No. 24-1061

United States Court of Appeals for the Federal Circuit

ALLERGAN USA, INC., ALLERGAN HOLDINGS UNLIMITED CO., ALLERGAN PHARMACEUTICALS INTERNATIONAL LTD., JANSSEN PHARMACEUTICA NV, EDEN BIODESIGN, LLC,

Plaintiffs-Appellants,

v.

MSN LABORATORIES PRIVATE LTD., MSN PHARMACEUTICALS, INC., SUN PHARMACEUTICAL INDUSTRIES LIMITED,

Defendants-Appellees,

Appeal from the United States District Court for the District of Delaware in Nos. 1:19-cv-01727-RGA, 1:20-cv-01479-RGA, 1:21-cv-01064-RGA, 1:21-cv-01065-RGA, Judge Richard G. Andrews.

BRIEF FOR THE ASSOCIATION FOR ACCESSIBLE MEDICINES AS AMICUS CURIAE IN SUPPORT OF SUN PHARMACEUTICAL INDUSTRIES LIMITED'S PETITION FOR REHEARING EN BANC

Michael E. Joffre
Kristina Caggiano Kelly
STERNE KESSLER GOLDSTEIN & FOX PLLC
1101 K Street, NW
Washington, DC 20005
(202) 371-2600

Counsel for Amicus Curiae

October 10, 2024

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF INTEREST

Case Number 2024-1061

Short Case Caption Allergan USA, Inc. v. MSN Laboratories Private Ltd.

Filing Party/Entity Association for Accessible Medicines.

Instructions:

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Date: 10/10/2024

Signature: /s/ Michael E. Joffre

Name: Michael E. Joffre

1. Represented Entities. Fed. Cir. R. 47.4(a)(1).	**2. Real Party in Interest.** Fed. Cir. R. 47.4(a)(2).	**3. Parent Corporations and Stockholders.** Fed. Cir. R. 47.4(a)(3).
Provide the full names of all entities represented by undersigned counsel in this case.	Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities. ☑ None/Not Applicable	Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities. ☑ None/Not Applicable
Association for Accessible Medicines.		

☐ 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).

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

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☑ None/Not Applicable ☐ Additional pages attached

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INTEREST OF *AMICUS CURIAE*[1]

The Association for Accessible Medicines (AAM) is a nonprofit, voluntary association representing manufacturers and distributors of generic and biosimilar medicines and bulk active pharmaceutical chemicals, as well as suppliers of other goods and services to the generic pharmaceutical industry. AAM's members provide patients with access to safe and effective generic and biosimilar medicines at affordable prices. AAM's core mission is to improve the lives of patients by providing timely access to safe, effective, and affordable prescription medicines.

Amicus and its members have a significant interest in the issues raised by this appeal: namely, ensuring that a patentee may not exploit formalisms to circumvent the basic rule that an inventor may obtain only one patent for an invention and must adequately describe that invention. *En banc* review should be granted and the panel's decision should be reversed.

INTRODUCTION

This Court's obviousness-type double patenting (ODP) jurisprudence has long stood for a basic principle: a patentholder cannot obtain a patent claim on an obvious variant of an existing claim. The panel decision here turns that basic ODP

[1] No counsel for any party authored this brief in any part, and no party, counsel, or person other than *amicus*, its members, and its counsel contributed money to fund the preparation and submission of this brief. *See* Fed. R. App. P. 29(a)(4)(E).

doctrine on its head in two ways, either of which is sufficient to grant *en banc* review.

