

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

INARI AGRICULTURE, INC.,
Petitioner,

v.

CORTEVA AGRISCIENCE LLC,
Patent Owner.

Case No. IPR2024-01014
Patent No. 8,901,378

PETITIONER'S REPLY TO PATENT OWNER'S RESPONSE

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1001	U.S. Patent No. 8,901,378
1002	Prosecution History of U.S. Patent No. 8,901,378
1003	Prosecution History of European Patent Application No. 04 751 097.9
1004	Prosecution History of European Patent Application No. 15 168 051.9
1005	Provisional Application No. 60/467,772
1006	Non-Provisional Application No. 10/837,105 (“April 2004 Application”)
1007	Declaration of Aron Silverstone (“Silverstone”)
1008	Curriculum Vitae of Aron Silverstone
1009	U.S. Patent Publication No. 20060037095 (“Barbour”)
1010	https://www.corteva.com/who-we-are/our-history.html
1011	U.S. Department of Agriculture Budget Summary and Annual Performance Plan 2006
1012	A. Kohli et al., <i>The Quest to Understand the Basis and Mechanisms that Control Expression of Introduced Transgenes in Crop Plants</i> , Plant Signaling & Behavior 1:4, 185-195 (2006)
1013	F Altpeter et al, <i>Particle bombardment and the genetic enhancement of crops: myths and realities</i> , Molecular Breeding 15:305–327 (2005)
1014	<i>Still the seed: plant biotechnology in the twenty-first century</i> , pp. 291-354 in Jack Ralph Kloppenburg Jr., <i>First the Seed: The Political Economy of Plant Biotechnology</i> (Second Edition), 2004
1015	A. Kohli et al, <i>Transgene integration, organization and interaction in plants</i> , Plant Molecular Biology 52:247–258 (2003)
1016	L. Mehlo et al, <i>Structural Analysis of Transgene Rearrangements and Effects on Expression in Transgenic Maize Plants Generated by Particle Bombardment</i> , Maydica 45:277-287 (2000)
1017	March 5, 2024 Deposition of Paul Cristou (Exhibit 1044 in <i>Inari Agriculture, Inc. v. Corteva Agriscience LLC</i> , PGR2023-00022)
1018	U.S. Patent No. 7,179,965
1019	U.S. Patent No. 8,598,413
1020	April 10, 2013 Office Action re: U.S. Patent No. 8,598,413
1021	U.S. Patent No.8,785,728
1022	U.S. Patent No. 8,575,434
1023	Feb. 4, 2013 Office action re: U.S. Patent No. 8,575,434
1024	U.S. Patent No. 8,592,653
1025	U.S. Patent No. 8,062,847
1026	U.S. Patent Publication No. 2010/0167403

1027	January 21, 2004 Declaration of Paul Christou, Ph.D (Exhibit 2012 in <i>Inari Agriculture, Inc. v. Corteva Agriscience, LLC</i> , PGR2023-00022)
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1032	DAS-O1507-1 (TC1507) (“D1” as reflected in EX1003)
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1075	Patent Owner's Preliminary Response, PGR2024-00019 (filed June 26, 2024)

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1081	U.S. Patent No. 5,444,178
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1083	MPEP 2411.04 as of April 30, 2004 (<i>i.e.</i> , alleged priority date), https://www.uspto.gov/web/offices/pac/mpep/old/E8R0_2400.pdf
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1089	U.S. Patent No. 8,592,653
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1094	Prosecution History of U.S. Patent No. 8,952,223
1095	May 2, 2013 Amendment re: U.S. Patent No. 8,575,434
1096	S. Trapmann et al, <i>Certified reference materials for GMO analysis—more than 25 years of GMO CRM production at EC JRC, Analytical and Bioanalytical Chemistry</i> (2025) 417:2387–2403
1097	ERM-BF418a Certificate of Analysis

1098	Declaration of Charles T. Steenburg in Support of Admission <i>Pro Hac Vice</i>
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I. INTRODUCTION

The Challenged Claims are unpatentable for the reasons the Board highlighted when instituting review: PO ***still*** “has not produced or pointed to any evidence to show TC1507 corn ‘readily available’ to the public without restriction as of the filing date of [PO’s] 2004 application” (the ’378 Patent’s great-grandparent, EX1006). Institution Decision (ID), 21. Instead, PO commercialized TC1507 subject to contractual restrictions ***precluding*** “research.” EX1003, 545. Such restricted commercialization cannot substitute for a deposit, which ensures public access for “research purposes.” EX2007, 1.

Despite bearing the burden of production, PO offers no relevant evidence establishing that TC1507 was readily available without restriction as of the relevant 4/30/04 filing date required to remove Barbour as prior art. This abject failure of proof—neglecting long-standing Office policy—confirms the Challenged Claims are unpatentable over Barbour.

Lacking any evidence, indeed, offering none at all, PO resorts to fanciful arguments that would undermine public policy, defy long-standing agency regulations, and contradict PO’s own representations to the EPO. PO likewise advances a speculative and unsupported “commodity corn” theory while neglecting to disclose that it is ***currently suing Petitioner*** for having undertaken such a brute-force TC1507 search over fifteen years after the relevant 4/30/04 date.

