**No. 2024-1061**

*In the*

# 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, 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 OF *AMICI CURIAE* ALVOGEN PB RESEARCH & DEVELOPMENT LLC AND INARI AGRICULTURE, INC. IN SUPPORT OF APPELLEES' PETITION FOR REHEARING EN BANC

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# 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** Alvogen PB Research & Development LLC

**Instructions:**

1. Complete each section of the form and select none or N/A if appropriate.
2. Please enter only one item per box; attach additional pages as needed, and check the box to indicate such pages are attached.
3. In answering Sections 2 and 3, be specific as to which represented entities the answers apply; lack of specificity may result in non-compliance.
4. Please do not duplicate entries within Section 5.
5. Counsel must file an amended Certificate of Interest within seven days after any information on this form changes. Fed. Cir. R. 47.4(c).

I certify the following information and any attached sheets are accurate and complete to the best of my knowledge.

Date: 10/10/2024

Signature: /s/Jeremy Lowe

Name: Jeremy Lowe

| **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.<br><br>☑ 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.<br><br>☐ None/Not Applicable |
| Alvogen PB Research & Development LLC | | See attached |
| Inari Agriculture, Inc. | | None |
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☑ 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)?

☐ Yes (file separate notice; see below) ☐ No ☑ N/A (amicus/movant)

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).

**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

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**3. Parent Corporations and Stockholders** Fed. Cir. R. 47.4(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.

Alvogen PB Research & Development LLC:

Alvogen Lux Holdings S.a.r.l. (Luxembourg) and Aztiq Pharma Partners S.a.r.l. (Luxembourg) are the parent companies of New Alvogen Group Holding, Inc., which is the parent company of Alvogen Group Inc., which is the parent company of Alvogen Pharma US, Inc., which is the parent company of Alvogen PB Research & Development LLC. No publicly held companies own 10% or more stock in Alvogen PB Research & Development LLC.

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# TABLE OF ABBREVIATIONS

| Abbreviation | Description |
|---|---|
| AIA | Leahy-Smith America Invents Act, 125 Stat. 285, 287 (2011) |
| Alvogen | Alvogen PB Research & Development LLC |
| ANDA | Abbreviated New Drug Application |
| CREATE Act | Cooperative Research and Technology Enhancement Act of 2004, Pub. L. No. 108-453, 118 Stat. 3596 (2004) |
| FDA | U.S. Food and Drug Administration |
| ODP | Obviousness-Type Double Patenting |
| Opinion | Opinion for the Court dated August 13, 2024 in *Allergan USA, Inc. v. MSN Laboratories Private Ltd.*, Appeal No. 2024-1061 |
| Hatch-Waxman Act | Drug Price Competition and Patent Term Restoration Act, Public Law 98-417 (1994) |
| Inari | Inari Agriculture, Inc. |
| MPEP | Manual of Patent Examining Procedure (9th ed. Rev 10.2019, June 2020) |
| PTA | Patent Term Adjustment |
| PTE | Patent Term Extension |
| PTO | U.S. Patent and Trademark Office |
| USDA | U.S. Department of Agriculture |

| **Abbreviation** | **Description** |
|---|---|
| URAA | Uruguay Round Agreements Act, Pub. L. No. 103-46, 108 Stat. 4809, 4984 (1994) |

## INTEREST OF AMICUS CURIAE

This brief focuses solely on the Opinion's holding that obviousness-type double patenting is not applicable in this case.

Amicus curiae Alvogen PB Research & Development files ANDAs seeking FDA approval to market pharmaceutical products. Alvogen is engaged in several patent lawsuits under the Hatch-Waxman Act at any given time. The rehearing presents a unique opportunity to clarify "loss of exclusivity" based on the end of patent term, which typically coincides with generic competition and lower prices. *See* Cong. Budget Off., Prescription Drugs: Spending, Use, and Prices 20 (2022). Patent terms that extend beyond the statutory grant forestall generic competition and maintain high prices.

Amicus curiae Inari Agriculture, Inc.[1] pioneers gene editing technology for food crops. Inari files numerous ex parte reexaminations targeting large patent families cultivated by the dominant industry firms. American farmers and small innovators continue to face the threat of

[1] Alvogen and Inari submit this brief with the consent of Appellees, and Appellants do not oppose it. Fed. R. App. P. 29(a)(2). No counsel for any party authored this brief in any part, and no party, counsel, or person other than Alvogen and Inari contributed money to fund the preparation and submission of this brief. Fed. R. App. P. 29(a)(4)(E).

