2024-1401

United States Court of Appeals for the Federal Circuit

ACADIA PHARMACEUTICALS INC.,

Plaintiff-Appellee,

– v. –

AUROBINDO PHARMA LTD., AUROBINDO PHARMA USA, INC., TEVA PHARMACEUTICALS USA, INC.,

Defendants,

MSN LABORATORIES PRIVATE LTD., MSN PHARMACEUTICALS, INC.,

Defendants-Appellants.

On Appeal from the United States District Court for the District of Delaware in No. 1:20-cv-00985-GBW

CORRECTED BRIEF OF *AMICUS CURIAE* INARI AGRICULTURE, INC. IN SUPPORT OF PETITION FOR REHEARING *EN BANC*

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AUGUST 29, 2025

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UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF INTEREST

Case Number 2024-1401

Short Case Caption Acadia Pharms. Inc. v. Aurobindo Pharma Ltd.

Filing Party/Entity Inari Agriculture, Inc.

Instructions:

1. Complete each section of the form and select none or N/A if appropriate.
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I certify the following information and any attached sheets are accurate and complete to the best of my knowledge.

Date: 08/22/2025 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. ☑ 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
Inari Agriculture, Inc.		See attached

☑ 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

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

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.

Inari Agriculture, Inc.:

Inari Agriculture, Inc. does not have any parent companies. No publicly held companies own 10% or more stock in Inari Agriculture, Inc.

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Abbreviation	Description
AIA	Leahy-Smith America Invents Act, 125 Stat. 285, 287 (2011)
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
Hatch-Waxman Act	Drug Price Competition and Patent Term Restoration Act, Public Law 98-417 (1994)
IP	Intellectual Property
MPEP	Manual of Patent Examining Procedure (9th ed., Rev. 01.2024)
PTA	Patent Term Adjustment
PTE	Patent Term Extension or Hatch-Waxman Extension
USPTO or PTO	U.S. Patent and Trademark Office
URAA	Uruguay Round Agreements Act, Pub. L. No. 103-46, 108 Stat. 4809, 4984 (1994)
USDA	U.S. Department of Agriculture

INTEREST OF AMICUS CURIAE

Inari Agriculture, Inc.[1] ("Inari") was founded in 2016 to develop gene-editing technology that selectively improves agronomic traits—raising yields while reducing inputs such as water and fertilizer. Inari partners with independent seed companies to deliver improved seeds built on its platform. Inari respects valid patent rights and holds pioneering patents of its own; it also advances the state of the art by combining Inari's technology with earlier developments once the relevant patents expire.

A 2023 USDA report warns that large patent-holding firms in agriculture can "delay competition after patents have expired," restraining choice and raising costs across agricultural markets.[2] That same report notes that 95% of corn IP (utility and plant variety) and 84% of soybean IP are controlled by the Big Four—an extreme concentration of power over foundational plant technologies.[3] The prior

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

[2] *More and Better Choices for Farmers*, USDA Agricultural Marketing Service, at 8, 53 (March 2023), https://www.ams.usda.gov/sites/default/files/media/SeedsReport.pdf.

[3] *Id*. at 43, 77, 80. The Big Four are Corteva (Dow and DuPont), Bayer (Monsanto), Syngenta (ChemChina-Sinochem), and BASF. Between 2002 and 2022, these four firms collectively published over 44,000 patents in food and

administration also voiced concerns about patents that "unnecessarily reduce competition in seed and other input markets beyond that reasonably contemplated by the Patent Act."[4]

Inari believes ODP is a critical statutory safeguard that cuts through the patent thickets cultivated by international conglomerates. Without ODP, powerful incumbents, including foreign state-owned firms,[5] can harm American farmers, inhibit new market entrants, and weaponize the patent system to preserve their dominance over the U.S. seed supply. The damage spreads from field to food aisle—American farmers face inflated seed prices, and American families face higher grocery bills.

Inari actively opposes such predatory practices through policy advocacy,

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agriculture. GlobalData, Global: Top Food and Agriculture Patents Holders (2002–2022), GlobalData-Data Insights (May 12, 2024), https://www.globaldata.com/data-insights/macroeconomic/global-top-food-and-agriculture-patents-holders-in-the-sector-2131915/.

