

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 RESPONSE

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I. Introduction

Petitioner's entire challenge rests on the assumption that to be entitled to its filing date of April 2004, Patent Owner needed to deposit a TC1507 seed. Pet., 28-32. Based on that assumption, Petitioner attempts to assert the publication of the same application that it argues is not enabling for the purposes of § 112 is allegedly enabled anticipatory prior art. A seed deposit is unnecessary, however, when the biological material is otherwise "known and readily available" upon issuance of the patent. Petitioner's own expert, Dr. Silverstone, and evidence demonstrates that there is no question that biological material possessing the TC1507 event was "known and readily available" when the '378 patent issued. In fact, at Institution, the Board found that "it is undisputed that corn harvested from TC1507 plants was 'known and readily available to the public' by 2010," four years before the '378 patent issued. Institution Decision ("ID"), Paper 15, 23. Indeed, Dr. Silverstone testified that "It is [his] understanding that Inari has accessed corn seed with TC1507," (EX2003, 89:16-20) while asserting in this proceeding there is no access without a seed deposit (e.g., EX1007, ¶ 83).

Petitioner and Dr. Silverstone admit that with a TC1507 seed in hand, a person of ordinary skill in the art could readily practice the claimed invention, thus enabling the challenged claims as of their April 2004 filing date. This should have precluded Institution and ended the inquiry: the only asserted reference—Barbour (EX1009)

published in 2006—is simply not prior art and cannot anticipate or render obvious any of the challenged claims. Accordingly, Patent Owner respectfully requests that the Board find that Petitioner has not established the unpatentability of claims 1-8 of the '378 patent.

II. The '378 Patent

The '378 patent, titled “Corn Event TC1507 and Methods for Detection Thereof,” was filed on October 28, 2010, as U.S. Patent Application No. 12/914,271. EX1001, Cover.¹ The application that led to the '378 patent is based on a series of applications originally filed as non-provisional Application No. 10/837,105, filed on April 30, 2004, which claims the benefit of priority to U.S. Provisional Application No. 60/467,772, filed on May 2, 2003. Petitioner refers to Application No. 10/837,105 as the “April 2004 Application” when asserting that it allegedly does not satisfy the enablement requirement. Pet., 27; EX1006. But Petitioner then provides a different name (“Barbour”) for the publication of Application No. 10/837,105, i.e.,

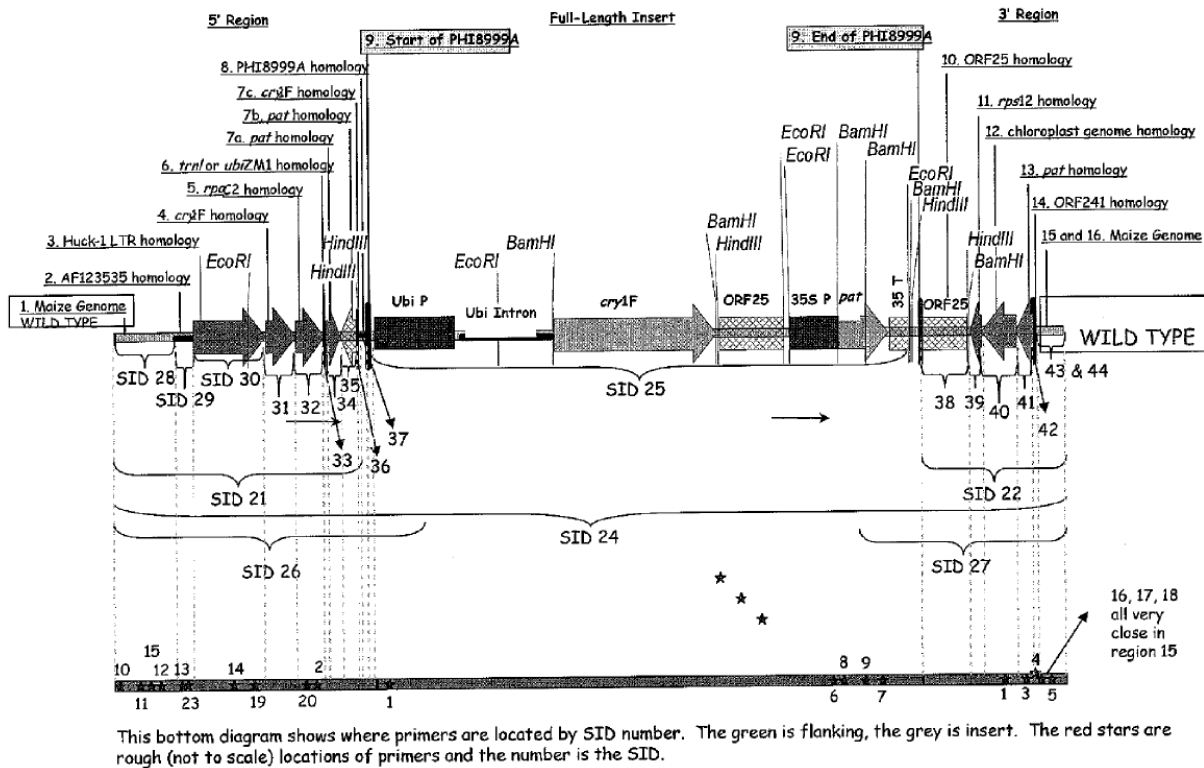
¹ Petitioner has not uniformly stamped its exhibits. Accordingly and unless otherwise noted, citations are to one of the following (1) Petitioner’s stamped pages if they exist; (2) original pagination if present; or (3) a numerical page of the exhibit, counting page 1 as the first page of the exhibit.

the same April 2004 Application, in an attempt to assert an allegedly enabling anticipatory disclosure. Pet., 41-67; EX1007, ¶¶ 114-166; EX1009. There is no dispute that the disclosures of these documents are the same. ID, 9 (“It is also undisputed that Barbour, the sole alleged prior art, is the published 2004 application.”); Pet., 5, 44-45; EX1007, ¶¶ 114-166; EX2003, 28:5-21.

The '378 patent is directed to a transgenic insect resistant corn plant, TC1507, and methods for detecting TC1507 based on a DNA construct inserted into the corn plant's genome. EX1001, Abstract; EX1006, 55.² The '378 patent provides a DNA construct capable of being introduced and replicated in a host plant cell that confers insect resistance. EX1001, 2:44-51; EX1006, 6:6-11. At the core of this technology is a DNA construct, comprised of a DNA molecule PHI8999A, containing two key expression cassettes. EX1001, 2:51-53, FIG. 1; EX1006, 6:11-12. The first cassette includes a strong constitutive maize ubiquitin promoter, followed by a 5' untranslated exon and intron from the same gene, a Cry1F gene for insect resistance, and a 3' ORF25 transcriptional terminator. EX1001, 2:53-63; EX1006, 6:12-18. The second cassette includes a strong constitutive CaMV 35S promoter, a PAT gene for herbicide tolerance, and another CaMV 35S terminator. EX1001, 2:63-3:5; EX1006, 6:18-24. The illustration below shows the full-length DNA construct, flanked by

² Citations to the pages of EX1006 refer to the Petitioner's pagination.

specific DNA sequences at both ends.