II. UNDISPUTED FACTS

The relevant facts are straightforward and undisputed despite PO's pervasive distractions:

1. Barbour (EX1009) renders the Challenged Claims unpatentable unless they are entitled to the ancestral 4/30/04 filing date. *See* Petition, 41-67; ID, 9 n.5, 19-21.

2. TC1507 germplasm is necessary to practice the Challenged Claims. *See* Petition, 29-41; ID, 10-13.

3. PO never deposited TC1507 germplasm. *See* ID, 13, 17.

4. PO commercialized TC1507 subject to a "technology agreement" *prohibiting* "research" use of TC1507 aside from two irrelevant exceptions PO does not rely on.¹ *See* EX1003, 545; Petition, 33; ID, 14-15.

5. Had PO deposited TC1507 seed, such deposit would have been "readily available" as required and *permitted* the public to use the deposited seed and its "progeny" for "research purposes." EX2007, 1.

6. PO is suing Petitioner for allegedly having obtained TC1507 seed in 2020 in commodity corn—contradicting PO's contrived theory that commercializing TC1507 made it "readily available to the public." *See* EX1072, 41 (¶135), 43 (¶140), 104-105 (¶¶406-411); EX1073, 104-105 (¶¶62-64).

¹ *See infra* note 4.

III. RELEVANT LAW

The relevant legal principles are likewise straightforward notwithstanding PO's numerous diversion attempts.

PO bears the "burden of production" to "show that Barbour is not prior art" because the '738 Patent is entitled to its ancestor's 4/30/04 filing date. ID, 9. This requires "producing additional evidence and presenting persuasive argument based on new evidence or evidence already of record." *Dynamic Drinkware v. Nat'l Graphics*, 800 F.3d 1375, 1379 (Fed. Cir. 2015).

Such evidence and argument must establish that the 4/30/04 application enables the claims per §112. ID, 10, 14 (citing *Chiron*).

When (as here, *see supra* §II) germplasm is necessary to practice patent claims but there is no deposit, §112 requires proof it was both "known and readily available" to POSAs. 37 C.F.R. §1.802(b); *In re Lundak*, 773 F.2d 1216, 1218 (Fed. Cir. 1985). These are separate hurdles. MPEP §2404.01("[N]either concept alone is sufficient."); 52 Fed. Reg. 34,080, 34,088 (Sept. 9, 1987). Merely referencing samples does not necessarily make them "accessible without restriction to the public." 52 Fed. Reg. at 34,090. The "readily available" language instead "indicate[s] public accessibility to those wishing to test the biological material." *Id.* at 34,088.

This “known and readily available” concept is a narrow exception to the general rule requiring deposits for plant utility patents. PO stressed that general rule to the Supreme Court in *J.E.M. AG Supply v. Pioneer Hi-Bred* when successfully arguing that plant utility patents are permissible despite parallel protection schemes with lesser requirements. PO emphasized §112’s “demanding disclosure standards” and how they “***typically requir[e] a deposit of biological materials, with full public access*** to the deposit.” EX1074, 10, 21.

J.E.M. states unequivocally that plant utility patents must “meet the specifications of §112,” including “a deposit of seed that is publicly accessible.” 534 U.S. 124, 131 (2001). The Supreme Court reiterated that [*t]he description requirement for plants includes a deposit of biological material*, for example seeds, and mandates that such material be accessible to the public.” *Id.* at 142.

Despite bearing the burden of production, PO never cites any decision concluding that a plant’s commercial availability excused failing to deposit seed.

The Office indeed warns that it “will accept commercial availability in lieu of a deposit only when the evidence is ***clear and convincing*** that the public has access to the material.” MPEP §2404.01; *see also* 54 Fed. Reg. 34,864, 34,875 (Aug. 22, 1989) (promulgating §1.802(b)). PO failed to present such evidence during prosecution and simply ignores its burden here.

By failing to make a deposit, PO ran “a great risk” given §112’s “disclosure requirements.” *In re Howarth*, 654 F.2d 103, 107 (CCPA 1981) (affirming enablement rejection). The Office cited *Howarth* when explaining the “readily available” standard. 52 Fed. Reg. at 34,090. The Office has likewise warned applicants to deposit essential biological material whenever there is “any doubt” it is “readily available.” EX1083, 18-19; EX1084, 19.

IV. ARGUMENT

PO’s admissions (*supra* §II) confirm that patentability turns solely on whether TC1507 seed was both “known *and* readily available” to entitle the Challenged Claims to the great-grandparent’s 4/30/04 filing date even though PO never deposited such seed.

Despite bearing the relevant production burden, PO offers no evidence establishing that TC1507 seed was readily available as of 4/30/04. *See infra* §IV.A.1. PO instead resorts to attorney argument and misrepresents *Petitioner’s* evidence confirming that TC1507 was *not* readily available as of 4/30/04.

None of PO’s “what if?” attorney argument theories for how POSAs purportedly could have accessed TC1507 seed withstands scrutiny. *See infra* §IV.A.2. PO’s arguments instead neglect controlling law and PO’s own representations.