"patent-holding firms ... delay[ing] competition" even "after patents have expired." *More and Better Choices for Farmers*, USDA Agricultural Marketing Service, 3 (March 2023), https://www.ams.usda.gov/sites/default/files/media/SeedsReport.pdf; *see also* Executive Order 14036, Promoting Competition in the American Economy, 86 Fed. Reg. 36987, 36993 (July 14, 2021) (voicing concerns about patents that "unnecessarily reduce competition in seed and other input markets beyond that reasonably contemplated by the Patent Act."). The fundamental right to practice expired patent claims is thus vital to protect American farmers and innovative start-ups alike.

## INTRODUCTION

The Opinion allows for the first time common ownership of two patents with different expiration dates that claim obvious variants of the same invention. Section 101 prevents this outcome—"a patent." The other relevant statutory provisions, namely Sections 121, 154, 156 and 253, do not support a first-filed, first-issued, last-expiring exception to ODP.

In addition, the Opinion finds no support in legislative history, which includes policy statements that instruct the PTO to reject claims on the basis

of ODP even "if the patents are filed on the same day, issue on the same day and expire on the same day." 150 Cong. Rec. S7521 (daily ed. June 25, 2004) (statement of Sen. Hatch).

Finally, the Opinion is not compatible with the basic tenets of ODP because it (1) extends the term of the earlier-expiring patent beyond its statutory grant, (2) allows for the common ownership of duplicative patents that are not united by a terminal disclaimer, and (3) denies the public its expectation that when the earlier patent expires, the invention claimed in that patent becomes part of the public domain.

Respectfully, the Court should grant the Petition for Rehearing En Banc.

## ARGUMENT

### A. The Statute Does Not Support the Opinion

First, the Opinion finds no support in Section 101, "which states that an inventor may obtain 'a patent' (i.e., a single patent) for an invention." *In re Cellect LLC*, 81 F. 4th 1216, 1226 (Fed. Cir. 2024), *cert. denied sub nom*, *Cellect, LLC v. Vidal*, No. 23-1231, 2024 WL 4426602 (U.S. Oct. 7, 2024); 35 U.S.C. § 101. The Opinion results in two patents for the same invention.

Second, Section 253's disclaimer is the only statutory mechanism available to reconcile ODP. 35 U.S.C. § 253. The terminal disclaimer cuts back term from the later patent; it does not add term to the earlier patent. The disclaimer unites patents in a way that "is tantamount for all practical purposes to having all the claims in one patent." *In re Van Ornum*, 686 F.2d 937, 948 (C.C.P.A. 1982) (quoting *Application of Braithwaite*, 379 F.2d 594, 601 (C.C.P.A. 1967)). Here, the claims are not united by a terminal disclaimer and cannot be said to exist "in one patent." *Id*.

Third, Section 154's definition of term contains no language that would permit one patent to benefit from the PTA of another patent. 35 U.S.C. § 154. Rather, this section upholds ODP because it prevents PTA from extending beyond the terminal disclaimer. *See Cellect*, 81 F. 4th at 1229. Here, the Opinion results in a child patent that, having received no PTA, now benefits from its parent's PTA.

Fourth, Section 121's safe harbor is not an exception to ODP because, by definition, divisional claims cover an "independent and distinct" invention. *Studiengesellschaft Kohle mbH v. N. Petrochemical Co.*, 784 F.2d 351, 358-60 (Fed. Cir. 1986) (Newman, J., concurring) (citing pre-1952 cases) *cited*

*with approval by Boehringer Ingelheim Int'l GmbH v. Barr Lab'ys, Inc.*, 592 F.3d 1340, 1350 (Fed. Cir. 2010); 35 U.S.C. § 121. Here, the continuation claims do not invoke Section 121 and remain prohibited by ODP.

Finally, while Section 156 can hypothetically extend duplicative patents that expire before the PTE expires, 35 U.S.C. § 156, its application still remains true to ODP. *See Merck & Co. v. Hi-Tech Pharmacal Co.*, 482 F.3d 1317, 1323 (Fed. Cir. 2007) ("The purpose of the terminal disclaimer—to prevent extension of patent term for subject matter that would have been obvious over an earlier filed patent remains fulfilled … [and] [a]t the same time, the purpose of the patent term extension … is also satisfied.").

