

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

INARI AGRICULTURE, INC.,
Petitioner,

v.

CORTEVA AGRISCIENCE LLC,
Patent Owner.

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

PATENT OWNER'S SUR-REPLY

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I. Introduction

Petitioner's Reply dodges the evidence firmly establishing that corn seed embodying the claimed TC1507 event was known and readily available by at least April 2004. Publications alerted the public to the availability of TC1507 corn seed: it was known. The public also had TC1507 corn and corn seed in hand, including in 2003: it was readily available. In fact, Petitioner admitted that TC1507 corn was available "*without restriction*" after the 2003 growing season and asserts that it "lawfully purchased publicly available corn cobs" encompassing the TC1507 event. Pet., 49-60; *see also* ID, 1-3 (Dissent); EX1073, 104 (¶ 62); EX2003 89:16-20. Petitioner and overwhelming evidence thus establish that TC1507 corn seed was known and readily available, satisfying enablement as of the April 2004 filing date on which the '378 patent relies. Accordingly, the later publication of the '378 patent specification as Barbour 2006 is not prior art. The '378 patent claims should therefore be found patentable.

II. Public Accessibility for the Purposes of § 112 Does Not Mean Unrestricted Use

Petitioner's arguments distill down to a single point: because Patent Owner did not make its TC1507 seeds *usable* without restriction, the '378 patent claims are not enabled and not entitled to the April 2004 filing date. But Petitioner's repeated attempts to expand the standard for public *access* to biological material under § 112 to require *unrestricted use* of the patented material (*e.g.*, Pet., 4, 18, 33, 60; Reply,

1, 7, 21-24) contravenes USPTO regulations, legal precedent, and the patent statute.

USPTO deposit regulations seek to facilitate “*access* to the biological material [when] necessary to satisfy the statutory requirements for patentability under 35 U.S.C. 112.”¹ 54 Fed. Reg. 34864, 34864 (Aug. 22, 1989) (Final Rule);² *In re Argoudelis*, 434 F.2d 1390 (CCPA 1970). They require “no greater restriction on *access* to a deposit ... than is permitted on access to the written description itself.” 54 Fed. Reg. at 34872. The rules do not require a patentee to provide for unfettered *use* of the biological material, including for testing or research. *See, e.g.*, Reply, 2, 7, 19-24. Just as access to a patent’s written description (e.g., as a published application or issued patent) does *not* create an unrestricted license to *use* the patented invention during its enforceable term, nothing requires that a deposited or commercially available seed must be free of any restrictions on its use. Tellingly, Petitioner has not cited any authority that research and testing are permitted with a

¹ The Examiner rejected the claims of the ’378 patent during prosecution on the basis of enablement and did *not* require a seed deposit. POR, 17 n.6. As Patent Owner asserted pre-institution, this should have ended the inquiry and continues to serve as an independent reason for why the issued claims comply with § 112.

² Emphasis added unless noted.;

https://archives.federalregister.gov/issue_slice/1989/8/22/34861-34901.pdf.

patented seed deposit during the term of the patent. *See id.*, 19, 21-24 (relying solely on EX2007). Neither a seed deposit nor an otherwise “readily available” seed comes with a license from the patentee for unrestricted use.

The USPTO’s rules speak in terms of *access* to the biological material—whether via seed deposit or the known and readily available standard—and do not confer a right to unfettered *use*. 37 C.F.R. §§ 1.802(b) (“unless *access* to such material”), 1.808(a)(1) (“*Access* to the deposit”). In promulgating the rules, the USPTO rejected requiring an affirmation “to comply with 35 U.S.C. 271 as a condition precedent to obtaining a sample of deposited biological material” because a requesting party “is already bound” under the law “not to infringe a corresponding valid patent.” 54 Fed. Reg. at 34873. Moreover, Rule 1.808(b) is not “purely ministerial” (*see* Reply, 22): it was implemented to address potential abuses of the seed deposit system. 37 C.F.R. § 1.808(b); 54 Fed. Reg. at 34872. While that section itself may not “subject anyone to legal liability” (Reply, 22), it provides a notice function to assess potential infringement during the enforceable life of a patent. *See* 54 Fed. Reg. at 34872 (“[S]amples of the deposit may be furnished without any specific identification or notification for requests made *after* the term of the patent.”).

