

Nos. 2022-1293, 2022-1294, 2022-1295, 2022-1296

IN THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

IN RE: CELLECT, LLC.,

Appellant,

Appeals from the United States Patent and Trademark Office, Patent Trial and Appeal Board, in Nos. 90/014,453, 90/014,454, 90/014,455, 90/014,457

**UNOPPOSED MOTION FOR LEAVE TO FILE BRIEF OF INARI
AGRICULTURE, INC. AS AMICUS CURIAE IN SUPPORT OF
DIRECTOR'S OPPOSITION TO REHEARING EN BANC**

Scott A. McKeown
WOLF, GREENFIELD & SACKS, P.C.
601 Massachusetts Avenue, NW
Washington, DC 20001
(202) 389-6025
smckeown@wolfgreenfield.com

Charles T. Steenburg
WOLF, GREENFIELD & SACKS, P.C.
600 Atlantic Avenue
Boston, MA 02210
(617) 646-8265

*Counsel for Amicus Curiae Inari
Agriculture, Inc*

CERTIFICATE OF INTEREST

Counsel for Amicus Curiae certifies the following:

1. **Represented Entities.** Provide the full names of all entities represented by undersigned counsel in this case. Fed. Cir. R. 47.4(a)(1).

Inari Agriculture, Inc.

2. **Real Party in Interest.** 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. Fed. Cir. R. 47.4(a)(2).

None

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

None

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

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)?

N/A (amicus/movant)

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

Date: December 28, 2023

/s/ Scott A. McKeown

Scott A. McKeown

REQUESTED RELIEF AND STATEMENT OF CONSENT

Pursuant to Federal Rule of Appellate Procedure 29(b) and Federal Circuit Rules 27 and 35(g), Inari Agriculture, Inc. (“Inari”) respectfully moves for leave to file the accompanying amicus curiae brief in support of the Director’s opposition to Cellect, LLC’s petition for rehearing en banc (D.E. 96). Inari’s brief and motion for leave are timely pursuant to Federal Circuit Rule 35(g) because they are being filed within 14 days after the Director’s December 14, 2023 opposition (D.E. 174) to Cellect’s petition. Appellant consents to, and Appellee does not oppose, the relief sought in this motion.

INTEREST OF AMICUS CURIAE AND REASONS FOR GRANTING REQUESTED RELIEF

Inari was formed in 2016 to develop pioneering technology to selectively edit plant genes to enhance agronomic traits and increase crop yields and decrease inputs such as water and fertilizer. Inari partners with independent seed companies to develop improved seeds using Inari’s technology. Inari respects valid patent rights and has pioneering patents of its own. But Inari also builds upon past advances to create seeds coupling Inari’s own technology with earlier developments once the relevant patents expire.

Double patenting is a critical tool for policing the patent system’s *quid pro quo* and preventing earlier patent owners from threatening innovators—like Inari—seeking to leverage legacy technology after their patents expire.

To this end, Inari has filed numerous *ex parte* reexamination requests based on the panel's decision. Those reexamination requests target patent thickets cultivated by entrenched incumbents in the seed business. Such incumbents abuse the patent system by exploiting loopholes in the Patent Term Adjustment (PTA) system to perpetuate their monopolies and prevent American farmers from practicing technologies claimed in expired patents. The panel's decision is accordingly of particular significance to farmers, seed suppliers, and related innovators such as Inari.

For the foregoing reasons, Inari respectfully requests that this Court grant leave to participate as amicus curiae and to file the accompanying amicus curiae brief in support of the Director's opposition to Cellect's request.

Respectfully submitted,

Date: December 28, 2023

/s/ Scott A. McKeown
Scott A. McKeown
WOLF GREENFIELD & SACKS, P.C.
601 Massachusetts Avenue, NW
Washington, DC 20001
(202) 389-6025

Charles T. Steenburg
WOLF GREENFIELD & SACKS, P.C.
600 Atlantic Avenue
Boston, MA 02210
(617) 646-8265

CERTIFICATE OF COMPLIANCE

This motion complies with the type-volume limitation of Federal Rule of Appellate Procedure 27(d)(2). It contains 333 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f) and Fed. Cir. R. 32(b)(2), as determined by Microsoft Word.