Tellingly, PO separately argues that no deposit was required because TC1507 was allegedly readily available when the '378 Patent *issued* in 2014. The Board already squarely rejected this theory, which neglects controlling law. ID, 16-18; *infra* §IV.B. PO's argument that TC1507 was "readily available" as of 2014 also contradicts PO's ongoing litigation against Petitioner for having accessed TC1507 even more recently. *See infra* §IV.A.1.c.

A. The Challenged Claims Are Not Entitled to the Great-Grandparent Applications's Priority Date Because PO Never Deposited TC1507 Seed And It Was Not Otherwise "Known and Readily Available" as of April 30, 2004

1. PO Cites No Relevant Evidence and Fails to Satisfy Its Production Burden

Despite bearing the "burden of going forward with evidence" to remove Barbour as prior art despite never depositing TC1507 seed (*Dynamic Drinkware*, 800 F.3d at 1379), PO offers no such evidence establishing the seed was "readily available" as of 4/30/04. PO instead asks the Board to *infer* such availability from PO's own commercialization efforts starting in 2003. But "[t]he Office will accept commercial availability as evidence that a biological material is known and readily available *only when the evidence is clear and convincing* that the public has access to the material." MPEP §2404.01. PO offers no such evidence despite the Office's specific guidance and warnings concerning this narrow exception to the

general rule requiring deposits when biological material is needed under §112. PO thus waived any such argument.

Tellingly, PO introduces no documentary evidence indicating whether TC1507 was readily available to POSAs as of 4/30/04. Among PO's seven exhibits, only one (EX2004) existed and was accessible to POSAs as of 4/30/04. EX2004 merely confirms that PO commercialized TC1507 starting in 2003. *See* POR, 8 (characterizing TC1507). But as MPEP §2404.01 emphasizes, commercialization alone does not constitute clear and convincing evidence that seed was readily available. Nor does "[t]he mere reference to...the biological material itself in any document or publication" (for example, EX2004) "necessarily mean that the...material is readily available." MPEP §2404.01.

For one, it does not establish "that all restrictions on the accessibility" of the material will "be irrevocably removed" when the patent issues. *Id.* PO indisputably commercialized TC1507 subject to strict "no research" restrictions, which would have been inapplicable had PO made a deposit. *See infra* §IV.A.3.

Separately, commercialization and related references do not establish that seed was available at a reasonable price. *See* MPEP §2404.01 ("A product could be commercially available but only at a price that effectively eliminates accessibility to those desiring to obtain a sample."). Yet PO offers no evidence concerning the

price it charged for TC1507 at any point—much less the inaugural 2003 growing season.

Nor does PO offer any “declarations of accessibility by those working in the field.” MPEP §2404.01. PO offers no witness of its own. Instead, PO relies solely on purported “admissions” from *Petitioner’s* expert Dr. Silverstone. But when cross-examining Dr. Silverstone, PO persistently demanded that he *assume* POSAs possessed “a corn plant that had the TC1507 event.” EX2003, 34:22-35:2; *see also* 11:11-12 (“*If* you have a seed in your hand that possessed the TC1507 event”); 32:10 (“*if* a person had a seed”); 38:12 (“*if* you have a TC1507 seed in hand”); 38:23 (“*if* you have access to the seed”); 57:15-17 (“*if*...you had a corn seed in hand with the TC1507 event”). Such forced assumptions repackage PO’s own speculation and attorney argument.

2. PO’s Attorney Arguments Fail

None of PO’s “what if?” theories establishes that TC1507 seed was “readily available” to POSAs as of 4/30/04. PO cites no supporting facts or relevant law despite bearing the production burden. PO instead asserts without basis that POSAs “had access—without restrictions—to TC1507 corn in the commodity system and even in farmer’s fields.” POR, 29. But PO’s own actions—including its ongoing litigation against Petitioner—belie PO’s arguments.

a. PO's Contracts Barred Providing TC1507 to POSAs

PO's suggestion that POSAs could obtain TC1507 seed via "farmer's fields" (POR, 29) lacks any evidentiary support. PO never explains how POSAs would even identify farmers—much less convince them to cooperate.

Despite bearing the production burden, PO never identifies any search tools allowing POSAs to identify TC1507 growers. *See* EX2003, 58:8-9 ("The sales of products is not open information to the public."). That certain farmers may "label their fields" (POR, 28) is immaterial and doesn't establish that POSAs would know where to look for such fields across the globe. PO does not identify a single farm, field, or publicly available tracking mechanism whereby POSAs would even know where to look.

Nor does PO establish why farmers would cooperate and provide such information to third parties voluntarily. Such collusion would have risked legal liability given the restrictive "Technology Agreement" (EX1003, 545) PO forced farmers to sign. Those contractual prohibitions *expressly barred* farmers from providing TC1507 seed even if POSAs lucked upon such growers. PO's "Technology Agreement" prohibited farmers from providing the "seed or its progeny...to anyone for crop breeding, seed production or research." EX1003, 545; *see also* EX1085, 11:25-12:1 (obtaining seed "from a farmer" would implicate "technology use agreement").