Court filings and the Supreme Court’s decision in *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc.*, 534 U.S. 124 (2001), are consistent. *See* Reply,

4, 23, 25. That action did not address the standard for public accessibility to comply with § 112, but Pioneer Hi-Bred International, Inc.’s (“Pioneer”) statements were nevertheless consistent with Patent Owner’s position here. While Pioneer stated that complying with § 112 “typically” requires a seed deposit and “full public *access*” (EX1074, 10, 21), it also asserted that utility patents come with stronger exclusionary protections. *Id.*, 12. The Supreme Court echoed this, stating that “utility patent holders receive greater rights of exclusion than holders of a PVP certificate. Most notably, *there are no exemptions* for research or saving seed under a utility patent.” *J.E.M.*, 534 U.S. at 143. *J.E.M.* and Pioneer’s brief and patents³ are thus entirely consistent with the USPTO’s regulations that require public *access* but do not require unrestricted *use*.

Petitioner asserts that seed deposits be accessible for “research” based on a

³ Pioneer’s patents simply restate the applicable USPTO rules regarding *access*. *See* Reply, 23 n.6. Patent Owner similarly reiterated the rule that “all restrictions ... on the availability to the public ... will be irrevocably removed.” *Id.*, 23. None of these documents admits that there are no restrictions on *use* for access to seed deposit materials.

Material Transfer Agreement (“MTA”) from a single depository. Reply, 19, 21-24;⁴ EX2007. But Petitioner ignores that the MTA expressly states that “[p]urchaser shall have the sole responsibility for obtaining any intellectual property licenses necessitated by its possession and *use* of the Biological Materials.” EX2007, 2. Thus, Petitioner is incorrect that a seed deposit for TC1507 would have “indisputably ... been available for ‘research.’” Reply, 19, 20 n.4, 24 (quoting EX2007, 1).

The history of the USPTO regulations forecloses Petitioner’s argument. An early version of proposed Rule § 1.201(b) (issued as present day § 1.802(b)) stated that “[b]iological material will be considered to be known and readily available ... if samples of the biological material are known and accessible without restriction *to those who desire to obtain and test* the biological material.” 52 Fed. Reg. 34080, 34084 (Sept. 9, 1987).⁵ Petitioner cites this language favorably (Reply, 3, 20) and misleadingly omits that this sentence was deleted from the proposed rule. 53 Fed.

⁴ Petitioner’s arguments regarding third-party transfers (Reply, 22) truncates the full response, which acknowledges the “shortcomings in the proposed rule” as it relates to potential for seed deposit abuse. 54 Fed. Reg. at 34872.

⁵ https://archives.federalregister.gov/issue_slice/1987/9/9/34077-34102.pdf.

Reg. 39420, 39420 (Oct. 6, 1988).⁶ The Office stated that “[t]he definition of ‘known and readily available’ is not intended to be limited by [the] rule.” *Id.* Thus, Rule § 1.802(b) does not expressly permit the use of biological material for testing purposes, whether by access to a seed deposit or from commercially available sources. Petitioner is simply wrong that a seed deposit would have “permitted the public to use the deposited seed and its ‘progeny’ for ‘research purposes.’” Reply, 2 (emphasis in original).

USPTO rules do not exempt research uses for seed deposits from patent-infringement liability and they expressly include a notice function to assist in policing patent infringement. These facts are highly relevant to the “known and readily available” standard that applies here. Under USPTO regulations, § 112 compliance can be met *either* with a seed deposit *or* a demonstration that the biological material “is known and readily available to the public.” 37 C.F.R. § 1.802(b). The rules also state that a deposit of biological material that complies with the rules “will be considered to be *readily available*.” *Id.* Therefore, TC1507 corn seed sold under Patent Owner’s technology use agreement (“TUA”) (EX1003, 545) that restricts research uses, which federal courts have condoned as appropriate exclusionary rights under utility patents for plants, should not be any less “readily

⁶ https://archives.federalregister.gov/issue_slice/1988/10/6/39418-39432.pdf.

available” than a seed deposit that itself is subject to potential patent infringement for research purposes. *See Monsanto Co. v. McFarling*, 302 F.3d 1291, 1297-99 (Fed. Cir. 2002); *Monsanto Co. v. Scruggs*, 249 F. Supp. 2d 746, 757 (N.D. Miss. 2001); 54 Fed. Reg. at 34873.