Thus, the statute does not clearly recognize any exception to ODP. The legislative history does not either.

**B. The Legislative History Does Not Support the Opinion**

The legislative history over the past 30 years makes clear that (1) the main purpose of ODP is to prevent a patentee from owning duplicative patents with different expiration dates, and (2) a terminal disclaimer is the only way to reconcile ODP by uniting the patents as one.

In the Patent Law Amendments Act of 1984, incorporating the Hatch-Waxman Act, the Committee Report states that it "expects" the PTO to continue the prohibition against ODP:

> The Committee expects that the [PTO] will reinstitute in appropriate circumstances the practice of rejecting claims in commonly owned applications of different inventive entities on the ground of double patenting. *This will be necessary in order to prevent an organization from obtaining two or more patents with different expiration dates covering nearly identical subject matter.* In accordance with established patent law doctrines, double patenting rejections can be overcome in certain circumstances by disclaiming the terminal portion of the term of the later patent, thereby eliminating the problem of extending patent life.

130 Cong. Rec. H10,527 (1984) (emphasis added); *see also In re Hubbell*, 709 F.3d 1140, 1153 (Fed. Cir. 2013) (Newman, J., dissenting) (discussing the legislative history). The "problem" the Committee references is the later-expiring patent "extending patent life" of the earlier-expiring patent. 130 Cong. Rec. H10,527. The Committee emphasizes that ODP is necessary "to prevent an organization from obtaining two or more patents with different expiration dates covering nearly identical subject matter." *Id*. The

Committee acknowledges the necessity of a terminal disclaimer in order to reconcile ODP. *Id.*

The CREATE Act of 2004 uses ODP as its backdrop. The CREATE Act narrows the scope of prior art for joint research efforts and, in doing so, allows for the broader application of ODP. Cooperative Research and Technology Enhancement (CREATE) Act of 2004, Pub. L. No. 108-453, § 2, 118 Stat. 3596 (2004) (codified as amended at 35 U.S.C. § 103(c) (2018)). The legislative record considers ODP "a matter of public policy" and reaffirms its continued application:

> The double patenting doctrine exists as a matter of public policy to prevent a multiplicity of patents claiming patentably indistinct inventions from becoming separately owned and enforced. Thus, it applies to situations where multiple patents have issued, even if the patents are filed on the same day, issue on the same day and expire on the same day.

150 Cong. Rec. S7521 (daily ed. June 25, 2004) (statement of Sen. Hatch). The Committee Report states that the ODP prohibition "shall apply to such patents" benefiting from the CREATE Act. H.R. Rep. No. 108-425, at 6 (2004). And ODP applies regardless of whether the patents "are filed on the same day, issue on the same day and expire on the same day." 150 Cong. Rec.

S7521. This record highlights the importance of the non-alienation principle (discussed below) and directs the application of ODP to commonly owned, duplicative patents regardless of their filing or issuance date.

The uncodified AIA § 3(b)(2) incorporates ODP by reference to the legislative history of the CREATE Act:

> The enactment … is done with the same intent to promote joint research activities that was expressed, including in the legislative history, through the enactment of the … "'CREATE Act."

Leahy-Smith America Invents Act, § 3(b)(2), 125 Stat. 285, 287 (2011); *see also* Joe Matal, *A Guide to the Legislative History of the American Invents Act: Part I of II*, 21 FED. CIR. B. J. 465, 486 (2012) ("One significant feature of the legislative history of the CREATE Act, effectively given the force of law by section 3(b)(2) of the AIA, is its assurance that double-patenting rules will apply to patent-disclosure subject matter and claimed inventions deemed to be commonly owned pursuant to pre-AIA § 103(c)."). Thus, ODP continues to serve as the backdrop even for the most recent statutory amendments.

### C. The Case Law Does Not Support the Opinion

One principle underlying ODP is to prevent the "unjustified timewise extension" of a patent term. *Van Ornum*, 686 F.2d at 943-44. This principle

emerged from the Supreme Court's recognition that "a new and later patent for the same invention would operate to extend or prolong the monopoly beyond the period allowed by law." *Miller v. Eagle Mfg. Co.*, 151 U.S. 186, 198 (1894). In *Miller*, the prohibition applied to the later-expiring patent. The Opinion does not follow *Miller* in this regard.