First, the panel's decision creates an apparently inadvertent but enormous loophole through which ***multiple, separate entities*** will be able to own—and enforce—admittedly obvious variations of the ***same patent claim***. This Court's ODP jurisprudence was designed for decades to foreclose such a scenario, *see In re Hubbell*, 709 F.3d 1140, 1145 (Fed. Cir. 2013) (ODP prevents "multiple infringement suits by different assignees asserting essentially the same patented invention"). Yet the panel's decision expressly contemplates it. By categorically removing the applicability of ODP from certain patents, the panel is no longer requiring a terminal disclaimer, which requires patents to be commonly owned throughout their lives. Instead, under the panel's decision, patentholders can now separate ownership and licensing of patent claims that are indisputably obvious variants of one another. Beyond undermining a fundamental tenet of ODP, the panel's decision provides a playbook for brand-name drug companies to unlawfully extend their monopolies and deprive patients and taxpayers of less expensive generic and biosimilar alternatives by separating, via ownership or licensing, obvious variants of the same invention. Absent review by this Court, other drug patentholders are sure to follow the roadmap endorsed by the panel's decision.

Those concerns are particularly acute here. Indeed, the well-documented prevalence of patent thickets and use of continuation strategies in the pharmaceutical context make ODP especially important for generic and biosimilar pharmaceutical companies to challenge overextended patent monopolies. *See, e.g.*, *Sun Pharm. Indus., Ltd. v. Eli Lilly & Co.*, 611 F.3d 1381, 1389 (Fed. Cir. 2010) (affirming that claims to a method of treatment were invalid for ODP); *Pfizer, Inc. v. Teva Pharms. USA, Inc.*, 518 F.3d 1353, 1363 (Fed. Cir. 2008) (affirming that claims to a drug were invalid for ODP); *AbbVie Inc. v. Mathilda & Terence Kennedy Inst. of Rheumatology Trust*, 764 F.3d 1366, 1373 (Fed. Cir. 2014) (same).

Second, the panel's decision improperly elevates filing and issuance dates over expiration dates, which have always been the critical factor in assessing ODP. And with good reason—"[t]he double patenting doctrine has always been implemented to effectively uphold th[e] principle . . . that when a patent expires, the public is free to use not only the same invention claimed in the expired patent but also obvious or patentably indistinct modifications of that invention." *Gilead Scis., Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208, 1214 (Fed. Cir. 2014). By allowing issuance dates to trump expiration dates, the panel forecloses patients and the public from having access to admitted obvious variants of the same invention

and extended the power of patent term adjustment ("PTA") in a way that Congress never intended.

The panel erred in an additional way that is sufficient to warrant *en banc* review. Specifically, the panel relegated an optional limitation as entirely superfluous for purposes of evaluating the written-description requirement. Like ODP, the written-description requirement similarly prevents the extension of patent monopolies beyond the scope of the invention that the patent applicant possessed. Here, the district court correctly found that the asserted claims lacked written description. The panel opinion reversing that decision upends the delicate balance of interests and again provides a specific roadmap for brand-name pharmaceutical companies to game invalidty: a limitation that may well be critical for avoiding prior art is "optional" for written description purposes. That result is untenable.

The petition should be granted.

ARGUMENT

The panel opinion eliminates two long-standing doctrines of patent law, both of which are essential to the balance of interests achieved by those doctrines. First, the panel opinion erroneously exempts earlier-filed patents from ODP challenges in view of a later-filed duplicative progeny. Second, the panel opinion erroneously

eliminates the written-description requirement for express claim limitations that are recited as "optional."

I. The Panel Eliminates a Crucial Component of Obviousness-type Double Patenting

In an attempt to preserve the patent term adjustment ("PTA") awarded to a first-filed patent, the panel created a giant loophole in ODP jurisprudence that cannot be squared with decades of this Court and the Supreme Court's jurisprudence. Under the panel decision, ODP categorically does not apply to first-filed, first-issued patents despite being admitted obvious variants of their later-expiring progeny.