Identifying and obtaining TC1507 seed via “farmer’s fields” would thus be impossible unless POSAs risked legal liability by (1) inducing farmers to violate PO’s “Technology Agreement” or (2) stealing corn from under farmers’ noses. Neither hypothetical even arguably suggests TC1507 was “readily available.”

b. TC1507 Was Not Readily Available From Commodity Corn, Which Would Have Required Searching for a Needle in a Haystack

PO’s suggestion that TC1507 was readily available to POSAs as of 4/30/04 “via the commodity system” (POR, 29) also fails. The “commodity system” means how, following harvest, TC1507 corn would be “mixed with *every other variety* being grown.” EX2003, 58:11-16. Under PO’s theory, POSAs would purchase such commodity corn, test it for TC1507, and hope for positive results. But such a hypothetical, needle-in-haystack search plainly does not render TC1507 “*readily* available” to excuse PO’s failure to make a deposit. Indeed, when questioning Petitioner’s expert, PO demanded that he “*put aside how available* [TC1507] was.” *Id.*, 57:12-14. That instruction exemplifies PO’s lack of “any evidence to show TC1507 corn ‘*readily available*’ to the public without restrictions.” ID, 21. Indeed, PO’s Petitioner’s expert stressed that “it would have been *extremely difficult* to get [TC1507] in hand” as of 4/30/04. EX2003, 53:22-54:3. PO never disputes this point—much less offer clear and convincing evidence as the MPEP requires to excuse PO’s failure to deposit TC1507.

PO cites no authority suggesting that indiscriminately testing commodity crop streams can substitute for a deposit. Nor does PO cite any evidence—much less a “clear teaching in [PO’s] disclosures”—concerning “where” within the commodity system POSAs “might unearth” TC1507. *Ex Parte Hata*, 6 USPQ2d 1652, 1653 (BPAI 1987) (affirming enablement rejection given lack of deposit, noting lack of “clear teaching in appellants’ disclosure as to where” POSAs “might unearth [relevant] microorganisms”); *see also Application of Merat*, 519 F.2d 1390, 1396 n.9 (CCPA 1975) (“The specification contains no disclosure of where chickens having the nr gene may be obtained....”)

PO never suggests that farmers or commodity brokers would assist POSAs in searching for TC1507 against contractual obligations. Such assistance (*e.g.*, identifying when and where corn is sold after harvest, identifying the specific storage facility, “elevator,” or train-car hopper, EX2003, 58:11-16) indeed would risk severe legal liability. *See supra* §IV.A.2.a. Instead, the hypothetical search would have been completely **unguided** even though TC1507 looks no “different from any other corn grain.” EX2003, 58:17-18. Finding TC1507 corn amidst tons of innumerable other varieties (which PO never even tries quantifying) would have been a far cry from “readily” accessible.

Furthermore, PO neglects “the crucial issue...whether” TC1507 “commonly occur[ed]” in the commodity corn system as of 4/30/04 or instead “rarely

occur[ed].” *Hata*, 6 USPQ2d at 1653-54 (“[W]e find nothing in the disclosure or in the declarations relied upon by appellants which sheds any light on the rarity of the microorganisms encompassed by the appealed claims.”).

PO indeed ignores evidence that TC1507 rarely occurred in commodity corn as of 4/30/04—that is, after a single TC1507 growing season. The first season of a new transgenic crop involves “**very limited** sales” and “seed availability.” EX2003, 45:10-11, 45:22-46:5. Subsequent trade literature concerning TC1507 (“Herculex I”) noted “wider availability” in 2005 (EX1050, 19), confirming it was “less available” before. EX2003, 46:24-47:4. Similarly, PO began commercializing next-generation “Herculex XTRA” in 2006, sold “10 times more” in 2007, and finally achieved “full availability” in 2008. EX1086, 4.

Given that TC1507 was “not of common occurrence” as of 4/30/04, “it might not be found for a very long time, if found at all.” *Hata*, 6 USPQ2d at 1654 (quoting *In re Argoudelis*, 434 F.2d 1390 (CCPA 1970)). Seeking TC1507 in commodity corn at the time would have required “an iterative, trial-and-error process,” which “does not provide an enabling disclosure” under §112. *Idenix Pharms. v. Gilead Scis.*, 941 F.3d 1149, 1162 (Fed. Cir. 2019).

Expecting POSAs to “search[] for a needle in a haystack” is objectively unreasonable and cannot substitute for an enabling disclosure—regardless whether the actual searching would have been “routine.” *Id.*; see also *Amgen Inc. v. Sanofi*,

987 F.3d 1080, 1085 (Fed. Cir. 2021) (specification didn’t enable claims despite “well-known screening techniques”), *aff’d*, 598 U.S. 594 (2023).

Indeed, POSAs indisputably would “have to be extremely motivated and do a lot of work to identify TC1507 seed in the commodity system” as of 4/30/04. EX2003, 58:19-21; *see also id.*, 53:22-54:3 (“***extremely difficult*** to get in hand”); 62:12-13 (“***very difficult***”). That is the antithesis of a seed “***readily available***” to justify omitting a deposit. Tellingly, PO offers no evidence concerning how expensive the needle-in-a-haystack operation would be. *See supra* IV.A.1; MPEP §2404.01 (“A product could be commercially available but only at a price that effectively eliminates accessibility to those desiring to obtain a sample.”)