The motion complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type-style requirements of Fed. R. App. 32(a)(6). It has been prepared in a proportionally-spaced typeface using Microsoft Word in 14-point Times New Roman type style.

Date: December 28, 2023

/s/ Charles T. Steenburg
Charles T. Steenburg
WOLF, GREENFIELD & SACKS, P.C.
Attorney for Appellees

CERTIFICATE OF SERVICE AND FILING

I hereby certify that a true and correct copy of the foregoing has been filed using the Court's CM/ECF system. All counsel of record were served via CM/ECF on the 28th day of December, 2023.

Date: December 28, 2023

/s/ *Charles T. Steenburg*
Charles T. Steenburg
WOLF, GREENFIELD & SACKS, P.C.
Attorney for Appellees

Nos. 2022-1293, 2022-1294, 2022-1295, 2022-1296

IN THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

IN RE: CELLECT, LLC.,

Appellant,

Appeals from the United States Patent and Trademark Office, Patent Trial and Appeal Board, in Nos. 90/014,453, 90/014,454, 90/014,455, 90/014,457

**BRIEF OF AMICUS CURIAE INARI AGRICULTURE, INC. IN SUPPORT
OF DIRECTOR'S OPPOSITION TO REHEARING *EN BANC***

Scott A. McKeown
WOLF, GREENFIELD & SACKS, P.C.
601 Massachusetts Avenue, NW
Washington, DC 20001
(202) 389-6025
smckeown@wolfgreenfield.com

Charles T. Steenburg
WOLF, GREENFIELD & SACKS, P.C.
600 Atlantic Avenue
Boston, MA 02210
(617) 646-8265

*Counsel for Amicus Curiae Inari
Agriculture, Inc*

CERTIFICATE OF INTEREST

Counsel for Amicus Curiae certifies the following:

1. **Represented Entities.** Provide the full names of all entities represented by undersigned counsel in this case. Fed. Cir. R. 47.4(a)(1).

Inari Agriculture, Inc.

2. **Real Party in Interest.** 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. Fed. Cir. R. 47.4(a)(2).

None

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

None

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

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)?

N/A (amicus/movant)

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

Date: December 28, 2023

/s/ Scott A. McKeown

Scott A. McKeown

TABLE OF CONTENTS

| | |
|--|----|
| INTEREST OF AMICUS CURIAE | 1 |
| REASONS FOR DENYING REHEARING EN BANC..... | 2 |
| I. The Panel’s Decision Vindicates the Patent System’s <i>Quid Pro Quo</i> And the Public’s Right To Use A Claimed Invention Once The Patent Expires | 3 |
| A. The Right to Practice Expired Claims Is Crucial to Farmers, Who Face Oligopolists Wrongly Suppressing Competition Even After Patents Expire..... | 4 |
| B. Inari is Forced to File Reexamination Requests to Ensure Freedom to Operate and Preserve the Patent System’s <i>Quid Pro Quo</i> in the Face of the Oligopoly’s Systematic Double Patenting..... | 7 |
| II. Unlike Patent Term Extension, Patent Term Adjustment is Subject to Gamesmanship, As Patent Attorneys Openly Tout | 9 |
| CONCLUSION..... | 13 |

TABLE OF AUTHORITIES

CASES

| | |
|--|--------|
| <i>Abbvie Inc. v. Mathilda & Terence Kennedy Inst. of Rheumatology Tr.</i> , 764 F.3d 1366 (Fed. Cir. 2014) | 3, 8 |
| <i>Bonito Boats, Inc. v. Thunder Craft Boats, Inc.</i> , 489 U.S. 141 (1989) | 2 |
| <i>Gilead Scis., Inc. v. Natco Pharma Ltd.</i> , 753 F.3d 1208 (Fed. Cir. 2014) | passim |
| <i>In re Cellect, LLC</i> , 81 F.4th 1216 (Fed. Cir. 2023) | 2, 12 |
| <i>J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l</i> , 534 U.S. 124 (2001) | 3 |
| <i>Kewanee Oil Co. v. Bicron Corp.</i> , 416 U.S. 470 (1974) | 3 |
| <i>Novartis AG v. Ezra Ventures LLC</i> , 909 F.3d 1367 (Fed. Cir. 2018) | 9 |
| <i>Novartis Pharms. Corp. v. Breckenridge Pharm. Inc.</i> , 909 F.3d 1355 (Fed. Cir. 2018) | 8 |
| <i>Odiorne v. Amesbury Nail Factory</i> , 2 Mason 28 (D. Mass. 1819) | 3 |

