may give an Executive Branch interpretation particular power to persuade."). The agency's view is particularly important here because Congress codified FDA's regulations into the statute, and those regulations constitute FDA's interpretation and implementation of the listing provision, including the "claims the drug" clause. In this instance, FDA's views have literally become part of the law. And the agency's views are all the more important because the industry has been following FDA's guidance for decades. *See id.* at 386 (respect for agency's interpretation "especially warranted" when the interpretation "was issued roughly contemporaneously with enactment of the statute and [has] remained consistent over time"). The full Court should thus reconsider the question, giving appropriate attention to FDA's perspective.

C. The panel's decision will invite a wave of antitrust litigation.

Class action and individual plaintiffs have sued innovative manufacturers on claims that allegedly improper listing decisions violate the antitrust laws. *E.g.*, *In re Lantus Direct Purchaser Anti. Litig.*, No. 16-12652 (D. Mass. filed Dec. 30, 2016); *In re Actos End Payor Anti. Litig.*, No. 13-cv-9244 (S.D.N.Y. filed Dec. 31, 2013). The panel's decision threatens to unleash more such suits, as more listing decisions now could be called into question. To be sure, innovative manufacturers may have a regulatory

compliance defense and may emphasize FDA's prior guidance. But the availability of that defense and the strength of those arguments will not spare them lengthy court battles, expensive discovery, and the threat of treble damages. Sanofi, for example, is still litigating such a case more than seven years after it started. The panel's decision thus could have significant follow-on consequences for innovative manufacturers—and, by extension, for patients.

D. The panel overruled Federal Circuit precedent.

Panels must follow precedent. Fed. Cir. R. 40(a)(4). As noted, in *Apotex*, the Court held that "claims" in the listing provision means "reads on." 347 F.3d at 1343-44. The panel here disagreed, impermissibly overruling *Apotex*.

To be sure, the panel purported to cabin and distinguish rather than overrule. The panel dismissed *Apotex*'s reference to "reads on" as dictum. Op. 25. It also concluded that the reference came in describing the infringement clause rather than the "claims the drug" clause. Op. 26. But that is an implausible reading of *Apotex*.

For starters, *Apotex* held that jurisdiction existed because the parties' dispute turned on two questions of patent law: whether the patent claimed ("read on") the product and whether the patent holder could reasonably assert infringement. 347 F.3d at 1343-44. The reference to "reads on" thus was part of the holding (or was one of two alternative holdings). It cannot be cast aside as dictum.

Nor is it possible to read *Apotex*'s reference to "reads on" as describing the infringement clause. Here is the key sentence: "[A] patent must be listed if it contains

a product claim that reads on the drug that is the subject of the NDA or, with respect to a method of use claim, if it is reasonable to conclude that a person who makes, uses, or sells the drug would infringe the claim." *Apotex*, 347 F.3d at 1344. The Court clearly used "reads on" to describe what it means to "claim the drug," not to describe when "infringement could reasonably be asserted."

At a minimum, whether the panel overruled *Apotex* is a close enough question that the full Court should consider it. It bears repeating that the Second Circuit has read *Apotex* as holding that "claims" means "reads on." *Takeda*, 11 F.4th at 132. The panel's decision cannot square with that understanding.

CONCLUSION

Sanofi respectfully requests that the Court grant rehearing en banc.

Dated: February 4, 2025

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5), the type-style requirements of Fed. R. App. P. 32(a)(6), and the type-volume limitations of Fed. Cir. R. 40(i)(3), because it is proportionally spaced, has a typeface of 14-point Garamond font, and contains 2,599 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f) and Fed. Cir. R. 32(b)(2).

Dated: February 4, 2025

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CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing on the CM/ECF system, which will send a notification of such filing to the appropriate counsel.

Dated: February 4, 2025

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