III. The Public Had Access to Corn Seed Embodying TC1507 by at Least April 2004⁷

Petitioner has not disputed that corn seed embodying the TC1507 event was *known* to the public by April 2004.⁸ Numerous publications alerted the public to the availability of this seed offering, including in late 2002. Pet., 49-51; EX1003, 542; EX1047, 42; EX1048, 4; EX1049, 8. Petitioner and its expert also confirmed that Herculex I used in many of these publications refers to corn embodying the TC1507 event. Pet. 49-51; EX2003, 41:14-24, 42:12-43:23; EX1007, ¶ 132. Thus, the

⁷ USPTO regulations and case law have established that seed deposits and access must result before patent issuance. *Infra* § V. Patent Owner nevertheless addresses the Board’s requirement that availability be shown as of the April 2004 filing date. ID, 13-16.

⁸ Petitioner appears to suggest that only evidence filed by Patent Owner counts. Reply, 7. But evidence is evidence, and Patent Owner is not required to resubmit Petitioner’s own evidence to rely on it. *See* 37 C.F.R. § 42.6(d).

evidence establishes that TC1507 corn seed was *known*.

There is also no legitimate dispute that TC1507 corn seed was *readily available*, i.e., accessible, to the public. As an initial matter, Petitioner repeatedly states that biological material needs to be made available to a person of ordinary skill in the art. *E.g.*, Reply, 3, (“to POSAs”), 9, 24 (“did not render TC1507 seed ‘readily available’ to POSAs”), 25-26. But the rules and case law refer to the general public. 37 C.F.R. § 1.802(b) (“known and readily available to the *public*”). While the public includes one of ordinary skill, it is not so limited. And, notably, Petitioner does not dispute that corn growers or farmers and researchers—the public—were able to knowingly obtain TC1507 seed in 2003. EX2003, 49:21-50:4; EX1047, 42; EX1048, 4; EX1056, 1150 (identifying article as being received October 13, 2003). Petitioner similarly does not dispute that TC1507 corn entered the commodity stream in 2003, i.e., the public could buy TC1507 corn from corn growers. Pet., 49-51; Reply, 11-12; EX2003, 49:21-50:4; EX1007, ¶¶ 132-134, 140. Petitioner’s expert also explained that commodity streams are “often screened” and that TC1507 was “routinely screened.” EX2003, 68:13-69:5. Thus, purchasers of corn at grain elevators knew exactly where to look for downstream access to TC1507 corn in 2003. EX2003, 39:6-44:9, 44:10-45:19; EX1007, ¶¶ 133, 143; Pet., 49-53. This is the same type of access that Petitioner asserts it had and is all that is required under the rules to meet the “known and readily available” standard. EX1073, 104 (¶ 62).

A. Restrictions Under a Technology Use Agreement Did Not Affect Access

Petitioner failed to present any evidence that the public did not have—or importantly was denied—*access* to TC1507. And the only testimony it presented from Dr. Silverstone shows that it *was* accessible. *E.g.*, EX1007, ¶¶ 132-134, 140; EX2003, 39:6-44:9, 44:10-45:19. Failing to prove that TC1507 was not accessible, Petitioner resorts to arguing that such access came with restrictions. Patent Owner’s TUA does *not* undercut the ready availability of TC1507 corn seed. *See* Reply, 19-25. USPTO regulations regarding biological materials do not forbid restrictions on *use*, which is all that Petitioner and its expert have argued a TUA restricts—use, not access. Pet., 52-53; Reply, 2 (“PO commercialized TC1507 subject to a ‘technology agreement’ prohibiting ‘research’ use of TC1507.”), 9-10, 19-21; EX1003, 545-547; *see also, e.g.*, EX2003, 52:3-11 (“I am referring to restrictions on use.”). As Petitioner itself points out, restrictions in a TUA are *permissible* applications of a patentee’s exclusionary rights. Reply, 20, 24. In *Pioneer Hi-Bred International v. Ottawa Plant Food, Inc.*, 283 F. Supp. 2d 1018, 1024-25 (N.D. Iowa 2003), the district court upheld the validity of a technology agreement that precluded research of a parental seed line. *Accord* *McFarling*, 302 F.3d at 1298-99; *Scruggs*, 249 F. Supp. 2d at 753. Enforcement of these valid exclusionary rights with a TUA does not preclude a finding of “known and readily available” in the same way that a seed

deposit does not become inaccessible even when those who access it are “already bound” under law “not to infringe a corresponding valid patent.” 54 Fed. Reg. at 34873.