STATUTES

| | |
|---|--------|
| 35 U.S.C. § 154 | 10, 12 |
| 35 U.S.C. § 156(f) | 10 |
| Act of Apr. 10, 1790, § 1, 1 Stat. 110 | 3 |

OTHER AUTHORITIES (EXECUTIVE BRANCH)

| | |
|---|------|
| Executive Order on Promoting Competition in the American Economy (July 9, 2021), https://www.whitehouse.gov/briefing-room/presidential-actions/2021/07/09/executive-order-on-promoting-competition-in-the-american-economy/ | 6 |
| <i>FTC v. Syngenta et al.</i> , Case No. 1:22-cv-00828-TDS-JEP (M.D.N.C.), Docket No. 79 (Dec. 23, 2022 Amended Complaint)..... | 5, 6 |
| Thomas J. Vilsack, Secretary of Agriculture, and Kathi Vidal, Under Secretary of Commerce for Intellectual Property and Director of the U.S. Patent and Trademark Office, <i>Increasing transparency, boosting competition, and supporting innovation can deliver better choices for farmers in the seed marketplace</i> (March 3, 2023), https://www.uspto.gov/subscription-center/2023/increasing-transparency-boosting-competition-and-supporting-innovation-can | 6 |
| USDA Agricultural Marketing Service, <i>More and Better Choices for Farmers</i> (March 2023), https://www.ams.usda.gov/sites/default/files/media/SeedsReport.pdf | 4, 5 |
| USDA Economic Research Service, <i>Two companies accounted for more than half of corn, soybean, and cotton seed sales in 2018–20</i> (last updated October 2, 2023), https://www.ers.usda.gov/data-products/chart-gallery/gallery/chart-detail/?chartId=107516 | 5 |

OTHER AUTHORITIES (PRIVATE PARTIES)

| | |
|--|----|
| Dennis Crouch, <i>Patent Term Adjustment for Fun and Profit</i> (Oct. 17, 2006), https://patentlyo.com/patent/2006/10/patent_term_adj.html | 11 |
| Eric K. Steffe & Lori M. Brandes, <i>Patent Term Adjustment</i> (July 2020), https://www.sternekessler.com/news-insights/publications/patent-term-adjustment | 12 |

| | |
|---|----|
| <i>Maximizing Patent Term Adjustment Under Exelixis</i> (Jan. 24, 2013), https://www.foley.com/insights/publications/2013/01/maximizing-patent-term-adjustment-under-exelixis/ | 11 |
| | |
| N. Nicole Endejann, <i>Developing Effective Exclusivity Strategies for Clients in the Pharmaceutical and Biotechnology Industries,</i> 2013 WL 571777 | 11 |
| | |
| Scott E. Kamholz, <i>Patent Term Adjustment for Fun and Profit,</i> https://cdn.patentlyo.com/media/docs/2006/10/PTA_20for_20Fun_20and_20Profit.pdf | 11 |
| | |
| Verne A. Luckow, <i>Complex Interactions Between FDA and PTO Regulations Affecting Exclusivity Periods and the Patent Term of Biopharmaceutical Drug Products,</i> 2011 WL 5833344 | 10 |

INTEREST OF AMICUS CURIAE¹

Inari Agriculture, Inc. (“Inari”) was formed in 2016 to develop pioneering technology to selectively edit plant genes to enhance agronomic traits to increase crop yields and decrease inputs such as water and fertilizer. Inari partners with independent seed companies to develop improved seeds using Inari’s technology. Inari respects valid patent rights and has pioneering patents of its own. But Inari also builds upon past advances to create seeds coupling Inari’s own technology with earlier developments once the relevant patents expire.

Double patenting is a critical tool for policing the patent system’s *quid pro quo* and protecting innovators—like Inari—from earlier patentees seeking to leverage legacy technology after their patents expire.

To this end, Inari has filed numerous *ex parte* reexamination requests based on the panel’s decision. Those reexaminations target patent thickets cultivated by entrenched incumbents in the seed business. Such incumbents exploit loopholes in the Patent Term Adjustment (PTA) system to perpetuate their monopolies and prevent American farmers from practicing technologies claimed in expired patents.