**c. PO’s Lawsuit Against Petitioner For Having
Obtained TC1507 Years Later Further Confirms
TC1507 Seed Was Not Readily Available as of 4/30/04**

Aside from neglecting the “***readily*** available” requirement, PO’s “commodity system” theories contradict PO’s ongoing lawsuit against Petitioner² “alleg[ing] that [Petitioner] wrongly acquired seeds containing TC-1507.” *Corteva Agriscience v. Inari Agric.*, CV-23-1059, 2025 WL 1380763, at *2 (D. Del. May 13, 2025). PO accuses Petitioner of “***conversion*** of seeds” embodying the “TC-

² PO mentions the lawsuit only for RPI purposes. *See* POR, 50-51. Petitioner (Inari Agriculture Inc.) acknowledges its privity with Inari Agriculture NV.

1507” event (EX1072, 105 (¶409))—that is, “interfer[ing] with the right of another to control” property. Restatement (Second) of Torts §222A (1965). Yet Petitioner obtained TC1507 **in 2020** by purchasing “corn cobs of undisclosed provenance, which after analysis were found to include the TC1507 event.” EX1073, 104 (¶62). Simply put, Petitioner screened commodity corn. Yet PO objected and sued Petitioner because it had “no business relationship with [PO] that would have allowed Inari to use” TC1507. EX1072, 41 (¶135).

PO’s lawsuit contradicts PO’s suggestion that screening commodity corn renders TC1507 “readily available” to excuse a deposit. Strikingly, PO ***touts*** how Petitioner “obtained TC1507 seed.” POR, 42; *see also* 44 (“Petitioner’s own access”). ***But PO is suing Petitioner for having obtained access as it now insists any member of the public is free to attempt.***

Even aside from PO’s litigation, the fact that Petitioner obtained TC1507 in **2020** via trial-and-error screening is immaterial to whether TC1507 was readily available as of **4/30/04** (or even the ’378 Patent’s 12/2/14 issue date).³

³ PO’s lawsuit contradicts any suggestion that “corn harvested from TC1507 plans was ‘known and readily available to the public’ by 2010.” ID, 23. But the issue is immaterial because TC1507 corn certainly was ***not*** readily available as of 4/30/04.

**d. PO's Own Standard Practice is to Deposit Seed—
Even After Commercialization**

PO never denies its own standard practice of depositing seed. *See* Petition, 60. PO follows this practice *even after commercializing the relevant plant*.

For example, PO's "Herculex® XTRA" corn embodies PO's U.S. Patent Nos. 7,956,246; 8,592,653; and 8,952,223. EX1087; EXS1088-1090. PO commercialized Herculex® XTRA starting in 2006 (EX1091), with "full availability" in 2008 (EX1086, 4). Yet the Office issued enablement rejections for the corresponding applications in **2010** and **2013**. EX1092, 171-175; EX1093, 162-166; EX1094, 158-162. Tellingly, PO made no commercial availability arguments in those cases.

PO overcame the first two enablement rejections by committing to make deposits, with "all restrictions upon availability to the public...irrevocably removed upon granting of the patent." EX1092, 188; EX1094, 178. PO's initial response to the third omitted this language, and the Office maintained the rejection. EX1093, 203-206. PO then represented that the deposited "*seeds will be irrevocably and without restriction or condition released to the public* upon the issuance of a patent." *Id.*, 213. PO made this representation in July 2013—seven years *after* Herculex® XTRA began entering the commodity system. Such deposits and representations would have been unnecessary if screening commodity corn constituted an alternative. PO is talking out of both sides of its mouth.

e. Enablement of the Barbour Prior Art Involves a Different Timeframe and a Different Legal Standard

Lacking any relevant evidence of its own (*supra* §IV.A.1), unable to square its unsupported theory with its litigation against Petitioner (*supra* §IV.A.2.c), and likewise unable to deny its own standard deposit practices (*supra* §IV.A.2.d), PO resorts to Petitioner’s explanation why Barbour was enabled for **§102** purposes as of Barbour’s February **2006** publication date. See POR, 43-50. This argument fails for three independent reasons.

First, factually speaking, there was more TC1507/Herculex I in commerce as of 2/16/06 (after three growing seasons) than 4/30/04 (after just one). EX2003, 45:10-11, 45:22-46:5, 62:2-6; EX1050, 19; *see also* EX1086, 4 (2006-2008 timeline for Herculex® XTRA). Indeed, as sales after a growing season are linked to commodity prices, PO offers no evidence that the 2003 growing season was successful, or even an attractive time to sell commodity corn. With “more of the TC1507 corn planted, it increases” POSAs’ “ability to be able to find it” in the commodity stream. EX2003, 62:2-6; *see also* Petition, 55 (“**By 2006**”).

Second, legally speaking, “prior art patents and publications are *presumed* to be enabled” under §102, and PO “has the burden to prove” otherwise. *Intas Pharms. v. Atossa Therapeutics*, PGR2023-00043, Paper 37 at 16-17 (PTAB Jan. 29, 2025) (citing *Apple v. Corephotonics*, 861 F. App’x 443, 450 (Fed. Cir. 2021)). By contrast, patents in IPRs are *not* presumed valid, and PO bears the burden of

production to remove Barbour as prior art. *Supra* §III. But PO “has not produced or pointed to any evidence to show TC1507 corn ‘readily available’ to the public without restrictions as of the filing date of the 2004 application.” ID, 21.