EX1001, FIG. 1.

The inventors used biolistic transformation to shoot gold particles coated with the previously described expression cassettes, containing the Cry1F and PAT genes, into plant cell embryos, allowing for the random insertion of the construct into the plant's genome. EX1001, 17:52-18:48 (Example 1); EX1006, 27:11-28:19 (Example 1). The embryos were transferred to medium, and positively transformed plants containing both the Cry1F and PAT genes were evaluated. EX1001, 17:52-18:48 (Example 1). The event TC1507 was then selected from a population of independent transgenic events due to its superior characteristics, including insect

resistance and agronomic performance. *Id.* Selective breeding techniques were employed to develop insect-resistant corn plants. *Id.* This process involved crossing the transformed plants with other corn varieties and carefully selecting progeny that contained the inserted DNA construct. *Id.* The resulting plants exhibited both insect resistance due to the Cry1F gene and herbicide tolerance from the PAT gene, providing farmers with a powerful tool for crop protection and management.

The remaining Examples of the '378 patent detail the molecular characterization of the TC1507 corn event, including isolation and DNA sequencing of the transgene insert and flanking genomic regions, and development of event-specific detection methods. EX1001, 18:50-38:20; EX1006, 28:21-46:4.

Claim 1 is the only independent claim and recites:

1. A corn plant comprising a DNA construct, said DNA construct comprising a first and a second expression cassette, wherein said first expression cassette in operable linkage comprises
 - (a) a maize ubiquitin promoter;
 - (b) a 5' untranslated exon of a maize ubiquitin gene;
 - (c) a maize ubiquitin intron;
 - (d) a Cry1F encoding DNA molecule; and
 - (e) a 3' ORF25 transcriptional terminator; and said second expression cassette comprising in operable linkage
 - (i) a CaMV 35S promoter;

(ii) a pat encoding DNA molecule; and
(iii) a 3' transcriptional terminator from
(CaMV) 35S comprising the nucleic acid
sequence of positions 5843 to 6032 of SEQ
ID NO: 25; and wherein the first and second
expression cassettes are flanked by SEQ ID
NO: 26 at the 5' end and SEQ ID NO: 27 at
the 3' end.

EX1001, claim 1.

Claims 2-8 depend from claim 1 and recite a seed of the corn plant of claim 1
(claim 2), methods for producing and breeding additional insect resistant corn plants
from the TC1507 plant of claim 1 (claims 3-7), and the DNA construct of the corn
plant of claim 1 comprising SEQ ID NO: 24 (claim 8). EX1001, claims 2-8.

III. Person of Ordinary Skill in the Art

For purposes of this proceeding, Patent Owner does not dispute Petitioner's
definition of the qualifications of a person of ordinary skill in the art ("POSA"). *See*
Pet., 11; EX1007, ¶¶ 18, 50. Petitioner notes that Dr. Silverstone has characterized
himself as having at least the skill of a POSA. EX1007, ¶ 19; EX2003, 16:8-11
("and I am a POSA"). Accordingly, his opinions, testimony, and admissions must
be viewed from the perspective of a POSA.

IV. Claim Construction

In its Institution Decision, the Board determined there was "no need to

expressly construe any claim term” in this proceeding. ID, 8. Accordingly, and without acquiescing to any proposed claim construction Petitioner set forth in the Petition, Patent Owner agrees with the Board that no construction is necessary for disposing of the present proceeding. Patent Owner reserves the right, however, to address Petitioner’s proposed construction(s) in any other proceeding related to the ’378 patent claims.

V. The Relevant Facts Are Undisputed

The question before the Board is a legal one, and the relevant facts are not in dispute.

The claimed subject matter of the ’378 patent relates to and encompasses the TC1507 event in corn. EX1007, ¶¶ 65-73; EX2003, 9:9-10:8 (“Claim 1 describes the TC1507 event.”).

TC1507 seed was available and planted in the U.S. during the 2003 growing season under the Herculex I trademark. Pet., 49-50 (“TC1507 corn had been commercialized under PO’s ‘Herculex’ trademark for three growing seasons—2003, 2004, and 2005.”); EX1007, ¶¶ 131-133; EX1003, 542 (“TC1507 (Herculex 1) maize of this invention was sold by both Pioneer/Du Pont and Dow in 2003.”); EX1011, 1127; EX1032, 1; EX1040, 30; EX1041, 33; EX1042, 43; EX1043, 33-34;

EX1048³, 4 (“This year [2003], the new generation Bt trait Herculex I will be in farm fields.”); EX2004 (2004 article interviewing farmers who “tried Herculex™ I on their farms during 2003, its first season of commercial availability”).

Farmers and POSAs knew that TC1507 seed was available for the 2003 growing season. EX1038, ¶ [0119] (patent application filed in 2003 stating “seeds having Herculex® I transgenic events (available from Dow Agrosciences, Mycogen Seeds, and Pioneer Hi-Bred International)”); EX1047, 42 (“Corn growers now have the option of purchasing a new Bt trait [branded as Herculex I] developed by Dow AgroSciences LLC and Pioneer Hi-Bred International Inc.”); EX1048, 4; EX2003, 39:6-44:9.

TC1507 seed was also available to farmers in the 2004 and 2005 growing seasons. Pet., 49-51; EX1007, ¶¶ 131-133; EX1039, 119:9-11 (“Examples of crops that have been rendered tolerant to herbicides [are] commercially available under the trade names . . . Herculex I®.”); EX1040, 30; EX1041, 33; EX1042, 43; EX1049, 8 (identifying “Pioneer Hi-Bred Herculex I” on the “list of biotech seed products available for the 2004 planting season”); EX1050, 19 (2005).

³ Petitioner’s EX1048 does not include any pagination. Patent Owner will therefore cite to the PDF page numbers when referring to specific pages of EX1048.

And this continued availability was widely reported and known. Pet., 49-51; EX1007, ¶¶ 131-133; EX1039, 119:9-11; EX1040, 30; EX1041, 33; EX1042, 43; EX1049, 8; EX1050, 19 (2005); EX1056, 1150. Dr. Silverstone himself knew of the TC1507 event well before this proceeding because it “was commonly discussed in the early 2000s.” EX2003, 65:1-6.