Attempting to avoid uncontroverted evidence that TC1507 corn seed was available to the *public*, Petitioner raises a new argument that Patent Owner’s TUA eliminates ready access to a *skilled artisan*. Reply, 9-10. This attorney argument, unsupported by evidence, ignores Petitioner’s expert’s admission that publications like those of EX1047 and EX1048 would have been read by a person of ordinary skill. EX2003, 39:6-41:8. It also ignores Dr. Silverstone’s additional admission that any private person, including those of ordinary skill in the art, could obtain TC1507 corn seed pursuant to a TUA. EX2003, 66:7-24 (Q: “So you could get the material, right?” A: “Yes.”). Put together, the evidence demonstrates that, even if a person of ordinary skill were the appropriate target, they would have known (1) where to access the corn seed embodying TC1507, from at least Dow AgroSciences and Pioneer; and (2) would have been able to obtain it pursuant to a TUA. *E.g.*, EX1047, 42; EX1048, 4; EX2003, 39:6-45:19, 66:7-24, 89:11-20. Nothing else was necessary to practice the claimed invention.

The skilled artisan would not have had to get the material from a farmer (*see* Reply, 9), and Petitioner’s argument in this regard is a red herring. If, as Petitioner admits, a farmer already had TC1507 corn (i.e., through the purchase of seed), then

the public already had it. No further access is needed. And as Dr. Silverstone and Petitioner both admit (EX2003, 89:11-20; EX1073, 104 (¶ 62), 105 (¶ 64)), Inari accessed corn embodying TC1507 in the commodity stream, so Patent Owner's TUA did not appear to erect a hurdle that Petitioner now attempts to establish here.

B. The Public Had Access to TC1507 as Part of the Commodity System

In its Reply, Petitioner backpedals from its admissions that not only was corn embodying TC1507 available to the public as part of the grain commodity system, it was available “without restriction[.]” *See* Reply, 10-13; Pet., 55 (“POSAs could have screened commercially available bulk corn from the 2003, 2004, or 2005 growing seasons and thereby gained possession of TC1507 as claimed.”); *see also* EX2003, 51:13-52:21; EX1007, ¶¶ 131, 133-134, 143; EX1048, 4. Petitioner's arguments now about purportedly limited access should be given no weight since they contradict arguments and admissions that led to institution.⁹ Further, Petitioner's arguments in reply are without merit.

⁹ Judicial estoppel can be applied in the context of an administrative tribunal. *Egenera, Inc. v. Cisco Sys., Inc.*, 972 F.3d 1367, 1380-81 (Fed. Cir. 2020). Here, Petitioner should be held to “the consequences of its choices.” *Sonos, Inc. v. Implicit, LLC*, IPR2018-00766, Paper 67 at 20-21 (P.T.A.B. Sept. 19, 2023).

First, Petitioner’s own access to TC1507 corn from the commodity system is evidence of access and belies Petitioner’s assertion that finding TC1507 corn in the commodity stream would be like looking for a needle in a haystack. *See* Reply, 10, 12-13; EX2003, 89:16-20; EX1073, 104 (¶ 62), 105 (¶ 64). Petitioner offers no evidence supporting its argument, relying instead on attorney argument (Reply, 10, 11) and unsupported expert testimony. *Id.*, 11 (relying on EX2003, 58:11-16);¹⁰ *see* EX2003, 64:5-24 (Dr. Silverstone admitting that he has “personally ... not been involved with any sales or commercializing of the TC1507 event at any time”). Attorney argument is not evidence. *Elbit Sys. of Am., LLC v. Thales Visionix, Inc.*, 881 F.3d 1354, 1359 (Fed. Cir. 2018) (holding that “[a]ttorney argument is not evidence’ and cannot rebut other admitted evidence” (quotation omitted)); *Gemtron Corp. v. Saint-Gobain Corp.*, 572 F.3d 1371, 1380 (Fed. Cir. 2009) (unsworn attorney argument is not evidence). Moreover, Petitioner mischaracterizes counsel’s

¹⁰ Dr. Silverstone’s testimony (EX2003, 58:11-16) does not discuss storage facilities or train car hoppers. Thus, no evidence of record supports that these components are part of the commodity system. Nevertheless, any assertion that a skilled artisan would have known these are part of the commodity system as Dr. Silverstone himself appeared knowledgeable (EX2003, 50:10-15), further undermines Petitioner’s needle-in-the-haystack argument.

questioning (Reply, 10) that sought to elicit confirmation that with TC1507 seed in hand, which Dr. Silverstone had previously admitted was available in 2003, the claimed invention could be practiced. EX2003, 57:11-58:2. On that point, there is no dispute. Pet., 55 (citing EX1007, ¶¶ 139-140); EX1007, ¶¶ 134, 149-166; EX2003, 10:4-21, 14:11-20, 15:7-24, 19:13-20:11, 38:21-22.