Finally, the standard for “determining the enablement of a prior art reference under §102” is “*inapposite*” to “§112 enablement.” *Intas*, Paper 37 at 19-20. *Intas* held that prior art may be enabled by a “later reference” even though such evidence is *impermissible* under §112. *Id.* Likewise, an “otherwise non-enabled prior art publication” (POR, 47) can be enabled by commercial plant sales occurring after the publication. *In re Elsner*, 381 F.3d 1125, 1127 (Fed. Cir. 2004) (April 1995 publication and “October 1996” sale). By contrast, such post-filing activities are irrelevant for §112 enablement. *Application of Glass*, 492 F.2d 1228, 1232 (CCPA 1974). Further, the Board requires “clear and convincing” evidence to excuse the lack of a deposit for §112 purposes. MPEP §2404.01. No such threshold applies to §102 IPR challenges.

Barbour thus anticipates under §102 even though the 4/30/04 application does not enable the Challenged Claims under §112. The statutes “rest on different foundations, serve different purposes, and are not comparable.” *Glass*, 492 F.2d at 1232 (“nothing ‘unfair’ about” later-issued patents being irrelevant under §112 despite constituting pre-AIA §102(e) prior art).

Tellingly, PO never addresses these distinctly different purposes” (Petition,

57-58 (quoting *Howarth*) nor otherwise disputes that “*Howarth* affirmed the Board’s enablement rejection even though the relevant information—how to make necessary starting materials—had been disclosed in” foreign filings that were technically “publicly available” despite being obscure. Petition, 59. Nor does PO even acknowledge the “clear and convincing” evidentiary requirement to excuse the lack of a deposit for §112 purposes. MPEP §2404.01.

PO instead wrongly asserts that “[t]here is no relevant distinction between the standards.” POR, 43. But as *Howarth* explained and PO ignores, the foreign filings that were insufficient for §112 would have been treated just like readily available U.S. patents “for prior art purposes under s 102.” 654 F.2d at 107. Indeed, prior art under §102 need **not** be “readily available.” PTO Notices, 1401 OG 248 (Apr. 15, 2014) (“[c]rowdsourcing” benefits when “information that resides within the technical community is often not **readily available** to examiners”).

Tellingly, the Office specifically cited *Howarth* when explaining the “readily available” standard. 52 Fed. Reg. at 34,090. The Office explained that “an applicant must show that **anyone** skilled in the art would actually possess the requisite knowledge or would reasonably be expected to check the source which the applicant relies upon to complete his disclosure.” *Id.* PO makes no such showing concerning commodity corn. And much like the *Howarth* specification

never identified the foreign patents the applicant subsequently cited (POR, 44), the 4/30/04 application (EX1006) never indicates where to look for TC1507 in commodity corn.

3. PO Commercialized TC1507 Subject to Contractual Research Prohibitions, Which Would Be Inapplicable Had PO Deposited TC1507

Unable to support its “commodity” stream and “farmer’s field” attorney arguments (*supra* §IV.A.2), PO wrongly asserts that even *restricted* TC1507 seed sales excuse PO’s failure to deposit TC1507. POR, 30-37. But as PO stressed to the EPO, PO’s contracts expressly prohibited providing the seed for “research purposes.” EX1003, 543 (emphasis original). Nor could buyers conduct research themselves. *Id.*, 545. POSAs seeking to use TC1507 for research “would not be able to do that.” EX2003, 49:10-20.

By contrast, had PO deposited TC1507, even PO’s own exhibit confirms that the deposit *would* have been available for “research purposes.” EX2007, 1. Such research is precisely what PO’s “Technology Agreement” (EX1003, 545) *prohibits*. TC1507 sales pursuant to such agreement thus cannot substitute for a deposit.

PO attempts to skirt its prior representations to the EPO (POR, 29-30), but never disputes “the *facts* surrounding the TC1507 seed sales agreements remain the same.” ID, 15 (“[PO’s] representations to the EPO suggest that the TC1507

seeds sold by [PO] in 2003 do not meet the ‘readily available to the public’ standard”). Further, PO’s previous characterizations simply confirm the Technology Agreement’s express terms. Farmers had to agree “to not use this seed or its progeny or provide it to anyone for crop breeding, seed production or research (other than to make agronomic comparisons and conduct yield testing).”⁴ EX1003, 545. PO has a track record of enforcing such terms. *E.g., Pioneer Hi-Bred Int’l v. Ottawa Plant Food*, 283 F. Supp. 2d 1018, 1058 (N.D. Iowa 2003). PO’s restrictions refute PO’s attempt to excuse its failure to deposit TC1507.

Tellingly, PO ignores the Technology Agreement’s “prohibition on ‘research’” even though Petitioner highlighted it. Petition, 33 (quoting EX1003). That restriction is incompatible with the “readily available” requirement because it restricts those “wishing to test the biological material.” 52 Fed. Reg. at 34,088.