A. The Panel's Elevation of Issuance Dates and PTA are Contrary to Statute and ODP Jurisprudence

The panel erred by elevating issuance and filing dates over expiration dates. By doing so, the panel effectively relegated *Gilead* and *Cellect*—which appropriately aligned expiration dates for obvious variant claims notwithstanding PTA—to niche cases that are inapplicable in the vast majority of circumstances. That result is irreconcilable with the text of the PTA statute and with the legislative history. Indeed, Congress expressly recognized the grant of PTA is not absolute, and critically, § 154(b) expressly excludes PTA for any patent "the term of which ***has been disclaimed*** beyond a specified date." 35 U.S.C. § 154(b)(2)(B) (emphasis added). Thus, unlike PTE, PTA has not now and has never been an absolute

protection that could somehow insulate admittedly obvious claims. Even worse, it is subject to gaming and improper calculation, as a number of Senators have recently recognized.[2]

These gaming concerns are directly relevant here. Indeed, the applicant prosecuted claims to a composition first, incurred delays, was awarded PTA for its first-issued patent, and thereafter chose to prosecute ***admittedly obvious*** variants of the claims that issued quickly and expired first. *See* Slip Op. at 19-20. The panel categorically declared that "ODP does not apply" to this common fact pattern. *Id.* at 19. The panel reasoned that a terminal disclaimer filed in the already-issued parent would disclaim "only PTA." *Id.* at 20. It calls this result "untenable"—apparently concerned with the equities of reneging on PTA to which the patentee was found entitled. *Id.* This concern is misplaced.

Here, as frequently occurs, the patentee leveraged its prosecution of the first-filed application to secure expedient issuance of multiple progeny, including claims drafted long after the original application was filed and *specifically targeted* a competing product. Despite their effective shorter term, these later patents are

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[2] Durbin, Senate Democrats Urge USPTO, Drug Companies to Address Errors in Patent Term Adjustment to Prevent Unwarranted Pharma Monopolies, United States Senate Committee on the Judiciary (Sept. 18, 2024) https://www.judiciary.senate.gov/press/dem/releases/durbin-senate-democrats-urge-uspto-drug-companies-to-address-errors-in-patent-term-adjustment-to-prevent-unwarranted-pharma-monopolies.

highly valuable—or else the patentee would not seek them. The extent to which they expire before the adjusted term of the first-filed patent merely reflects the fact that prosecution of the parent paved the way for rapid expansion of the family. That the patentee may need to surrender some of its PTA on the parent is a fair price and can be factored into the cost-benefit analysis of pursuing serial patent applications in the first place. *See In re Cellect, LLC,* 81 F.4th 1216, 1228 (Fed. Cir. 2023) (cert. denied) ("Terminal disclaimers were the solution to the problems created by the multiple challenged patents.").

B. The Panel's Failure to Consider Alienation Creates an Enormous Loophole in ODP Jurisprudence

Under the panel's decision, admittedly obvious first-filed, first-issued patents are no longer subject to ODP invalidation. Because they are not subject to ODP, a terminal disclaimer would no longer be required. As part of a terminal disclaimer, the patent applicant provides that the patent subject to ODP will share common ownership with the patent forming the basis of the challenge and share a common patent term. *See* 37 C.F.R. § 1.321(c)(3) (providing that the subject patent "shall be enforceable only for and during such period that said patent is commonly owned with the application or patent which formed the basis for the judicially created double patenting"); *see also id.* at § 1.321(d)(3). The purpose there is simple: only a single patentholder should be able to enforce obvious variants of the same claim. By contrast, under the panel's decision, an obvious first-filed patent

and its progeny could be assigned to two different entities—subjecting generic or biosimilar manufacturers to harassment from multiple lawsuits by multiple branded or licensed companies over effectively the same invention. This result is far more "untenable" than the result that the panel was trying to avoid. Slip Op. at 20.

Indeed, it was this non-alienation principle that has been a critical bedrock of ODP jurisprudence for nearly 100 years. "[S]plitting up of one indivisible right into two and subjecting the infringer to suits by two different owners of the right infringed justified applying the defense of double patenting…." *Sandy MacGregor Co. v. Vaco Grip Co.*, 2 F.2d 655, 657 (6th Cir. 1924) (citing *Underwood v. Gerber,* 149 U.S. 224 (1893)). The non-alienation principle applies regardless of when the patents are filed, issue, or expire. *See* 150 Cong. Rec. S7521 (daily ed. June 25, 2004) (explaining that double patenting is not allowed even "if the patents are filed on the same day, issue on the same day and expire on the same day") (statement of Sen. Hatch); *Underwood*, 149 U.S. at 225–29. And anti-alienation applies with good reason: competitors would need to take multiple licenses or defend against successive lawsuits for practicing the same invention—exactly the situation that ODP was designed to prevent. *Underwood*, 149 U.S. at 225-29; *Hubbell*, 709 F.3d at 1145; *In re Fallaux*, 564 F.3d 1313, 1319 (Fed. Cir. 2009).