Second, Petitioner cites no case law or USPTO rules that require Patent Owner to cite authority that “*testing* commodity crop streams can substitute for a deposit,” because neither the seed deposit regulations nor the “known and readily available” standard require permitting *testing* uses. See Reply, 11; *supra*, § II. Nevertheless, the present facts are entirely distinguishable from the *Ex parte Hata* and *In re Merat* cases on which Petitioner relies. See Reply, 11.

In *Ex parte Hata*, the Board upheld the enablement rejection of claims to a method of treating an infectious disease using *Lactobacillus*, where appellant had not established that the recited *Lactobacillus* strains were common and could be readily sourced. 6 U.S.P.Q.2d 1652, 1654 (BPAI 1987). Rather, the Board concluded that “nothing in the disclosure or in the declarations relied upon by appellants ... sheds any light on the rarity of the microorganisms.” *Id.* The Board further reasoned that this absence of evidence suggested that the “microorganisms encompassed by the appealed claims are, in fact, rare.” *Id.* In contrast, here Petitioner’s attorney argument that “TC1507 rarely occurred in commodity corn as

of 4/30/04” (Reply, 12) directly contradicts its Petition and evidence of record. Pre-institution, Dr. Silverstone testified that TC1507 corn was “*widely* planted in the United States over the course of three growing seasons,” including 2003. EX1007, ¶ 131. Again, pre-institution, Petitioner admitted that TC1507 commodity corn “was indisputably commercially available following the 2003, 2004, and 2005 growing seasons,” which, as Dr. Silverstone testified, includes the end of 2003, beginning of 2004. Pet., 52; EX1007, ¶ 143; EX2003, 43:24-44:9, 49:21-50:4, 51:13-52:21. Thus, *Ex parte Hata* is simply inapplicable to the present facts.

If anything, the Board’s reasoning in *Ex parte Hata* supports enablement of the present claims. The Board stated that “[w]e do not view *Argoudelis* to establish deposition of a microorganism as the *only* way to satisfy the enablement requirement of the first paragraph of 35 U.S.C. 112.” *Ex parte Hata*, 6 U.S.P.Q.2d at 1654 (emphasis in original). A deposit may be required “if it is not commonly occurring or not shown to be obtainable from a commonly occurring microorganism by a verbally enabling disclosure.” *Id.* TC1507 corn was not uncommon. Multiple publications announced the availability of TC1507 corn seed and its source. *E.g.*, EX1047, 42 (Dow AgroSciences and Pioneer); EX1048, 4 (same); *see also* EX1056, 1150 (Korea Food and Drug Administration). Moreover, Dr. Silverstone explained that the TC1507 corn that would have been grown from this available seed was sent to grain elevators and “routinely” screened for approved events like TC1507.

EX2003, 58:11-16, 68:13-69:5. Inari itself appears to have had no trouble accessing TC1507 corn via this route (*id.*, 89:16-20), which is further evidence that the TC1507 event was “known and readily available.”¹¹

In re Merat is also inapt. It relates to an indefiniteness rejection, and not enablement. *In re Merat*, 519 F.2d 1390, 1393-94 (CCPA 1975). The court’s reference in a footnote to the enablement standard was not relevant to its holding. *Id.*, 1396 n.9. It therefore does not undermine Patent Owner’s showing of enabled claims in the present case.

Third, there is no evidence of record to support Petitioner’s new argument that TC1507 was “not of common occurrence.” Reply, 11-12 (quoting *Ex parte Hata*). Rather, after admitting that TC1507 corn seed was sold to the public in 2003 and would have been available in the commodity stream in late 2003 (and early

¹¹ While Inari’s answer indicates that it accessed TC1507 in 2020 (EX1073, 104 (¶ 62), 105 (¶ 64)), Petitioner has not offered any evidence that it would have been impossible or even more difficult to have obtained TC1507 via the same or similar grain elevators or other channels by April 2004. Indeed, substantial evidence demonstrates that TC1507 corn was known and readily available to the public by April 2004. EX1048, 4; EX2003, 49:21-50:4; EX1007, ¶¶ 132-134, 140; *see also* Pet., 49-50, 55.