¹ No counsel for any party authored this brief in any part, and no party, counsel, or person other than amicus contributed money to fund the preparation and submission of this brief.

REASONS FOR DENYING REHEARING EN BANC

Patent double dipping is wrong. The Costanza-esque amicus support of such misguided practices only highlights the obvious. That some companies may lose their ability to dip the very same chip for a second helping is not a reason to rehear this case. Instead, it is a resounding reinforcement of proper patent etiquette and centuries of safeguards.

Obviousness-type double patenting (OTDP) protects the public by “enforc[ing] the fundamental right of the public to use the invention claimed in the earlier-expiring patent and all obvious modifications of it after that patent’s term expires.” *Gilead Scis., Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208, 1217 (Fed. Cir. 2014). Once a patent expires, “the subject matter of the patent passes to the free use of the public.” *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 152 (1989).

The panel’s decision safeguards the public’s fundamental right, which is critical to American farmers. Once a patent has expired, “any extension past that date constitutes an inappropriate timewise extension for” commonly owned claims that are merely “obvious variations” of the expired claim. *In re Cellect, LLC*, 81 F.4th 1216, 1229 (Fed. Cir. 2023).

I. THE PANEL’S DECISION VINDICATES THE PATENT SYSTEM’S *QUID PRO QUO* AND THE PUBLIC’S RIGHT TO USE A CLAIMED INVENTION ONCE THE PATENT EXPIRES

“The disclosure required by the Patent Act is the ‘*quid pro quo* of the right to exclude.’” *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int’l*, 534 U.S. 124, 142 (2001) (quoting *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 484 (1974)).

The very first Patent Act of 1790 made the *quid pro quo* explicit: the description requirement ensured “*the public may have the full benefit [of the invention], after the expiration of the patent term.*” Act of Apr. 10, 1790, § 1, 1 Stat. 110 (emphasis added).

Double patenting doctrine has enforced that *quid pro quo* for nearly as long. *See Odiorne v. Amesbury Nail Factory*, 2 Mason 28 (D. Mass. 1819) (Story, J.) (rejecting attempt to “perpetuate [inventor’s] exclusive right”). The 1790 Patent Act allowed inventors to seek “*a* patent” for their inventions—just like § 101 authorizes “*a* patent” today. *See Abbvie Inc. v. Mathilda & Terence Kennedy Inst. of Rheumatology Tr.*, 764 F.3d 1366, 1372 (Fed. Cir. 2014).

Once that patent expires, the public gains the “fundamental right” to use the claimed invention—including “all obvious modifications”—without fear of suit. *Gilead*, 753 F.3d at 1217. OTDP safeguards that freedom to operate. *Id.* The “fundamental right” reflects the *quid pro quo* underlying the U.S. patent system since it began. But Cellect and its amici conveniently never acknowledge it.

A. The Right to Practice Expired Claims Is Crucial to Farmers, Who Face Oligopolists Wrongly Suppressing Competition Even After Patents Expire

The fundamental right to practice expired patent claims is vital for American farmers. As the U.S. Department of Agriculture (USDA) recently stressed, “[a]n important feature of the IP system is that after a patent expires, the patented material enters the public domain.”² But an oligopoly of entrenched incumbents dominate seed distribution and suppress competition. “For years, American farmers and independent seed businesses have voiced concerns” regarding this “concentration and the consolidation of market power in agriculture.”³ In particular, the USDA has stressed the risk of “patent-holding firms…delay[ing] competition” even “*after patents have expired.*”⁴ Multiple federal agencies and state governments are confronting this threat—including the USDA in partnership with the PTO.

² USDA Agricultural Marketing Service, *More and Better Choices for Farmers* (March 2023) at 53,

<https://www.ams.usda.gov/sites/default/files/media/SeedsReport.pdf>

³ *Id.* at 3.

⁴ *Id.* at 53 (emphasis added).

Two companies—Corteva and Bayer/Monsanto—control over 70% of the U.S. corn seed market⁵ and 85% of corn-related intellectual property.”⁶ Together with BASF and ChemChina’s Syngenta Group, these oligopolists own 95% of corn-related IP, 97% of canola-related IP, and 84% of soybean-related IP.⁷

The USDA traces this “concentration...to the expansion of intellectual property rights” in “genetically modified (GM) varieties of seed.”⁸ As “biochemistry advanced,” the industry became “highly integrated.”⁹ Corteva, for example, amalgamated over fifty different legacy firms.