While the corn growing season varies across the U.S. depending on the latitude, corn is typically planted in spring after the last frost and harvested in the fall. *Id.* at 34:22-36:24. For the purposes of securing institution, Petitioner and Dr. Silverstone admitted that “corn **harvested** from TC1507 plants continued to express the TC1507 event and was indisputably commercially available following the 2003, 2004, and 2005 growing seasons.” Pet., 52 (emphasis in original); EX1007, ¶ 129 (“[A] POSA could screen commercially available corn to identify germplasm expressing the TC1507 event, thereby possessing the invention as claimed.”). Petitioner and its expert further admitted for the purposes of institution that “[s]uch corn was sold as a commodity—without any contractual restrictions.” Pet., 52; EX1007, ¶ 140 (“By 2006, TC1507 was widely found in ‘food or feed products’ commercially sold without restriction.”). Dr. Silverstone confirmed during his deposition that in the commodity system in the U.S., “corn can be sold anywhere from immediately after harvest to 3, 6, 9, 12 months later.” EX2003, 36:14-24. He further confirmed that corn possessing the TC1507 event would have been accessible

in “late 2003” in the commodity system and that such grain “is accessible without restrictions.” *Id.* at 51:13-52:21; *see also id.* at 50:10-15 (“Q: Now, for the crops that were produced with the TC1507 seed in 2003, were the same restrictions applied to them once sold? A: Those restrictions, to the best of my knowledge, were not applied to the grain that is sold from the harvest of the farms.”). Moreover, “it is undisputed that corn harvested from TC1507 plants was ‘known and readily available to the public’ by 2010.” *ID*, 23. The TC1507 event was available upon issuance and remains available today. *Id.* In fact, Dr. Silverstone testified that “It is [his] understanding that Inari has accessed corn seed with TC1507.” EX2003, 89:16-20.

Others besides farmers also had access to seed exhibiting the TC1507 event before the issuance of the ’378 patent. For example, researchers in Korea reported in 2004 that “insect and herbicide resistant TC1507 from Mycogen [was] provided by KFDA.” EX1056, 1150 (referring to Korea Food and Drug Administration as KFDA). In 2005, the European Commission issued a Validation Report related to TC1507. EX1054. For the validation, “DNA was extracted by the applicant . . . from 100% TC1507 hybrid kernels (Pioneer Brand Number 38P04-DAS-01507-1).” *Id.* at 5/11. Still other researchers reported that they obtained “[p]owdered certified reference material (CRM) of maize 1507 . . . from the Institute for Reference Materials and Measurements (IRMM; Geel, Belgium) and

commercialized by Fluka (Buchs, Switzerland).” EX1036, 1348. To generate the CRM, the IRMM obtained seed from Pioneer Overseas Corporation in May 2004. EX2005 (<https://crm.jrc.ec.europa.eu/p/q/ERM-BF418/ERM-BF418a-1507-MAIZE-blank/ERM-BF418a>, last accessed Mar. 13, 2025); EX2006 (Origin certificate “ERM-BF418_origin.pdf.”).

With a TC1507 seed in hand, a POSA could produce a plant that possesses the TC1507 event simply by planting and growing the seed. EX2003, 38:18-39:5 (“If you already have the seed, you could reproduce another plant with TC1507.”), 14:11-20, 57:12-58:2. Dr. Silverstone further testified that from a TC1507 seed, a POSA could produce additional TC1507-containing seeds. *Id.* at 10:1-12:11; EX1007, ¶¶ 134, 149-166. Dr. Silverstone also admitted that a POSA would have been able to breed “additional insect resistant corn plants as recited in claims 3-4 and 7” based on the disclosure of Barbour, which he acknowledged is the same disclosure filed in April 2004. EX1007, ¶ 159; EX2003, 81:21-82:20, 27:13-28:21; *see also* ID, 9 (“It is also undisputed that Barbour, the sole alleged prior art, is the published 2004 application.”). Indeed, the ’378 patent provides guidance for reproducing insect resistant TC1507 corn plants, which is consistent with Petitioner’s own evidence. EX1001, 9:59-10:7; *see generally* EX1049 (2004); *see also* EX1049, 4 (“The important point to note about this procedure is that the transformation procedure is only conducted once. The gene is moved (backcrosses)

into inbred lines by using conventional breeding methodology. Because transgenes are genetically dominant, only one inbred line of a hybrid needs to contain the transgene for it to be expressed in the hybrid.”).

There is no dispute that the DNA sequence for the TC1507 event was described in the as-filed April 2004 application. EX2003, 30:2-6; *see also* EX1007, ¶¶ 117-127. A POSA also would have been able to definitively confirm the presence of the TC1507 event using DNA test methods described in the original application filed in 2004. EX1007, ¶¶ 135-140; EX2003, 26:7-16, 27:13-32:16. Indeed, Dr. Silverstone testified that in 2003 “[i]f you knew the DNA sequence of the TC1507 insert as described on the patent, which includes the flanking regions . . . [t]hen, yes, you would be able to design detection tools for the TC1507 event.” EX2003, 26:17-27:12; *see also* EX1007, ¶¶ 135-140. He confirmed that the as-filed April 2004 application included those tools and that if a POSA “had the information in this application, they could assess the seed” using DNA techniques. EX2003, 31:13-32:16. Dr. Silverstone himself considered a research article that demonstrates POSAs were using DNA-based test methods even before the publication of Barbour in 2006 to identify the TC1507 event in corn. Specifically, Dr. Silverstone considered an article entitled “Detection of Genetically Modified Maize by Multiplex PCR Method,” that was submitted for publication in October 2003. EX1007, Appendix A – Materials Considered (citing EX1056). The authors

concluded that “this detection method, using multiplex PCR, could distinguish the five different lines [including TC1507] of GM Maize in a single reaction.” EX1056, 1155.⁴ Dr. Silverstone relied upon and considered additional documents similarly using DNA-based methods to specifically detect the TC1507 event well before the issuance of the ’378 patent. *E.g.*, EX1007, ¶ 132 (citing EX1036 (2006)), Appendix A (citing EX1054 (2005)).

Petitioner and Dr. Silverstone did not evaluate whether the provisional application enabled the issued claims. Pet., 29, n.4; EX2003, 77:18-21 (“Q: You didn’t consider whether that application [Provisional Application No. 60/467,772] was enabled for the purposes of providing your opinion in this case, did you? A: I did not.”); ID, 9, n.4 (noting the provisional application “is not at issue in this proceeding”). Nor has Petitioner challenged the sufficiency of the written description of the ’378 patent. Pet., 29-33. Indeed, Petitioner and Dr. Silverstone acknowledge that the ’378 specification describes how the original TC1507 event

⁴ Having reviewed this article (EX1056) in preparing his declaration, Dr. Silverstone inexplicably and not credibly testified that he was “not aware that [DNA-based tools] were available to a POSA before” the publication of the Barbour reference. EX2003, 23:10-14; *see also id.* at 25:1-7.

was developed, how to generate additional TC1507 corn plants and seeds, and how to screen for the TC1507 event using DNA-based assays. Pet., 7-9, 54-57; EX1007, ¶¶ 43-49, 65-71, 107, 109, 135-143; EX2003, 27:13-28:21, 38:18-39:5.