By contrast, depositing seed allows POSAs to conduct such testing and research. PO recently stressed that point in successfully opposing other AIA trial requests. PO explained that relevant deposits were “readily available to Petitioner

⁴ PO offers no argument concerning these narrow exceptions. “[A]gronomy” concerns “soil management” and “field crop...improvement, management, and production.” EX1079, 48. By contrast, depositing seed makes it available for *any* research. EX2007, 1.

for assessment,” yet Petitioner offered “no genetic analysis of the deposited seeds.” EX1075, 2, 34; EX1076, 2, 34; EX1077, 2, 34; EX1078, 3, 34. The Board agreed: “[b]y depositing the seeds Patent Owner is making the genetic sequence (genotype)” available. *Inari Agriculture v. Pioneer Hi-Bred Int’l*, PGR2024-00019, Paper 18 at 13 (Sept. 24, 2024); PGR2024-00020, Paper 18 at 13 (Sept. 24, 2024); PGR2024-00023, Paper 15 at 13 (Oct. 15, 2024); PGR2024-00025, Paper 15 at 13 (Nov. 1, 2024).

Genetic sequencing exemplifies “research” that PO’s “Technology Agreement” prohibits (EX1003, 545) but which depositing seed permits—as PO’s past arguments to the Board confirm.

a. PO’s Suggestion That “Seed Deposits Are Subject to Restrictions” Contradicts Controlling Law and PO’s Own Repeated Representations

PO wrongly reasons that “seed deposits are subject to restrictions themselves.” POR, 33. PO’s only cited support is a transfer agreement (EX2007) nominally restricting transfers to third parties. POR, 33-34. But PO neglects controlling law and misreads EX2007 (even aside from ignoring how it expressly *authorizes* “research”). PO also contradicts its own repeated representations to the Office and the Supreme Court.

§1.808(a)(2) stresses that:

Subject to paragraph (b) of this section, ***all restrictions*** imposed by the depositor on the availability to the public of the deposited material ***will be irrevocably removed*** upon the granting of the patent.

Paragraph (b) is purely ministerial and does not restrict public access to deposits or subject anyone to legal liability.⁵ It certainly does not restrict transfers to third parties. And in any event, arguing that the long-established deposit system authorizes restrictions is a demonstrably baseless attempt to distract from the relevant issues here.

When promulgating the regulations, the Office explicitly ***declined*** to permit restrictions on third-party transfers. 54 Fed. Reg. at 34,872:

The Office has decided ***not*** to adopt a rule permitting a depositor to require that a sample of a deposited biological material shall be furnished only if the requesting party has agreed not to make the material or a derivative thereof available to a third party without the depositor's permission.

As the Office explained, “no greater restriction on access to a deposit should be permitted than is permitted on access to the written description itself.” *Id.*

⁵ Paragraph (b) merely permits depositors to require that requests (1) be in “tangible form” (2) identify the requester, and (3) be disclosed upon request. §1.808(b). It is a narrow “exception to the ***general rule that all restrictions will be removed.***” MPEP §2410.01 (“no variations...will be accepted”).

In short, the portion of EX2007 cited by PO conflicts with Office regulations. And PO ignores a separate section stressing that applicable laws and regulations (including “37 C.F.R. provisions”) *supersede* agreement terms “[i]f there is any conflict.” EX2007, 3. Such conflict plainly exists here.

PO’s theory that deposits can be restricted also contradicts PO’s representations to the Supreme Court in *J.E.M.* PO touted how 37 C.F.R. §1.808 ensures deposits are “available to any member of the public to ascertain fully the teachings of the patent.” EX1074, 10. PO reiterated that the “public, *without restrictions*” had “access to the sample deposited” at the depository identified in the specifications. *Id.*, 12; *see also id.*, 21 (“*full public access to the deposit*”).⁶

Respondents’ theory also contradicts its representations to the Office when overcoming previous enablement rejections. *E.g.*, EX1093, 213 (“[T]he [deposited] seeds will be *irrevocably and without restriction or condition released to the public upon [patent] issuance.*”); EX1095, 13 (stressing reference to §1.808(a)(2), which “states: ‘*all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed* upon the granting of the patent.’”).

⁶ PO’s patents at issue in *J.E.M.* stressed such unrestricted access. *See, e.g.*, EX1080, 10:26-27; EX1081, 18:25-26; EX1082, 25:58-59.

PO's representations belie PO's theory that "seed deposits are subject to restrictions." POR, 33. Had PO deposited TC1507 seed, it indisputably would have been available for "research." EX2007, 1. By contrast, PO commercialized TC1507 subject to restrictions prohibiting "research." EX1003, 545. These restrictions confirm PO's commercialization of TC1507 did not render TC1507 seed "readily available" to POSAs and cannot substitute for a deposit.

b. PO Cites No Relevant Authority

PO cites no example excusing the lack of a seed deposit because the plant had been commercialized. PO's purported "controlling precedent" (POR, 31-33) is unrelated to deposits or otherwise to enablement. *McFarling* concerned a farmer who had violated a contract prohibiting saving seeds to replant. 302 F.3d 1291, 1298 (Fed. Cir. 2002). *Scruggs* likewise concerned defendants accused of selling "reconditioned seeds." 249 F. Supp. 2d 746, 751 (N.D. Miss. 2001). Neither concerns research or otherwise justifies PO's failure to deposit TC1507 seed.