Before the URAA, applying *Miller* to the filing date was ineffective inasmuch as the term extended from issuance. Similarly, applying *Miller* to the issuance date post-URAA is ineffective since the term extends from the filing date. Whether pre- or post-URAA, *Miller* can best be understood and consistently applied in the context of expiration dates. Thus, in both *Gilead Scis., Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208, 212 (Fed. Cir. 2014) and *AbbVie Inc. v. Mathilda & Terence Kennedy Inst. of Rheumatology Trust*, 764 F.3d 1366 (Fed. Cir. 2014), the Court understood *Miller* in the context of expiration dates, not filing or issuance dates. *Gilead*, 753 F.3d at 1217; *AbbVie*, 764 F.3d at 1373-74. And in both *Gilead* and *Abbvie*, the Court at least implicitly recognized that the full statutory term of the invention necessarily exists in its entirety in the earliest-expiring patent.

Another principle underlying ODP is non-alienation, which prevents "multiple infringement suits by different assignees asserting essentially the same patented invention." *Hubbell*, 709 F.3d at 1145 (citing *In re Fallaux*, 564 F.3d 1313, 1319 (Fed. Cir. 2009) (stating that a principle of the ODP doctrine is to prevent "harassment by multiple assignees")). This principle emerged from the Supreme Court's decision in *Underwood v. Gerber*, 149 U.S. 224 (1893), as summarized by the Sixth Circuit, that "splitting 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*); *see Van Ornum*, 686 F.2d at 945 (similarly summarizing *Underwood*).

The non-alienation principle is a "matter of public policy" and applies even "if the patents are filed on the same day, issue on the same day and expire on the same day." 150 Cong. Rec. S7521 (daily ed. June 25, 2004) (statement of Sen. Hatch); *see also Underwood*, 149 U.S. at 225-29. This necessarily envisions a terminal disclaimer in the later patent because otherwise the terminal disclaimer would expire with the earlier patent. *Eli*

*Lilly*, 251 F.3d at 967 n.5 ("A patent owner cannot avoid double patenting by disclaiming the earlier patent."). Therefore, the non-alienation principle requires common ownership throughout the entire period of enforceability and, consequently, necessitates simultaneous expiration of all commonly owned duplicative patents. *See Cellect*, 81 F. 4th at 1230 ("[T]he Board did not err in determining that a risk of separate ownership existed and, even in the absence of separate ownership, that a terminal disclaimer would have been required to ensure common ownership.").

A third principle is that "[t]he public should … be able to act on the assumption that upon the *expiration* of the patent it will be free to use not only the invention claimed in the patent but also modifications or variants which would have been *obvious* to those of ordinary skill in the art at the time the invention was made …." *In re Longi*, 759 F.2d 887, 892-93 (Fed. Cir. 1985) (emphases in original) (quoting *Application of Zickendraht*, 319 F.2d 225, 232 (C.C.P.A. 1963) (Rich, J., concurring)).

The Opinion does not permit the public to "act on the assumption" but rather burdens it with determining whether the invention has multiple terms. *Id*. In other words, the Opinion's reliance on the issuance date does

not preserve the "bargained-for right held by the public." *Gilead*, 753 F.3d at 1212, citing *Miller*, 151 U.S. at 197-98. Only the expiration date of the earlier patent provides the public with a stable benchmark that is not "vacillati[ng] … arbitrary, [and] uncertain." *Id*. at 1216. The Opinion is at odds with this principle.

### D. Applicants Maintain Control

Finally, applying ODP does not force applicants to choose between risking invalidation and filing a terminal disclaimer as a preemptive measure. In response to an ODP rejection, applicants can cancel or amend the duplicative claims. They can demonstrate that the inventions are independent and distinct. Or they can establish that the combination of prior art references is not proper under Sections 102/103.

It is always an applicant's choice whether to prosecute duplicative continuations. It is their choice whether to pay the issuance fee. And it is their choice to file a terminal disclaimer before the earlier patent expires. In fact, the PTO provides applicants with the estimated PTA prior to issuance. *See* MPEP § 2733. Thus, if an applicant wishes to strategically allow the continuation patent to issue, and therefore disrupt the term of an issued

patent, they are free to make that choice. But under no circumstances are they compelled to do so.

## CONCLUSION

For the reasons stated herein and in the Appellees' brief, the Court should grant the Petition for Rehearing En Banc.

Dated: October 10, 2024

Respectfully submitted,

/s/ Jeremy Lowe

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**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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