VI. Legal Standards

As the quid pro quo for receiving a patent, a patentee is required to provide a written description sufficient to enable a POSA to make and use the claimed invention. 35 U.S.C. § 112. “The object of the statute is to require the patentee to describe his invention so that others may construct and use it *after the expiration of the patent* and to inform the public during the life of the patent of the limits of the monopoly asserted, so that it may be known which features may be safely used or manufactured without a license and which may not.” *Schriber-Schroth Co. v. Cleveland Trust Co.*, 305 U.S. 47, 57 (1938) (internal quotation marks and citation omitted).⁵ In many cases, the latter aim is achieved via the written description itself. Where an invention relates to biological material (e.g., seeds) that cannot be described in writing alone, however, the Office may require an applicant to make a deposit of the material or otherwise demonstrate that the biological material is “known and readily available” to comply with § 112. *In re Wands*, 858 F.2d 731, 735-36 (Fed. Cir. 1988); *Ajinomoto Co. v. Archer-Daniels-Midland Co.*, 228 F.3d

⁵ Emphasis added in italics or bold unless otherwise noted.

1338, 1345-46 (Fed. Cir. 2000); *see also* 37 C.F.R. § 1.802(b) (“Biological material need not be deposited unless access to such material is necessary for the satisfaction of . . . [§]112.”); Manual of Patent Examining Procedure (“MPEP”) §§ 2402-2404. A biological deposit is not mandatory by default. *See, e.g., In re Wands*, 858 F.2d at 736 (“[A] deposit is not always necessary to satisfy the enablement requirement.”); Proposed Rules Regarding Deposit of Biological Materials for Patent Purposes, 52 Fed. Reg. 34080, 34087, 1987 WL 137485 (Sept. 9, 1987) (“The PTO proposal does *not* make a deposit mandatory for an invention which depends on the use of biological material.”) (emphasis in original). And whether a disclosure is enabled without the need for a deposit is decided on a case-by-case basis. *In re Wands*, 858 F.2d at 736; MPEP § 2403; *see also* MPEP § 2402 (explaining that the Office’s rules “do not address the substantive issue of whether a deposit is required under any particular set of facts”).

Although a deposit of biological material may provide *one* way for an applicant to satisfy the enablement requirement, it is not the *only* way. *In re Wands*, 858 F.2d at 735-36 (the enablement requirement “may be met in ways other than by making a deposit”). For example, an applicant can show that a biological material is “known and readily available” and thus enabled under § 112 without the need for a deposit. *In re Lundak*, 773 F.2d 1216, 1220-22 (Fed. Cir. 1985); *see also* 37 C.F.R. § 1.802(b); *Feldman v. Aunstrup*, 517 F.2d 1351, 1354 (CCPA 1975) (“No problem

exists when the microorganisms used are known and readily available to the public.”), *cert. denied*, 424 U.S. 912 (1976); MPEP § 2404.01 (“In an application where the invention required access to specific biological material, an applicant could show that the biological material is accessible because it is known and readily available to the public.”); 52 Fed. Reg. 34080, 34081, 1987 WL 137485 (Sept. 9, 1987). “The concepts of ‘known and readily available’ are considered to reflect a level of *public accessibility* . . . consistent with an ability to make and use the invention.” MPEP § 2404.01.

It is sufficient to enable the claimed invention *as of the filing date* by depositing a seed or otherwise showing that the biological material is known and readily available *by the issuance of the patent*. Binding precedent holds that “[i]t is not necessary that the general public have access to the culture prior to the issuance of the patent.” *In re Argoudelis*, 434 F.2d 1390, 1393 (CCPA 1970); *In re Lundak*, 773 F.2d at 1220-23 (“*Feldman* established that the availability of a [biological] sample to the public after the patent has issued will meet the enablement requirement.”); *Feldman*, 517 F.2d at 1355 (noting satisfaction of the enablement requirement with a biological sample “does not require such assured access to a microorganism deposit as of the filing date”); *Ajinomoto*, 228 F.3d at 1345-46; 37 C.F.R. § 1.802(b); MPEP §§ 2402, 2404.01. The Office has expressly acknowledged that “[i]f a biological material is *known and readily available at the time the patent*

is granted, and there is no reasonable basis to believe that the biological material will cease to be available during the life of the patent,” a seed deposit is unnecessary, and “no requirement for a separate deposit would be made.” 52 Fed. Reg. 34080, 34081, 1987 WL 137485 (Sept. 9, 1987).⁶

VII. Argument

A. There Is No Dispute the TC1507 Event Was “Known and Readily Available” When the ’378 Patent Issued

In its Institution Decision, the Board stated that “for the priority determination, the relevant time is April 30, 2004, the filing date of the 2004 application.” ID, 21; *see also id.* Dissent, 3. For claims where a biological sample may be required to enable the invention, enablement can be shown as of the filing

⁶ As Patent Owner noted in its Preliminary Response, this is exactly what happened during prosecution in the present case. POPR, Paper 9, 8-12. In fact, the Examiner was aware of the Herculex I product because it was included in search strings during prosecution. EX1002, 171, 173 (November 15, 2013 search for “TC1507” or “Herculex” or “HX1”), 194 (S2, S3), 244 (S2, S3). Consistent with the commercial availability of TC1507 seeds, the Examiner did not require a seed deposit prior to patent issuance of the ’378 patent in December 2014. *See* POPR, Paper 9, 11; EX1002, 161-162, 171, 173, 194, 244.

date by depositing the material or otherwise establishing it is “known and readily available” *as of the date of issuance* of the patent. *In re Argoudelis*, 434 F.2d at 1393; *In re Lundak*, 773 F.2d at 1220-23; *Feldman*, 517 F.2d at 1355; 37 C.F.R. § 1.802(b); MPEP §§ 2402, 2404.01; 52 Fed. Reg. 34080, 34081 1987 WL 137485 (Sept. 9, 1987).

An applicant is not required to make the biological material “available to the general public at the time of filing the application.” *In re Argoudelis*, 434 F.2d at 1393. Rather, “what is required is *assurance of access* (to the microorganism culture by the public upon issuance of a patent on the application) prior to or during the pendency of the application, so that, *upon issuance* of a U.S. patent on the application, ‘the public will, in fact, receive something in return for the patent grant.’” *Feldman*, 517 F.2d at 1355 (citation omitted). “There is no sense in making an applicant publicly disclose any part of his invention, much less its very essence, *before* he has been assured that he will obtain the protection he is seeking in return for that disclosure.”⁷ *In re Argoudelis*, 434 F.2d at 1395 (Baldwin, J., concurring);

⁷ At the time of *Argoudelis*, *Lundak*, and *Feldman*, patent applications were not published before issuance. 35 U.S.C. § 122 (1975), *amended by* American Inventors

In re Lundak, 773 F.2d at 1223 (“[T]he function of section 112 in ensuring *complete public disclosure* is only violated if the *disclosure* is not complete *at the time it is made public*, i.e., at the issue date.”) (citation omitted) (emphasis in original).