[4] *Executive Order 14036, Promoting Competition in the American Economy*, 86 Fed. Reg. 36987, 36993 (July 14, 2021) (revoked August 13, 2025).

[5] "The ultimate parent of Syngenta AG is Sinochem Holdings Co. Ltd. (Sinochem Holdings), a state-owned enterprise incorporated under the laws of China …." Syngenta AG, *Financial Report 2024* at 20 (Mar. 6, 2025), https://www.syngenta.com/sites/default/files/202503/Financial%20Report%202024.pdf.

PTO challenges, and amicus briefs.[6] A stable and predictable application of ODP helps protect farmers' livelihoods and American consumers' pocketbooks. It enables startups like Inari to innovate and deliver better choices to American farmers. Inari thus submits this brief urging consistent, principled application of ODP to promote competition and ensure equitable access to agricultural markets, increasing the choices available to American farmers.

I. INTRODUCTION

The parties in *Allergan USA, Inc. v. MSN Laboratories Private Ltd.*, 111 F.4th 1358 (Fed. Cir. 2024) did not present the threshold question—are duplicative patents with non-duplicative rights permissible under the statute?

According to the PTO, roughly 60,000 terminal disclaimers are filed annually.[7] That volume underscores the statutory and structural importance of ODP across the patent system. It also highlights why the panel's unresolved statutory

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[6] Amongst others, Inari filed amicus briefs in *Allergan* in support of Appellee's petition for rehearing en banc (ECF No. 47-2), and in *In re Cellect* in support of the Directors opposition to rehearing en banc (ECF No. 53).

[7] Dennis Crouch, Terminal Disclaimers: A Growing Concern in Patent Practice, *Patently-O* (May 10, 2024), https://patentlyo.com/patent/2024/05/terminal-disclaimers-practice.html. In 2024, the PTO recorded 134,461 RCE application filings. Patents Dashboard: Production—Unexamined Applications (Filing), https://www.uspto.gov/dashboard/patents/production-unexamined-filing.html.

questions in *Allergan* demand an authoritative en banc decision.

35 U.S.C. § 101 authorizes "a patent"—i.e., a single patent, for an invention; and 35 U.S.C. § 154 defines the term of that patent.[8] Read together, §§ 101 and 154 establish structural unity—one invention, one patent, one term. When two patents claim the same invention—or obvious variants—but have different rights, they disrupt statutory unity. ODP enforces that unity.

The terminal disclaimer provision of 35 U.S.C. § 253 provides the statutory mechanism to resolve ODP. Reconciling ODP expiration dates by truncating the longer term is the "very purpose" for which § 253 was enacted. *Gen. Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d 1272, 1280 (Fed. Cir. 1992). A terminal disclaimer creates a situation 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 *In re Braithwaite*, 379 F.2d 594, 601 (C.C.P.A. 1967)).

The longstanding principles underlying ODP—non-alienation, unlawful extension, and public access—are not ancillary policy concerns subject to judicial discretion. *See Gilead Scis., Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208, 1212-13

[8] The one patent one term framework has been a part of the statute since the beginning—e.g., the Patent Act of 1790 provided that applicants could file an application "praying that a patent may be granted therefor…." 110 1st Congress, Sess. 2, Ch. 7 (1790).

(Fed. Cir. 2014) (discussing ODP historical principles). Rather, they are direct expressions of the statute's singular grant of "a patent" for the invention.

By exempting certain parent applications from ODP, *Allergan* for the first time permits duplicative patents with non-duplicative rights.[9] The issue recurs here and warrants en banc review.

II. THE STATUTE PROHIBITS DUPLICATIVE PATENTS WITH NON-DUPLICATIVE RIGHTS

Section 101 "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. 2023). Section 154 fixes one patent term for the invention. Read with § 101's singular-patent grant, the invention's full statutory term resides in the earliest-expiring patent that claims it. *Id.* at 1221-22, 1229-30 (finding that PTA cannot adjust a term beyond the disclaimed date in any terminal disclaimer).