PO instead wrongly faults Petitioner for not citing authority expressly holding that commercialized seed must be available without restriction to comply with ¶112. POR, 35-38. But **PO** bears the burden of production to establish entitlement to the 4/30/04 filing date. That includes presenting "persuasive argument." *Dynamic Drinkware*, 800 F.3d at 1379. Yet PO never even mentions the contractual "no research" term it imposed.

The lack of authority recognizing commercialized seed as a substitute for deposits cuts against PO—not Petitioner. Nothing in the record suggests any other instance of an applicant citing its own commercial sales—much less sales subject to “no research” restrictions—as a reason why deposits were unnecessary.

Indeed, as PO represented to the Supreme Court, §112’s “demanding disclosure standards” “*typically require[e] a deposit of biological materials, with full public access to the deposit.*” EX1074, 10, 21. It is unsurprising that no authority exists expressly rejecting PO’s outlandish argument that commercializing seed subject to “no research” restrictions excuses PO’s failure to make a deposit.

4. PO’s Self-Serving Regulatory Efforts Did Not Make TC1507 Readily Available to POSAs

PO wrongly touts how it *selectively* provided “access” to TC1507 seed. POR, 10. Exhibits 1036, 1054, and 1056 reflect PO’s efforts to navigate international regulatory and related labeling requirements. EX1036, 1-2; EX1054, 10; EX1056, 1; *see also* EX1052, 1. PO itself “provided the [relevant] samples” to the European authorities. EX1054, 1. The samples for the Korean study came from Korean regulators, who had recently approved TC1507. EX1056, 1. And PO admits it provided the seed underlying the “certified reference material” in EX1036. POR, 10-11.

PO’s pursuit of commercial advantage by selectively providing TC1507 seed does not establish it was “readily available” to POSAs. *Ex parte Hibberd*, 227

USPQ 443, 447 (Sept. 24, 1985) (rejecting claims under §112 given lack of “evidence indicating a “contractual obligation to...supply samples to *anyone* seeking them”).

Moreover, PO wrongly conflates “access to seed” with access to the certified reference material. The latter is *not* a seed, but rather a “highly processed powder” (EX2006, 1), which does not permit POSAs to generate seed. Further, it was not publicly available until “2005.” EX1096, 2391; *see also* EX1097 (“August 2005” acceptance). EX1036 likewise was not submitted until 2006. EX1036, 1.

B. TC1507’s Purported Public Availability as of the ’378 Patent’s 2014 Issue Date is Legally Irrelevant

Separately, PO argues that the relevant timeframe for assessing TC1507 seed’s availability is the ’378 Patent’s 2014 issue date—notwithstanding PO’s assertion that the Challenged Claims are entitled to the great-grandparent’s 4/30/04 filing date. POR, 16-19. The Board already rejected PO’s theory and explained that PO’s authorities were “inapposite” and did not concern “commercial availability.” ID, 16. PO ignores the Board’s two specific critiques and simply repeats itself.

First, PO still cites “no authority that directs [the Board] to extend the law applicable to the deposit of biological material to commercial sales of such material.” ID, 18. Controlling precedent instead *precludes* such extension. *See White Consol. Indus. v. Vega Servo-Control*, 713 F.2d 788, 791 (Fed. Cir. 1983) (affirming invalidity for lack of enablement *despite* “commercial use made...after

the October 1968 filing date”: “A sufficient disclosure must exist as of the application filing date.”). A “disclosure” that is “insufficient” for §112 purposes “as of the time it is filed” cannot be “supplemented” with later developments “add[ing] to the knowledge of the art.” *Glass*, 492 F.2d at 1232.

Second, PO ignores that “commercial sales lack safeguards provided by, for example, 37 C.F.R. §1.804(b).” ID, 18. Section 1.804(b) requires a representation that later-deposited biological material is “specifically identified in the application as filed.” Subsequent commercial sales include no such guarantees.

V. CONCLUSION

The Challenged Claims are unpatentable.

Dated: July 11, 2025

/Scott A. McKeown/
Scott A. McKeown, Reg. No. 42,866

CERTIFICATE OF SERVICE UNDER 37 C.F.R. § 42.6 (E)(4)

I certify that on July 11, 2025, I will cause a copy of the foregoing document, including any exhibits or appendices filed therewith, to be served via electronic mail, as previously consented to by Patent Owner, upon the following:

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Date: July 11, 2025

/MacAulay Rush/
MacAulay Rush
Paralegal
WOLF, GREENFIELD & SACKS, P.C.

CERTIFICATE OF WORD COUNT

Pursuant to 37 C.F.R. § 42.24, the undersigned certifies that the foregoing Petition for *Inter Partes* Review contains 5,597 words excluding a table of contents, a table of authorities, a certificate of service or word count, or appendix of exhibits or claim listing. Petitioner has relied on the word count feature of the word processing system used to create this paper in making this certification.

Date: July 11, 2025

/MacAulay Rush/

MacAulay Rush

Paralegal

WOLF, GREENFIELD & SACKS, P.C.