The appropriate question for the Board should have been: when the ’378 patent issued, was TC1507-event containing seed or plant available? The Board itself confirmed it was: “[I]t is undisputed that corn harvested from TC1507 plants was known and readily available to the public by 2010,” which is well before the ’378 patent’s issue date in December 2014. ID, 23 (internal quotations omitted). For this reason alone, Patent Owner is entitled to its April 2004 filing date under § 112. This determination alone is sufficient for the Board to end the inquiry and confirm the patentability of all challenged claims of the ’378 patent.

B. Petitioner’s Evidence Also Establishes That the TC1507 Event Was “Known and Readily Available” by the April 2004 Filing Date

Even though the Board’s focus on the April 2004 filing date for TC1507 event availability was legal error, Petitioner’s own evidence, presented for the purposes of institution, also demonstrates that the TC1507 event was undisputably “known and

Protection Act of 1999, Pub. L. No. 106-113, § 4502, 113 Stat 1501 (current version at 35 U.S.C. § 122(b)).

readily available” by the April 2004 filing date.⁸

1. A Seed Deposit Is Unnecessary if the Biological Material Is “Known and Readily Available”

The Office’s rules do not require the deposit of a biological material “if it is known and readily available to the public or can be made or isolated without undue experimentation.” 37 C.F.R. § 1.802(b); *see also* MPEP § 2404.01 (“In an application where the invention required access to specific biological material, an applicant could show that the biological material is accessible because it is known and readily available to the public.”); *In re Wands*, 858 F.2d at 736 (“Although inventions involving microorganisms or other living cells often can be enabled by a deposit, a deposit is not always necessary to satisfy the enablement requirement. No deposit is necessary if the biological organisms can be obtained from readily available sources or derived from readily available starting materials through routine screening that does not require undue experimentation.”); *Feldman*, 517 F.2d at 1354 (“No problem exists when the microorganisms used are known and readily available to the public.”).

⁸ Petitioner’s evidence discussed in this section is further evidence that the TC1507 event was “known and readily available” upon issuance of the ’378 patent. *Supra*, § VII.A.

To meet the “known and readily available” standard, “the biological material must be both known and readily available – neither concept alone is sufficient.” MPEP § 2404.01. “The term ‘readily’ used in the phrase ‘known and readily available’ is considered appropriate to define that degree of availability which would be reasonable under the circumstances.” *Id.* Factors to consider in evaluating whether biological material is known and readily available include commercial availability, references to the biological material in printed publications, declarations of accessibility by those working in the field, and evidence of predictable isolation techniques. *Id.*; *see also* 52 Fed. Reg. 34080, 34089, 1987 WL 137485 (Sept. 9, 1987) (noting “there is no requirement to demonstrate that a biological material is known and readily available by any particular set of facts” and a “variety of circumstances” may be used). Examination of the relevant factors, especially Petitioner’s own admissions, weighs in favor of a finding that the requisite biological material was “known and readily available” by at least April 2004 and certainly by the December 2014 issue date of the ’378 patent.

2. Petitioner’s Own Evidence Establishes That TC1507 Was “Known and Readily Available”

Petitioner and its expert rely on numerous documents that report the existence and availability of seed and materials exhibiting the TC1507 event long before the ’378 patent’s 2014 issue date. For example, Petitioner relies upon EX1047. Pet.,

50; EX1007, ¶ 133. It is an article in the November 2002 issue of *Farm Journal* entitled “Bt’s New Bite.” EX1047, 42. The reporter states, “Corn growers now have the option of purchasing a new Bt trait developed by Dow AgroSciences LLC and Pioneer Hi-Bred International Inc., a DuPont company.”⁹ *Id.* Dr. Silverstone confirmed the availability of the magazine in November 2002. EX2003, 39:6-40:15. He further testified that “people working in agriculture,” including farmers, researchers, and POSAs, would read this magazine. *Id.* at 40:21-41:8. The 2002 article further states, “Branded as Herculex I, the trait expresses in corn the Cry 1F protein, which is toxic to black cutworm, fall armyworm, southwestern corn borer and European corn borer.” EX1047, 42. Dr. Silverstone testified that “[a] POSA would look at this and see that -- reading this with their knowledge of the industry, as I describe in the description of the POSA, that as described here, Dow and Pioneer are launching a new product on the market with Hercu- -- branded as Herculex 1.” EX2003, 41:14-24, 42:12-21. And even though the TC1507 event itself was not identified in the article by name, a POSA would have understood that the Herculex I that is being referred to is TC1507. *Id.* at 42:22-43:23. Dr. Silverstone further

⁹ Dr. Silverstone testified that Dow was a predecessor company of Corteva. EX2003, 42:1-11.

acknowledged that a POSA “reading this in November of 2002 would see that there would be some seed available in -- for the 2003 season for growing in the 2003 season.” *Id.* at 43:24-44:9. And a farmer could have potentially purchased the TC1507 seed in late 2002 and received it “in the spring, close to planting time.” *Id.* at 44:13-45:19.

This document and Dr. Silverstone’s testimony about it from the perspective of a POSA alone demonstrate that the TC1507 event was “known and readily available” by the spring of 2003. And Dr. Silverstone admitted, including for the purposes of institution, that seed with the TC1507 event was sold to farmers in 2003. EX2003, 49:21-50:4; EX1007, ¶¶ 132-134, 140. The record is replete, however, with additional evidence that confirms this known access at least by the time the ’378 patent issued, including before the filing date of the April 2004 application:

2003

- EX1048, 4: Article from February 2003 stating “This year, the new generation Bt trait Herculex I *will be* in farm fields. Developed by Dow AgroSciences and Pioneer Hi-Bred, it goes beyond European corn borer resistance to add black cutworm and fall armyworm resistance.

It also includes the LibertyLink trait.”¹⁰

- EX1038, ¶ [0119]:¹¹ Patent application filed April 14, 2003, stating “The present invention also includes the treatment of seeds having Herculex® I transgenic events (available from Dow Agrosiences, Mycogen Seeds, and Pioneer Hi-Bred International).”
- EX1040, 30:¹² The Dow Chemical Company SEC filing “FOR THE YEAR ENDED December 31, 2003,” stating that new products, including HERCULEX I insect protection “showed strong growth.”

2004

- EX1056, 1150: A 2004 research article that indicates “insect and herbicide resistant TC1507 from Mycogen [was] provided by KFDA.”
- EX1011, 1127: A USDA report stating that “In FY 2004, the USDA/GIPSA Proficiency Program was expanded to include two new

¹⁰ LibertyLink refers to the herbicide resistant aspect of TC1507. EX1048, 4.

¹¹ Herculex® I is not referenced in the third-party patent application’s underlying provisional application filed in May 2002.

¹² Page 30 reflects Petitioner’s stamped page and not the document’s original pagination.

corn biotechnology events commercialized in FY 2003: Herculex™ produced by DowAgroSciences and YieldGard™ Rootworm produced by Monsanto.”¹³

- EX1041, 33:¹⁴ The Dow Chemical Company SEC filing “FOR THE FISCAL YEAR ENDED December 31, 2004,” stating that “[s]ales for newer products,” including HERCULEX I insect protection traits “continued to grow.”