The Federal Trade Commission (FTC) and twelve states ranging from Texas to California are responding aggressively. They have sued Corteva and Syngenta for “maintain[ing] monopolies long after their lawful exclusive rights to particular crop-protection products have expired.”¹⁰ One Corteva employee bragged how Corteva had leveraged its position to suppress competition and maintain “a

⁵ USDA Economic Research Service, *Two companies accounted for more than half of corn, soybean, and cotton seed sales in 2018–20* (last updated October 2, 2023), <https://www.ers.usda.gov/data-products/chart-gallery/gallery/chart-detail/?chartId=107516>

⁶ USDA, *More and Better Choices for Farmers* at 77.

⁷ *Id.* at 42.

⁸ USDA, *Two companies....*

⁹ *Id.*

¹⁰ *FTC v. Syngenta et al.*, Case No. 1:22-cv-00828-TDS-JEP (M.D.N.C.), Docket No. 79 (Dec. 23, 2022 Amended Complaint), ¶ 1.

significant brand premium over the generics”— forcing farmers to pay higher prices than would prevail in a competitive market.¹¹

Given such threats of “concentrated market power,” the President ordered the PTO and USDA to collaborate and ensure that intellectual property does not “unnecessarily reduce competition in seed and other input markets beyond that reasonably contemplated by the Patent Act.”¹² To this end, Director Vidal and Secretary Vilsack jointly announced a working group “to enhance the quality of the patent examination process for innovations related to agricultural products.”¹³ They stressed that the patent laws “encourage the disclosure of inventions, and for ***others to build on those innovations.***”¹⁴

¹¹ *Id.*, ¶133.

¹² Executive Order on Promoting Competition in the American Economy (July 9, 2021), <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/07/09/executive-order-on-promoting-competition-in-the-american-economy/>

¹³ Thomas J. Vilsack, Secretary of Agriculture, and Kathi Vidal, Under Secretary of Commerce for Intellectual Property and Director of the U.S. Patent and Trademark Office, *Increasing transparency, boosting competition, and supporting innovation can deliver better choices for farmers in the seed marketplace* (March 3, 2023), <https://www.uspto.gov/subscription-center/2023/increasing-transparency-boosting-competition-and-supporting-innovation-can>

¹⁴ *Id.* (emphasis added).

B. Inari is Forced to File Reexamination Requests to Ensure Freedom to Operate and Preserve the Patent System’s *Quid Pro Quo* in the Face of the Oligopoly’s Systematic Double Patenting

Inari is an innovator leveraging earlier technologies while confronting the seed industry’s entrenched incumbents abusing the patent system. Inari’s pioneering gene editing platform enables Inari to couple existing GM traits (e.g., pest control) with new sustainability-focused benefits of Inari’s unique gene edits (e.g., reduced need for water and fertilizer).

Consistent with the joint PTO-USDA policy (*supra* § I.A), Inari has filed numerous *ex parte* reexamination requests to vindicate the Patent Act’s *quid pro quo* and confirm the public’s freedom to practice expired patent claims—the same right the *Collect* panel upheld. For example, Inari has filed eight reexamination requests concerning utility patents controlled by Corteva. Together, these eight claim sets purport to extend Corteva’s monopolies by **more than twenty years**.¹⁵

¹⁵ See Serials Nos. 90/019,130 (explaining why claims in U.S. Patent No. 10,947,555 are obvious variants of claims expiring **257 days** earlier); 90/019,131 (explaining why claims in U.S. Patent No. 8,283,522 are obvious variants of claims expiring **907 days** earlier); 90/019,132 (explaining why claims in U.S. Patent No. 8,952,223 are obvious variants of claims expiring **686 days** earlier); 90/019,306 (explaining why claims in U.S. Patent No. 6,943,282—purporting to exclude others from practicing the claims invention until September 13, 2027—are obvious variants of claims that already expired on June 3, 2020 (i.e., **2658 days** earlier); 90/019,310 (explaining why claims in U.S. Patent 9,596,871 are obvious variants of claims expiring **1257 days** earlier); 90/019,319 (explaining why claims in U.S. Patent 7,838,733 are obvious variants of claims expiring **360 days** earlier);