Section 253 is the statutory mechanism to preserve unity by cutting back the term of the later-expiring patent, unifying the claims as if they reside "in one patent." *See Gen. Foods* at 1280 (describing this unification as the "very purpose"

[9] In *Breckenridge*, the Court did not change ODP doctrine; it addressed the URAA transition and held that a post-URAA patent could not serve as an ODP reference to a pre-URAA patent. *See Novartis Pharms. Corp. v. Breckenridge Pharm. Inc.*, 909 F.3d 1355, 1366-69 (Fed. Cir. 2018).

of § 253); *In re Van Ornum*, 686 F.2d at 948.

35 U.S.C. § 121 shelters divisional applications filed under a restriction requirement with "independent and distinct" claims; duplicative claims, however, remain subject to ODP. *Boehringer Ingelheim Int'l GmbH v. Barr Labs., Inc.*, 592 F.3d 1340, 1351-52 (Fed. Cir. 2010).

The Hatch-Waxman term extension under 35 U.S.C. § 156 runs from the terminal disclaimer, preserving ODP alignment. *Merck & Co. v. Hi-Tech Pharmacal Co.*, 482 F.3d 1317, 1323–24 (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.").

The Hatch-Waxman Act's history reinforces ODP's role in preserving statutory unity. The House Judiciary Committee expected the PTO to continue preventing "two or more patents with different expiration dates covering nearly identical subject matter" absent a terminal disclaimer. 130 Cong. Rec. H10,527 (1984).

Similarly, 35 U.S.C. § 103(c) (pre-AIA), as amended by the CREATE Act,[10]

[10] Cooperative Research and Technology Enhancement (CREATE) Act of 2004, Pub. L. No. 108-453, § 2, 118 Stat. 3596 (2004).

narrowed the use of certain prior art for joint research inventions. The House Report stated that "the prohibition against double patenting shall apply to such patents." H.R. Rep. No. 108-425, at 6 (2004). The late Senator Hatch confirmed ODP applies to joint research patents "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 (2004). The pre-AIA § 103(c) prior art exception carries forward in AIA §§ 102(b)(2)(C) and 102(c); AIA § 3(b)(2) incorporates by reference the CREATE Act's legislative history.

The *Allergan* decision did not address the conflicts it creates with the statute—e.g., whether a parent patent that benefits from the prior art exception under §§ 102(b)(2)(C) and 102(c) would itself be an exception from *Allergan's* exception given Congress's mandate that ODP shall apply to such patents. These new conflicts do not arise from within the statute itself which, together with the legislative statements, delineate a unified statutory framework: one patent, one term.

Thus, ODP is not external judicial pressure bearing down on applicants. Rather, Congress designed the statute within the one patent per invention system and, in doing so, asks this Court to maintain the public policy against double patenting.

III. THE HISTORICAL PRINCIPLES ARE EXPRESSIONS OF THE STATUTORY FRAMEWORK

The principles traditionally cited as the foundations of ODP—non-alienation of ownership, unlawful extension of term, and predictable public access—are each grounded in the one patent per invention framework of the statute. None operates as an independent policy choice, each gives effect to statutory text.

Non-alienation. The principle of non-alienation flows from § 101's singular patent grant and § 253's unifying mechanism. From the outset, the Supreme Court treated the patent as a single, unitary entitlement. Issuing a second patent on the same invention splits that entitlement and disrupts statutory unity. *Underwood v. Gerber*, 149 U.S. 224, 231-32 (1893); *Sandy MacGregor Co. v. Vaco Grip Co.*, 2 F.2d 655, 657 (6th Cir. 1924) (summarizing *Underwood* that "splitting up of one indivisible right into two" justifies the double patenting defense).

Section 253 implements unity in practice—a terminal disclaimer operates as if all duplicative claims reside in one enforceable instrument. *In re Van Ornum*, 686 F.2d at 948; *In re Hubbell*, 709 F.3d 1140, 1145 (Fed. Cir. 2013); *see also In re 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.").

Modern shorthand often frames non-alienation by a potential consequence—

"harassment by multiple assignees"—but the doctrinal target is the split itself. Judge Rich described a terminal disclaimer covenant as "an imaginative solution to one of the more theoretical objections to double patenting, split ownership of two patents and potential harassment." *In re Griswold*, 365 F.2d 834, 840 n.5 (C.C.P.A. 1966). Consistent with that understanding, this Court has at least once "focused on two salient rights: enforcement and alienation," when assessing common ownership. *Immunex Corp. v. Sandoz Inc.*, 964 F.3d 1049, 1060, 1063 (Fed. Cir. 2020) (finding the patents "are not 'commonly owned,' and [ODP] does not apply.").