2005

- EX1039, 119:9-12: PCT application published in 2005, stating “Examples of crops that have been rendered tolerant to herbicides or classes of herbicides by genetic engineering methods include glyphosate- and glufosinate-resistant maize varieties commercially available under the trade names RoundupReady®, Herculex I® and LibertyLink®.”
- EX1050, 19: An article from August 2005 stating “Liberty herbicide

¹³ Page 1127 of EX1011 can be found in Part 2 at PDF page 418 of 435.

¹⁴ Page 33 reflects Petitioner’s stamped page and not the document’s original pagination.

tolerance is also on the rise, thanks to wider availability of Herculex I insect-resistant corn hybrids,” and that Herculex I will be stacked in a newly registered product Herculex XTRA.

- EX1054, 5/11: A 2005 report from the Community Reference Laboratory for GM Food and Feed of the European Commission indicating that tests were run on “100% TC1507 hybrid kernels (Pioneer Brand Number 38P04-DAS-01507-1).”
- EX1042, 43:¹⁵ The Dow Chemical Company SEC filing “For the fiscal year ended December 31, 2005,” stating that “[s]ales continued to ramp up for . . . HERCULEX™ I insect protection traits for corn.”

2006

- EX1036, 1347-48: A 2006 research article stating “The transgenic maize line TC-1507 (Herculex I™ from Mycogen, Dow AgroSciences, Pioneer, DuPont) was genetically engineered by biolistic transformation and harbors 2 transgenes, *cry1Fa2* and *pat*.” (emphasis in original). A PCR assay was evaluated using “Powdered certified

¹⁵ Page 43 reflects Petitioner’s stamped page and not the document’s original pagination.

reference material (CRM) of maize 1507” from the IRRM and commercialized by Fluka.

Admissions by Petitioner and Dr. Silverstone pre-institution corroborate that the TC1507 event was “known and readily available” at all relevant times:

- Admissions by Petitioner and Petitioner’s expert that “the TC1507 event had been commercialized under Patent Owner’s ‘Herculex’ trademark and widely planted in the United States over the course of three growing seasons (i.e., 2003, 2004, and 2005).” EX1007, ¶¶ 131-134; Pet., 49-50.
- Admissions by Petitioner that “PO had commercialized TC1507 starting in 2003—making TC1507 germplasm accessible.” Pet., 5, 49.
- Admissions by Petitioner and Petitioner’s expert that TC1507 was available without restriction. Pet., 52-53 (stating that “corn *harvested* from TC1507 plants continued to express the TC1507 event and was indisputably commercially available following the 2003, 2004, and 2005 growing seasons” and that “[s]uch corn was sold as a commodity—without any contractual restrictions”) (emphasis in original); EX1007, ¶ 134.
- Admissions by Petitioner and Petitioner’s expert that “POSAs could have identified TC1507 in bulk corn (i.e., following harvest) sold

commercially prior to July 6, 2006.” Pet., 53; EX1007, ¶ 135; *see also* Pet., 53-55, 64, 67; EX1007, ¶¶ 135-140.

- Admissions by Petitioner and Petitioner’s expert that “POSAs could have screened commercially available bulk corn from the 2003, 2004, or 2005 growing seasons and thereby gained possession of TC1507 as claimed.” Pet., 55 (citing EX1007, ¶¶ 139-140); EX1007, ¶¶ 140, 146; *see also* EX2003, 59:9-14 (confirming same).

Dr. Silverstone reinforced the admissions from the Petition and his declaration (EX1007) during his deposition. He testified that:

- TC1507 corn seed was available to farmers in 2003. EX2003, 43:20-45:4, 46:16-19, 49:21-50:4.
- TC1507 was in the commodity system at the end of 2003. *Id.* at 50:10-15, 51:10-53:13, 59:9-14.

He further testified that commodity streams were routinely tested for the presence of TC1507 containing corn. *Id.* at 68:13-69:5; EX1007, ¶ 140. And even that “[s]ome farmers label their fields -- some farmers put signage up to indicate what varieties are growing.” EX2003, 59:15-22. As Dr. Silverstone admitted in his deposition and for the purposes of securing institution, in 2003, “there would be TC1507 grain in the commodity system that would not have restrictions on use.” *Id.* at 51:13-52:21; *see also* EX1007, ¶¶ 131, 134, 143. Petitioner has argued and

admitted the same for the purposes of securing institution. Pet., 52 (“[C]orn *harvested* from TC1507 plants continued to express the TC1507 event and was indisputably commercially available following the **2003**, 2004, and 2005 growing seasons.”) (emphasis added and in original).

There can thus be no dispute that at least by the April 2004 filing date, as Petitioner and Dr. Silverstone asserted pre-institution, a POSA had access—without restrictions—to TC1507 corn in the commodity system and even in farmer’s fields for the motivated POSA.

3. Patent Owner’s Statements in Europe Are Irrelevant

Petitioner’s reliance on the rejection of “corresponding claims” for allegedly lacking enablement during prosecution of a European Patent Application (EX1004) (Pet., 69; EX1007, ¶¶ 80, 95, 112) and actions before the EPO are simply irrelevant here.

As an initial matter, the EPO and U.S. deposit rules differ as to when a deposit of biological material need be made. In Europe, the EPO requires deposit of a sample *before* the filing of the priority application. European Patent Convention Rule 31(1)(a) (EX2001); EX2002, 1 (“For example, at the USPTO, it may be possible to rely upon a biological deposit made after the filing date of the application . . . For EPO purposes, however, it will always be necessary for the deposit to be made **on or before the filing date**.”). But in the U.S., a deposit, if even necessary,

can occur any time before the patent issues. *See, e.g., In re Lundak*, 773 F.2d at 1216, 1222, 1220-21; *Feldman*, 517 F.2d at 1354-55; *Ajinomoto*, 228 F.3d at 1346; MPEP § 2402; *supra* §§ VI, VII.A.

That the patent applicant in Europe abandoned claims where a deposit had not been made is simply not relevant to the present proceeding in the U.S., where the law and European Patent Office rules are different. Nor is the PTAB the appropriate forum to raise foreign deposit and access rules, especially after admitting that TC1507 material is available in the U.S. to secure institution.