Each claim set wrongly deprives the public of the “benefit of the invention after the original period of monopoly expires,” *AbbVie*, 764 F.3d at 1373, and in particular “the fundamental right” to use the claimed invention—including “all obvious modifications”—without fear of suit, *Gilead*, 753 F.3d at 1217.¹⁶

For example, Corteva’s U.S. Patent No. 6,943,282 purportedly excludes others from practicing the claimed insect-resistant plants until ***September 13, 2027*** even though they are at most obvious variants of different Corteva patent claims that expired no later than ***June 3, 2020***—more than seven years earlier. To add insult to injury, Corteva’s ’282 Patent claims priority to an application filed on September 24, 1983. The forty-four-year period between 1983 (when Corteva disclosed the technology) and 2027 (when Corteva will ostensibly stop threatening farmers with this patent family) exemplifies rampant OTDP gamesmanship in the transgenic seed industry.

Similarly, Corteva’s U.S. Patent 9,596,871 purports to exclude farmers from using the claimed canola seeds and plants until May 1, 2035 despite the claims

90/019,321 (explaining why claims in U.S. Patent 8,609,935 are obvious variants of claims expiring **1114 days** earlier); and 90/019,322 (explaining why challenged claims in U.S. Patent No. 8,598,413 are obvious variants of claims expiring **237** days earlier).

¹⁶ None involves the intersection between pre-URAA and post-URAA patents—much less the particular “narrow question” the Court addressed in *Novartis Pharm. Corp. v. Breckenridge Pharm. Inc.*, 909 F.3d 1355, 1364 (Fed. Cir. 2018).

being obvious variants of others expiring more than three years earlier. Such PTA-based abuse exemplifies the same pattern of illegal conduct the FTC and numerous states target in suing Corteva for maintaining monopolies long after its lawful patent rights have expired. *See supra* § 1.A.

Inari requested reexamination of the '282 and '871 Patents to address these unlawful claims—much like those the *Cellect* reexaminations found unpatentable and which the panel affirmed.

* * *

There is no reason to rehear a decision properly grounded in centuries of precedent and sound patent policy. Rehearing would encourage oligopolists like Corteva to continue sowing uncertainty among American farmers. It would also wrongly impede Inari's efforts to propel the U.S. agricultural industry to a more competitive and sustainable future than the current concentration of market power the Executive Branch and many state governments are now forced to actively confront.

II. UNLIKE PATENT TERM EXTENSION, PATENT TERM ADJUSTMENT IS SUBJECT TO GAMESMANSHP, AS PATENT ATTORNEYS OPENLY TOUT

Cellect and its amici repeatedly cite *Novartis AG v. Ezra Ventures LLC*, 909 F.3d 1367 (Fed. Cir. 2018), yet neglect critical differences between PTA versus the Patent Term Extension (PTE) regime addressed in *Ezra*. The panel emphasized

certain statutory differences, and the Director reiterates them in opposing Cellect's petition. D.E. No. 174 at 6-7, 10.

There are also enormous *practical* differences between PTA and PTE, the latter of which does not even impact farmers.¹⁷

PTE's very nature inoculates it against gamesmanship. No rationale actor would try manipulating the PTE regime by delaying its own regulatory approval to start selling the drug, medical device, food additive, or color additive under review.

The PTA regime, by contrast, is rife with opportunities for abuse. Continuation practice tempts applicants to double dip—pursuing certain claim sets quickly to allowance while delaying others to reap PTA.

Patent attorneys regularly exploit such loopholes to maximize the amount of ostensible adjustment while avoiding reductions under the letter of section 154. Some even write articles touting their strategies—illustrating how applicants often welcome “issue date[s]” of their patents to be “*delayed*.¹⁸ By their own

¹⁷ PTE is limited to “drug product[s]” and “medical device, food additive, or color additive” products. 35 U.S.C. § 156(f). Inari, seed companies, and crop growers can therefore exercise their “fundamental right[s]” under *Gilead* without fear of PTE-related complications.