2004) to secure institution, Dr. Silverstone later speculated during his deposition that such sales would have been “very limited.” *Id.*, 12 (citing EX2003, 45:10-11, 45:22-46:5); *see also* EX2003, 51:13-52:21; EX1007, ¶¶ 131, 140, 143. Aside from the fact that Dr. Silverstone did not qualify his statements regarding the availability of TC1507 corn seed as “very limited” in his declaration (*e.g.*, EX1007, ¶¶ 131, 143), he also had not considered any sales figures or documents reporting acreage planted to substantiate his newly developed deposition position (EX2003, 47:5-21, 54:4-57:6). Dr. Silverstone’s unsupported, self-serving, and contradictory post-institution testimony should be given no weight. *Xerox Corp. v. Bytemark, Inc.*, IPR2022-00624, Paper 9 at 15 (P.T.A.B. Aug. 24, 2022) (precedential); 37 C.F.R. § 42.65(a); Fed. R. Evid. 602.

Regardless, substantial evidence supports Petitioner’s original position that TC1507 corn, whether to farmers or in the commodity stream, was “widely available,” including by April 2004. EX1040, 30 (noting that “volume grew 4 percent” in 2003 as a result of several new products, including Herculex I); EX1047, 42 (TC1507 available from at least two sources); EX1048, 4 (same). In April 2004, just before the relevant filing date, a news release issued, entitled “Mycogen Seeds hybrids with Herculex I earn high marks with corn growers.” EX2004. This document provides direct evidence that farmers had access to, planted, and *evaluated* TC1507 corn seed as meeting their satisfaction during the 2003 growing season. *Id.*

It also indicates that multiple hybrids were available: “Mycogen Seeds offered growers 11 hybrids with HerculexTM I Insect Protection.” Indeed, Ben Kaehler, National Sales Manager with Mycogen Seeds, stated that “Herculex I is offered in our top corn hybrids.” *Id.* TC1507 corn seed was not a niche market. And SEC filings for the 2003 year showed that “Agricultural Sciences sales were a *record* \$3.0 billion in 2003” and the increase in volume was, in part, due to the new Herculex I products. EX1040, 30. This is a far cry from a “rare” or “uncommon” product offering.

Petitioner’s cited cases, *Ex parte Hata*, *In re Merat*, *Idenix*, and *Amgen*, do not substitute for evidence and are inapposite. *See* Reply, 11-12. *Ex parte Hata* and *In re Merat* are addressed above, and *Idenix* and *Amgen* do not involve a deposit of biological materials.

Finally, Petitioner’s arguments about the potential expense of a needle-in-a-haystack operation fail to address the factor it raises—the price of the biological material itself. *See* Reply, 13. Not only is this speculative attorney argument, the suggestion that the price was prohibitive to *access* is directly contradicted by Petitioner’s newly submitted evidence. Specifically, a transcript of a 2007 conference states that the Herculex products co-developed by DuPont show “[t]remendous demand ... in the marketplace,” and that the newly released Herculex XTRA product “will sell 10 times more” than the year before and that “we will still

be sold out.” EX1086, 4. As mentioned above, there was direct evidence in April 2004, before the relevant filing date, that farmers grew crops with TC1507 corn seeds and were planning to do so again in the following year. EX2004. This evidence undermines any suggestion that the prices of the TC1507 corn seed or the crops sold in the commodity streams were cost prohibitive. It shows the opposite of a prohibitive cost—TC1507 seeds were flying off the shelves—and further suggests that everyone knew exactly how to get them.

* * *

Ample evidence demonstrates that TC1507 corn seed was known and accessible to the public as early as spring 2003 and no later than April 2004. *E.g.*, EX1003, 542; EX1047, 42; EX1048, 4; EX1049, 8; EX1007, ¶¶ 131-133, 140; EX2003, 46:16-19, 50:10-52:21, 82:21-85:12. The TC1507 event was adequately described in the patent specification. *E.g.*, EX1007, ¶¶ 43-49, 65-71, 107. And Dr. Silverstone repeatedly testified that a person of ordinary skill in the art would have been able to practice the claimed inventions having the specification and a TC1507 corn seed in hand. *E.g.*, EX2003, 11:24-12:11, 14:10-15:24, 33:23-35:4, 37:6-39:5. The '378 patent claims are therefore enabled as of April 2004, and Barbour 2006 is not prior art.