4. Any Alleged Restrictions on TC1507 Corn Sold to Farmers Does Not Render It Inaccessible¹⁶

Petitioner’s argument that restrictions on the *use* of TC1507 sold to growers contravenes enablement is antithetical to patent protection. It is inconsistent—and not the law—that to comply with the enablement requirement, a patentee must relinquish its right to exclude others from practicing the invention during the

¹⁶ Petitioner’s reference to statements from the prosecution of European Patent Application No. 04751097.9 (EX1003) regarding restrictions under standards related to novelty (without a grace period) in Europe are not relevant to the question of whether biological materials is “known and readily available” in the United States.

enforceable life of the patent. *See* Pet., 33, 60. Rather, § 112 simply requires that as of a patent’s issuance, the public is *capable* of making and using the claimed invention based on the disclosure and—if necessary—with access to relevant biological material. *E.g.*, *In re Argoudelis*, 434 F.2d at 1396 (“[T]here is no question that, at the time the patent issues, [a POSA] *will be able to* make and use the claimed antibiotic compounds from the written description included in the specification coupled only with his ordinary skill and the critical microbes, which will then be readily available to him.”). It does not require that the public has unfettered access to do what it will with a patentee’s invention. The Supreme Court aptly stated, “[t]he object of the statute is to require the patentee to describe his invention so that others may construct and use it *after the expiration of the patent.*” *Schriber-Schroth*, 305 U.S. at 57. During the life of the patent, on the other hand, the enablement requirement “inform[s] the public . . . of the limits of the monopoly asserted, so that it may be known which features may be safely used or manufactured without a license and which may not.” *Id.* (internal quotations and citation omitted); *see also Corteva Agriscience LLC v. Inari Agric., Inc.*, 743 F. Supp. 3d 603, 606 (D. Del. 2024) (“Competitors get the benefit of [the patent’s] knowledge . . . But the competitor does not get free license to use the original invention however it wishes.”).

Indeed, for over two decades, controlling precedent supports limits on use for

patented seeds. For example, in *Monsanto Co. v. McFarling*, the Federal Circuit affirmed a preliminary injunction against a farmer who was saving patented seeds and growing them season after season instead of buying new seeds each year. 302 F.3d 1291 (Fed. Cir. 2002), *cert. denied*, 537 U.S. 1232 (2003). There, the patent at issue covered “seeds as well as [] plants.” *Id.* at 1298-99, 1293. Patentee had developed genetically modified plants that resisted Roundup® brand herbicide. *Id.* at 1293. Monsanto authorized various companies to manufacture the patented seeds, which were then sold to farmers pursuant to a Technology Agreement. *Id.*¹⁷ The court confirmed the validity of such agreements and held that the patentee had shown there was a likelihood that it would prevail on the issue of patent infringement. *Id.* at 1297-99.

In a district court case with analogous facts, the court stated that “[i]t would be antithetical to the purposes of the patent laws to permit consumers [] to disregard the restrictions imposed by [patentee] and to instead unilaterally determine the circumstances under which a patent holder’s discovery is to be offered for use or sale.” *Monsanto Co. v. Scruggs*, 249 F. Supp. 2d 746, 757 (N.D. Miss. 2001). That

¹⁷ Monsanto’s Technology Agreement is similar to the Technology Agreement of record. *Compare id.* at 1293, 1298 with EX1003 at 545-47.

court, in considering the public interest factor, stated that “[t]he public interest is not served by allowing an infringer to profit at the expense of the holder of a lawfully issued patent.” *Id.* at 760-61 (“It is not in the public’s best interest to have patented technology pirated in that such would discourage future investment in innovative technology.”). These cases implicitly acknowledge that farmers, and the general public, can nonetheless access the patented invention: they must comply with patent laws. Dr. Silverstone similarly acknowledged that the general public could access TC1507 subject to these permissible restrictions. *See* EX2003, 66:7-24. Stated differently, restrictions on the use of a patented invention does not render the biological material inaccessible as Dr. Silverstone himself admitted. *Id.*

Petitioner’s suggestion that seed deposits come with no restrictions and are dissimilar to the restrictions on growers rings hollow. *See* Pet., 4, 33, 60. As Petitioner well knows, seed deposits are subject to restrictions themselves. *See* EX2007, 4 (Inari Agriculture N.V./S.A. Material Transfer Agreement with ATCC dated July 14, 2019).¹⁸ In 2019, Inari executed a Material Transfer Agreement with ATCC acknowledging that “Purchaser shall not distribute, sell, lend or otherwise

¹⁸ This Material Transfer Agreement includes a “Last updated” date of November 15, 2011, well before the ’378 patent issued in 2014.

make available or transfer to a person other than the Purchaser's Investigator or an entity not party to this MTA, the Biological Material, as defined above, for any reason, without ATCC's prior written agreement." *Id.* at 2. Moreover, that agreement expressly indicates that "[u]se of the Biological Materials may be subject to the intellectual property rights," and that "Purchaser shall have the sole responsibility for obtaining any intellectual property licenses necessitated by its possession and use of the Biological Materials." *Id.* While Dr. Silverstone himself was unaware of restrictions on seed deposits, "did not take into account any restrictions on samples that ATC[C] provides," and had "not looked at any agreements from ATCC" for the purposes of this proceeding, he conceded that "if the seed has a patent on it, they risk -- they certainly need to abide by the laws that govern our patent system" when accessing a seed from a depository. EX2003, 69:11-72:17, 74:17-76:6 (discussing EX1018 at claim 1). Indeed, the District Court in the District of Delaware recently stated that:

[T]he rules [37 C.F.R. § 1.808] do not require that Corteva give the world a blanket license to its invention just because it deposited the seeds. The public is entitled to ***availability*** of the deposits — not to exploit them in any way. A restriction on commercial use is entirely consistent with the Patent Office's rules.

Corteva Agriscience, 743 F. Supp. 3d at 619 (denying Inari's Rule 12(b)(6) motion

to dismiss).

When a seed deposit with restrictions on use is sufficient to comply with § 112, i.e., making the biological sample “known and readily available,” it is entirely consistent to find that commercial availability with *permissible* restrictions is also sufficient for providing public access, especially here, where Petitioner did not present any fact or provide evidence that TC1507 seed was *not* available during the relevant timeframe. Moreover, Petitioner has not cited any case that supports its contention that TC1507 seed needed to be available without *any* restrictions to comply with § 112. *See* Pet., 4, 33, 60. And the cases it does cite are distinguishable and do not control.

Specifically, *White Consolidated Industries, Inc. v. Vega Servo-Control, Inc.*, 713 F.2d 788, 790-91 (Fed. Cir. 1983), is distinguishable and does not control. It does not relate to the deposit of biological material and is instead directed to a machining tool that relied upon a certain computer translator. *Id.* at 789. Patentee sought to keep the translator, SPLIT—the best mode for carrying it out—as a trade secret. *Id.* It nevertheless argued that because SPLIT was available for purchase from the patentee, the claims were enabled. *Id.* at 791. The court disagreed, asserting that even though SPLIT was available to the public, it was available without its details known or any substitutes identified. *Id.* Thus, this integral part of carrying out the invention was simply not available, and keeping it as a trade

secret could result in extending the exclusionary scope of the claimed subject matter.

Id. Here, Patent Owner has described the TC1507 event, and the commercial availability of the corn, which Petitioner admits, is exactly the type of known and readily available information that enables the present claims. Pet., 7-9, 52-54-57; EX1007, ¶¶ 43-49, 65-71, 129, 131-134, 140, 159; EX2003, 9:59-12:11, 27:13-28:21, 38:18-39:5, 51:13-52:21, 81:21-82:20.