¹⁸ Verne A. Luckow, *Complex Interactions Between FDA and PTO Regulations Affecting Exclusivity Periods and the Patent Term of Biopharmaceutical Drug Products*, 2011 WL 5833344.

admission, and in their own words, patent prosecutors have long been “*manipulating patent prosecution to maximize PTA.*”¹⁹

For example, one patent attorney cataloged loopholes in an article entitled *Patent Term Adjustment for Fun and Profit*.²⁰ This piece—touted by a leading patent weblog as a “great guide to PTA²¹—recommends strategies such as “filing a continuation-in-part instead of a continuation.” The article explains how docketing procedures make the PTO “more likely to violate the fourteen-month-to-first action guarantee.” It likewise recommends that “applicants seeking to increase PTA” should take the “full five-month extension of time before filing an appeal brief” given loopholes in PTO regulations.

Other attorneys have touted related strategies such as waiting until the exact “three-month date” after allowance to “pay the issue fee.”²² Still others trumpet strategies for “maximiz[ing]” both A and B delay, including “taking a one-month

¹⁹ *Maximizing Patent Term Adjustment Under Exelixis* (Jan. 24, 2013), <https://www.foley.com/insights/publications/2013/01/maximizing-patent-term-adjustment-under-exelixis/>

²⁰ Scott E. Kamholz, *Patent Term Adjustment for Fun and Profit*, https://cdn.patentlyo.com/media/docs/2006/10/PTA_20for_20Fun_20and_20Profit.pdf

²¹ Dennis Crouch, *Patent Term Adjustment for Fun and Profit* (Oct. 17, 2006), https://patentlyo.com/patent/2006/10/patent_term_adj.html

²² N. Nicole Endejann, *Developing Effective Exclusivity Strategies for Clients in the Pharmaceutical and Biotechnology Industries*, 2013 WL 571777.

extension of time and replying to a pre-examination notice or restriction requirement at the three-month deadline.”²³

Inari’s reexamination requests (*supra* § 1.B) target multiple patents that were prosecuted using such strategies.²⁴

Several of Cellect’s amici admit the potential for PTA-related abuse, but suggest factfinders can resolve disputes on a case-by-case basis. D.E. 131-2 at 5; D.E. 141-2 at 8-11. Such an approach would unfairly burden innovators like Inari relying on the public’s “fundamental right” under *Gilead* and 233 years of patent practice. Once a given claim expires, farmers are entitled to use the claimed invention—including “all obvious modifications.” *Gilead*, 753 F.3d at 1217. Inari should not have to scrutinize *other* patents ostensibly covering such obvious variants to assess whether the applicants gamed the system. Instead, as the panel held, “*any* extension past [the first expiration] date constitutes an inappropriate timewise extension for” commonly owned claims that are “obvious variations” of the expired claim. *Cellect*, 81 F.4th at 1229. This rule safeguards the patent

²³ Eric K. Steffe & Lori M. Brandes, *Patent Term Adjustment* (July 2020), <https://www.sternekessler.com/news-insights/publications/patent-term-adjustment>

²⁴ For example, Corteva filed U.S. Patent No. 8,598,413 as a continuation-in-part rather than a continuation. Similarly, it waited almost the full three months to pay the issue fees for U.S. Patent Nos. 8,609,935 and 8,952,223. And with the ’935 Patent, Corteva took an extension to respond to a restriction requirement. These choices delayed prosecution, yet under the letter of 35 U.S.C. § 154 did not count against Corteva’s PTA.

system's *quid pro quo* and positions innovators like Inari to propel the U.S. agricultural industry beyond its present quagmire created by entrenched oligopolists abusing their market power.

CONCLUSION

The petition for rehearing en banc should be denied.

Respectfully submitted,

Date: December 28, 2023

/s/ Scott A. McKeown
Scott A. McKeown
WOLF GREENFIELD & SACKS, P.C.
601 Massachusetts Avenue, NW
Washington, DC 20001
(202) 389-6025

Charles T. Steenburg
WOLF GREENFIELD & SACKS, P.C.
600 Atlantic Avenue
Boston, MA 02210
(617) 646-8265

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 35(g)(3). It contains 2564 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f) and Fed. Cir. R. 32(b)(2), as determined by Microsoft Word.

The brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type-style requirements of Fed. R. App. 32(a)(6). It has been prepared in a proportionally-spaced typeface using Microsoft Word in 14-point Times New Roman type style.

Date: December 28, 2023

/s/ *Charles Steenburg*
Charles T. Steenburg
WOLF, GREENFIELD & SACKS, P.C.
Attorney for Appellees