Unlawful Extension. With duplicative claims under common ownership, differing expiration dates create an "unlawful" or "unjust" extension—i.e., a non-statutory extension—since the later date adds term beyond § 154. The Supreme Court has long identified the problem of a "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); *see also Suffolk Co. v. Hayden*, 70 U.S. 315, 319 (1865). Under today's post-URAA term regime, courts police the same non-statutory extension by using expiration as the benchmark. *AbbVie Inc. v. Mathilda & Terence Kennedy Inst. of Rheumatology Tr.*, 764 F.3d 1366, 1373-74 (Fed. Cir. 2014).

Read together, § 101's single grant and § 154's single term—implemented

through § 253 and reflected in the cases—place the invention's full statutory term in the earliest-expiring patent that claims it. When that term ends, exclusivity ends. Any later-expiring duplicative patent necessarily prolongs exclusivity beyond the statutory limit unless aligned by a terminal disclaimer—the "very purpose" of § 253. *Gen. Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d at 1280.

Predictable Public Access. The Court has stated that the public should "be able to act on the assumption that upon the expiration of the patent it will be free to use" the claimed invention and its obvious variants. *In re Longi*, 759 F.2d 887, 892–93 (Fed. Cir. 1985) (quoting *In re Zickendraht*, 319 F.2d 225, 232 (C.C.P.A. 1963) (Rich, J., concurring)). *Gilead* framed the historical principle as protecting the "bargained-for right held by the public." 753 F.3d at 1212, 1215-16. When duplicative patents carry different expiration dates, the public cannot act on that assumption. A terminal disclaimer restores a single, reliable expiration date, preserving the public's entry signal. *In re Van Ornum*, 686 F.2d at 948.

It follows that terminal disclaimers must be filed in both duplicative patents to preserve unity and the public notice function. The MPEP states in part that because "a terminal disclaimer is only effective in the application in which it is filed, it is necessary to require that the terminal disclaimer be filed in each application and/or patent that is subject to the common ownership requirement in order to provide complete notice to the public of this obligation." MPEP

§ 804.02(VI) (9th ed., Rev. 01.2024).

IV. APPLICANTS MAINTAIN CONTROL OVER ODP

Administering 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, demonstrate that the inventions are independent and distinct, or establish that the combination of prior art references is not proper under §§ 102, 103.

It is always an applicant's choice whether to prosecute duplicative applications and pay the issuance fee. 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 parent, they are free to make that choice. But under no circumstances are they compelled to do so. And if overlap is challenged while the earlier patent remains unexpired, a terminal disclaimer is available in the later patent. If the reference patent is expired, the applicant has elected to carry the ODP risk.

This strategic discretion is central to ODP enforcement, which allocates responsibility to the party best positioned to avoid conflict—the applicant. *In re Schneller*, 397 F.2d 350, 354 (C.C.P.A. 1968). ODP enforcement ensures those who elect duplicative continuation campaigns must keep their rights within the one patent per invention framework—either by avoiding duplication or unifying

expiration through § 253. In this way, ODP remains agnostic to the applicant's filing strategies and procedural maneuvers. *Hubbell*, 709 F.3d at 1145 (stating that ODP must be resolved "no matter how the extension is brought about.").

While it may be true for large multinational companies that a parent application can be delayed more than its duplicative continuation(s), and therefore can receive more PTA, that is not always the case. In many industries, innovative startups prioritize narrower patents to gain protection for their core innovations without incurring excessive costs or delays. ODP principles should not change based on the prosecution tactics of large patent-holding firms. Any consideration of the special interests of these firms must surely also account for the concerns of American farmers and innovative start-ups. "[E]ven a minimal concern for the public interest" requires strong and predictable enforcement of ODP. *In re Schneller*, 397 F.2d at 354.

V. CONCLUSION

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

Dated: August 22, 2025

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

Case Number: 2024-1401

Short Case Caption: Acadia Pharms. Inc. v. Aurobindo Pharma Ltd.

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Signature: /s/ Jeremy Lowe

Name: Jeremy Lowe