IV. Petitioner’s Delaware Lawsuit Is Not Inconsistent with the “Known and Readily Available” Standard¹²

Corteva’s suit against Petitioner does not contradict its arguments here. *See* Reply, 13-14. Once again, Petitioner conflates *access* to TC1507 corn seed with the *ability* to freely use Patent Owner’s innovations. There is no question that Inari obtained corn seed embodying TC1507. EX2003, 89:16-20; EX1073, 104 (¶ 62), 105 (¶ 64). While Inari asserts it obtained seed via the commodity stream (Reply, 14), that remains an open question before the district court. EX1072, ¶ 140; EX1085, 11:16-12:1 (“We wanted to know where did they get that [TC1507] event ... [b]ecause that’s covered by that technology use agreement.”).¹³ There is nothing contradictory about Corteva asserting its rights where it believes that Inari used TC1507 and other patented materials in contravention of permissible exclusionary rights. *Corteva Agriscience LLC v. Inari Agric., Inc.*, No. 1:23-cv-1059, 2025 WL 1380763, at *2 (D. Del. May 13, 2025) (citing D.I. 148 (EX1072,

¹² Petitioner, not Patent Owner, had an obligation to identify real parties in interest, which it still has failed to do via updated Mandatory Notices. *See* Reply, 13 n.2.

¹³ Corteva has not asserted patent infringement of the ’378 patent against Inari. Paper 26, 1. Nor is the TC1507 product part of Corteva’s conversion claims in the district court litigation.

public version of D.I. 148)).¹⁴

V. Everyone Agrees that the Public Had Access to TC1507 by Issuance

The parties and the Board agree that the TC1507 event was known and readily available by the time the '378 patent issued. *E.g.*, Pet., 5, 49-50; ID, 23; Reply, 26; EX1007, ¶¶ 131-140; EX1048, 4; EX1038, ¶ [0119]; EX1040, 30; EX1056, 1150; EX1011, 1127; EX1041, 33; EX1039, 119:9-12; EX1050, 19; EX1054, 5/11; EX1042, 43; EX1036, 1347-48. This is important because legal precedent requires that any biological material necessary to supplement a written disclosure must be available to the public by the time the patent issues, not before. POR, 17-19.

USPTO regulations state that “[w]hen a biological material is specifically identified in an application for patent as filed, an original deposit thereof may be made ... *subject to* § 1.809, during pendency of the application for patent,” i.e., before the patent issues. 37 C.F.R. § 1.804(a). Rule 1.809 permits both the deposit of a biological material or “[a]rguing why a deposit is not needed under the circumstances of the application or patent considered.” 37 C.F.R. § 1.809(b)(2). Indeed, as repeatedly mentioned, demonstrating that a biological material is “known

¹⁴ Petitioner’s arguments regarding Pioneer’s PGRs are unavailing. Reply, 20-21. An acknowledgement that Inari could have tested is a far cry from providing a license to test or a statement that no patent liability would result.

and readily available” substitutes for a seed deposit. 37 C.F.R. § 1.802(b). Thus, case law regarding the timing for deposits is directly analogous to when biological material must be known and readily available. POR, 16-19 (citing *In re Argoudelis*, 434 F.2d at 1393; *In re Lundak*, 773 F.2d 1216, 1220-23 (Fed. Cir. 1985); *Feldman v. Aunstrup*, 517 F.2d 1351, 1355 (CCPA 1975); 37 C.F.R. § 1.802(b); MPEP §§ 2402, 2404.01; 52 Fed. Reg. at 34081).

Petitioner’s continued reliance on *White Consolidated Industries, Inc. v. Vega Servo-Control, Inc.*, 713 F.2d 788 (Fed. Cir. 1983) still misses the mark. Reply, 26-27. There, the specification itself *never* described the element needed to practice the claimed invention. *White*, 713 F.2d at 790-91. That is *not* the case here. Petitioner does not challenge the adequacy of the written disclosure and repeatedly states that the ’378 patent adequately describes the TC1507 event, how to achieve it (with a TC1507 corn seed), and how to analyze its presence in corn seed and its progeny. Pet., 5, 44-45; EX1007, ¶¶ 114-166; EX2003, 28:5-21. Petitioner’s cherry-picked quotations from this inapt case are simply irrelevant, especially because *White* does not involve a patent related to biological materials.

It is also unclear how “commercial sales lack safeguards provided by, for example, 37 C.F.R. § 1.804(b).” Reply, 27. Rule § 1.804(b) relates to a statement that the deposited material is the same material as that described in the specification as-filed. 37 C.F.R. § 1.804(b). It does not speak to the availability of the sample.

There is no dispute here that the TC1507 corn seed sold under the Herculex I trademark is the same event described in the '378 patent fully complying with Rule § 1.804(b).

In any event, the possibility of a biological material becoming unavailable does not preclude enablement under § 112. 54 Fed. Reg. at 34875. In directing an examiner to “accept current availability as satisfying the requirement,” the USPTO stated that, “[t]he incentives provided by the patent system should not be constrained by the mere possibility that a disclosure that was once enabling would become non-enabling over a period of time through no fault of the patentee.” *Id.* (citing *In re Metcalfe*, 410 F.2d 1378 (CCPA 1969)).