The panel, however, critically failed to consider alienation. All of the policy analysis and logic underpinning its decision relies on the impact of terminal

disclaimers on the *term* of a patent monopoly. Slip Op. at 13-20. The opinion is entirely silent on the *other* important function of terminal disclaimers: ensuring co-ownership of duplicative patents. *See* 37 C.F.R. § 1.321(c)(3). The panel's focus on PTA thus blinded it to the consequences of permitting alienation. The panel's failure to consider alienation are grounds alone for granting *en banc* review.

II. The Panel's Treatment of "Optional" Violates 35 U.S.C. § 112.

The panel opinion creates a new rule that limitations recited as "optional" are *per se* superfluous. Slip Op. at 23. Under the panel's new rule, the limitation need not be described in the specification at all. *Id.* The panel's reasoning is that the word "optional" denotes "only two options, present or absent" and captures "both possibilities." *Id.* at 24. While that assessment may be correct for some claimed compositions, it was not here.

Specifically, the panel misidentified the written-description question as follows: "the issue is whether the inventors had possession of a formulation that lacked a component that is not claimed, or only optional." *Id.* at 22. But the issue is *not* whether the inventors were in possession of a formulation that merely *lacked* the component, but rather, possessed a formulation in which a component recited as optional was *actually optional*, i.e., a formulation in which the ingredient could be included or omitted and the formulation would work for its intended purpose either way.

Compounding that error, the panel held that "the word 'optional' does not indicate a component that must be specifically described, for § 112 purposes,." Slip Op. at 23. But patent parlance already provides a well-understood term for claiming a compound that may or may not include other components: "comprising."

Here, the claim recites a "pharmaceutical tablet *comprising*: about 75 mg of [eluxadoline];…*optionally*, a glidant and/or lubricant. Appx96(36:33-43) (emphases added). Accordingly, the claim includes eluxadoline and additional unrecited excipients. The specification identifies some of these unrecited excipients. Appx84(12:38-51); Appx5833-5835(118:12-120:2); Diss. 3. In contrast, the claim *must* accommodate, but not require, a glidant.

By treating the glidant as an ingredient that may be present or absent and need not be described—like any unrecited component in a comprising claim—the panel reads out the "optionally" limitation entirely. Slip Op. at 23-24. This violates longstanding precedent that "it is highly disfavored to construe terms in a way that renders them void, meaningless, or superfluous.'" *Intel Corp. v. Qualcomm Inc.,* 21 F.4th 801, 810 (Fed. Cir. 2021). The panel opinion here not only takes this disfavored path but makes it the *per se* consequence of claims using the term "optionally." Slip Op. at 22-23. That matters for written description—by treating the "optionally a glidant" limitation as superfluous, the panel creates a loophole to

the written-description requirement. And it removes from the market an innovative new generic formulation that does not need a glidant (like Sun did here). The written-description requirement should not be malleable in a manner that enables brands to craft inconsistent arguments that prevent generic and biosimilar products from coming to market expeditiously.

CONCLUSION

The Court should grant the petition.

DATE: October 10, 2024

Respectfully submitted,
/s/ Michael E. Joffre

Michael E. Joffre
Kristina Caggiano Kelly
STERNE KESSLER GOLDSTEIN & FOX PLLC
1101 K Street, NW
Floor 10
Washington, DC 20005
(202) 371-2600

Counsel for Amicus Curiae

FORM 19. Certificate of Compliance with Type-Volume Limitations

Form 19
July 2020

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATIONS

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