Petitioner’s statements regarding safeguards to maintain availability are disingenuous given its own reliance on evidence that TC1507 corn seed was known and available starting in 2003 and in subsequent years. *E.g.*, EX2003, 49:21-50:3; EX1047, 42; EX1048, 4; EX1049, 8; EX1056, 1150; *see also supra* § III. Petitioner has consistently asserted that TC1507 corn seed is and was commercially available, and Petitioner asserts that it obtained TC1507 corn in 2020 from commodity streams. EX1073, 104 (¶ 62), 105 (¶ 64); EX2003, 89:16-20.

VI. Patent Owner’s Deposit of Seeds for Other Applications Is Irrelevant

That Patent Owner has deposited seeds for other commercially available products is entirely irrelevant to the present proceeding. *See Reply*, 15. USPTO

rules permit seed deposits *or* a showing that the biological material was known and readily available. Rule § 1.802(a) permits the deposit of biological material *even if* the material is already known and readily available. 54 Fed. Reg. at 34868. Specifically, the Office adopted a revision in the final rule to address a comment that “an applicant has a universal and unconditional right to make a deposit ... regardless of whether the material is known and readily available.” *Id.* (“*Response*: The suggestion has been adopted in § 1.802(a).”). Proposed Rule 1.201(a), which later became Rule 1.802(a), had stated “[w]here a claimed invention is, or relies on, a biological material *which is not known and readily available to the public*” 53 Fed. Reg. at 39429. That language was removed in the final rule consistent with the Office’s commentary. Moreover, a deposit is not an admission that a deposit is necessary “or that a deposit in accordance with these regulations is or was required.” 37 C.F.R. § 1.802(c); 54 Fed. Reg. at 34868. Thus, Patent Owner is not “talking out of both sides of its mouth” as Petitioner wrongly alleges. Reply, 15.

VII. There Is No Relevant Distinction Between Enablement for the Purposes of §§ 112/102

The same evidence that Petitioner relies on to establish the commercial availability and thus enablement of Barbour 2006 under 35 U.S.C. § 102 pursuant to *In re Elsner*, 381 F.3d 1125 (Fed. Cir. 2004) (Pet., 47-53) is the same evidence that establishes that TC1507 was known and readily available at all relevant times to

establish enablement under § 112. There is no relevant distinction between the enablement standards that changes the facts. POR, 43-50.

Petitioner's repeated resort to *In re Howarth*, 654 F.2d 103 (CCPA 1981), does not square to the overwhelming evidence that TC1507 corn seed was known and readily available. *Howarth* related to a situation where material from a foreign patent publication was required to provide § 112 support, but those foreign patents were not identified in the written disclosure at issue. *Id.* at 105-06. There, as mentioned in Patent Owner's Response, the Board held that it was unclear whether the foreign patents, which were not identified by the patent applicant, were in the common knowledge for the purposes of establishing enablement. It thus upheld the rejection. Here, Petitioner has never challenged the adequacy of the written description of the '378 patent. It also has never argued that the public was unaware of where to obtain TC1507 corn seed. In fact, Petitioner itself made of record ample evidence to show that the public had access to corn seed embodying TC1507 and knew exactly where to get it. Notably, Petitioner's arguments in reply focus solely on "where to look for TC1507 in commodity corn," (Reply, 18-19) implicitly admitting the overwhelming evidence for TC1507 corn seed available from Dow AgroSciences and Pioneer.

VIII. Conclusion

Petitioner has not established by a preponderance of the evidence that claims 1-8 of the '378 patent are unpatentable. Accordingly, Patent Owner respectfully requests the Board confirm the patentability of all challenged claims of the '378 patent.

Respectfully submitted,

Dated: August 6, 2025

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CERTIFICATE OF COMPLIANCE WITH WORD COUNT

Pursuant to 37 C.F.R. § 42.24(d), the undersigned certifies that this Patent Owner's Sur-reply complies with the type-volume limits of 37 C.F.R. § 42.24(c)(4), because it contains 5,596 words, according to the word-processing system used to prepare this paper, excluding the words in the Table of Contents, Table of Authorities, Certification Under § 42.24(d), and Certificate of Service, as set forth in 37 C.F.R. § 42.24(c).

Respectfully submitted,

Dated: August 6, 2025

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing **Patent Owner's Sur-reply** was served on August 6, 2025, via e-mail directed to counsel of record for the Petitioner at the following:

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