Petitioner’s other cases (Pet., 33) are similarly inapt. In *Ex parte Grandics*, Appeal 2005-1337, 2005 WL 3067931 (BPAI 2005), there was a dispute as to what “Soma” plant was actually described. *Ex parte DeCastro*, 28 U.S.P.Q.2d 1391 (BPAI 1993), like *White*, did not involve the deposit of biological material and instead related to whether a trade name was sufficient for the purposes of identifying and enabling a “theophylline utilizing enzyme.” 28 U.S.P.Q.2d at 1392-94. There, unlike here, the specification did not include any description of the microbial source that could produce such enzymes or how to isolate the enzyme from them. *Id.*

Petitioner also relies on *In re Howarth*, 654 F.2d 103, 104-106 (CCPA 1981). Pet., 59-60. Petitioner asserts that “*Howarth* affirmed the Board’s enablement rejection even though the relevant information—how to make necessary starting materials—had been disclosed in publicly available patent filings in Rhodesia, Panama, and Luxembourg.” *Id.* at 59. But Petitioner misstates the actual holding of that case, which does not preclude reliance on publicly available information for

enablement under § 112, especially in the context of biological material. *In re Howarth*, 654 F.2d at 106-107. And more significantly, *Howarth* never states that the same priority application can both enable the claimed invention under § 102 and not enable the claimed invention under § 112.

And *In re Argoudelis* does not relate to restrictions on *use* for seed deposits. Rather, the question before the court was whether a patentee could keep the deposit itself secret and restrict access to the deposited material until the patent granted. The court held that it could, stating:

There is no good reason why an applicant who has invented a process and product involving the use of a new microorganism must surrender his starting materials to the general public before filing, whereas an applicant in the other arts need tell the public nothing until his patent issues. We do not believe that [§]112 was designed to achieve such a result.

434 F.2d at 1393. *In re Argoudelis* thus supports that it is *access* that matters and not whether or not that access is unfettered.

Here, Petitioner itself has established that TC1507 seed was “known and readily available” when sold to growers for the 2003 growing season, thereby rendering the cases it cited in the Petition as either irrelevant to the present inquiry or at best, clearly distinguishable.

5. Petitioner's Other Cases Are Inapposite

Petitioner relies heavily on *In re Elsner*, 381 F.3d 1125 (Fed. Cir. 2004), throughout its Petition. *See, e.g.*, Pet., 7, 47-53, 55, 58. *Elsner* is not applicable because it relates to the unique aspect of what constitutes an enabling disclosure for a prior-art *plant* patent where there is inherently little disclosure, compared to *utility* patents. 35 U.S.C. § 162 (“No plant patent shall be declared invalid for noncompliance with section 112 if the description is as complete as is reasonably possible.”). There, the court held that an accompanying foreign sale may enable the prior-art plant patent disclosure. *In re Elsner*, 381 F.3d at 1128. It did not hold that the foreign sales enabled the plant patent but instead remanded for additional factual findings. *Id.* at 1131.

Petitioner cites to three other cases, *US Endodontics, Konda*, and *Daiichi Sankyo*, that are factually distinct at least because none relates to plants or biological material requiring a deposit. Pet., 28. *US Endodontics, LLC v. Gold Standard Instruments, LLC*, PGR2015-00019, Paper 54 at 3-4 (P.T.A.B. Dec. 28, 2016) (endodontic instruments); *Flex Logix Techs., Inc. v. Konda*, IPR2020-00260, Paper 55 at 4-5 (P.T.A.B. July 29, 2021) (multi-stage networks); *Daiichi Sankyo Co., Ltd. v. Alethia Biotherapeutics, Inc.*, IPR2015-00291, Paper 75 at 3-4 (P.T.A.B. June 14, 2016) (antibodies).

C. The Claims Are Enabled and Entitled to Their April 2004 Filing Date

There is no dispute that with a TC1507 seed in hand and the disclosure from the originally-filed 2004 application, a POSA would have been able to make and use the claimed inventions without undue experimentation. Dr. Silverstone readily admitted that “[i]f you already have the seed, you could reproduce another plant with TC1507.” EX2003, 38:21-22; *see also id.* at 11:11-20, 38:3-39:5; EX1007, ¶¶ 134, 159. Such a plant is encompassed by claim 1 of the ’378 patent. EX2003, 9:13-20; EX1007, ¶¶ 49, 65-67.

Dr. Silverstone further testified that from a TC1507 seed, a POSA could produce additional TC1507-containing seeds. EX2003, 11:24-12:11, 14:11-15:24, 33:23-35:4. Such seeds are encompassed by claim 2 of the ’378 patent, which recites “wherein the corn plant is a seed.” EX2003, 9:21-10:8; EX1001, 85:42-43.

Dr. Silverstone’s declaration and testimony also confirms that a POSA would have been able to perform the method of claims 3-7 with access to a seed that possesses the TC1507 event. EX1007, ¶¶ 149-166. Specifically, Dr. Silverstone testified that a TC1507 plant could be bred into a new line:

I would grow the [TC1507] plant up, and then I could use it as either for -- as a pollen donor, so to take the pollen from the TC1507 plant and put that on to the silks of the

plant you want to breed with, or you can do the reverse
and use pollen from another plant on to the TC1507 plant.

EX2003, 14:11-20 (highlighted for reference *infra*).

Dr. Silverstone confirmed that once the pollen from the TC1507 plant is put on the silks from the new line, the pollinated corn plant produces seeds. EX2003, 14:21-15:6. He also testified that at least half the seeds from that breeding process would possess the TC1507 event, and therefore be insect resistant as recited in claim 7. *Id.* at 15:7-24, 19:13-20:11, 10:4-21 (“Part of what is there is a Cry1F gene that confers insect resistance.”).

The steps that Dr. Silverstone explained above directly map onto the challenged claims as shown by corresponding color in the following Figure.

3. A method of producing an insect resistant corn plant comprising:

(a) breeding with an insect resistant corn plant comprising in its genome DNA the DNA construct of claim 1 and

(b) selecting a progeny of (a) by analyzing the genome of the progeny for the presence of the DNA construct of claim 1.

4. The method of claim 3, wherein breeding comprises crossing the insect resistant corn plant of (a) with a second plant.

5. The method of claim 3, wherein the insect resistant corn plant of (a) is the pollen parent for the crossing.

6. The method of claim 4, wherein the second plant is the pollen parent for the crossing.

7. The method of claim 3, wherein the progeny comprises the insect resistance of the insect resistant corn plant of (a).

Figure 1. Claims 3-7 of the '378 Patent.

Dr. Silverstone confirmed that a TC1507 plant could be a pollen parent for the crossing or be the recipient of pollen where the other plant is the pollen parent. EX2003, 14:11-20.

With respect to step (b) of claim 3, Dr. Silverstone confirmed that a POSA would have been able to definitively identify the presence of the TC1507 event in seeds or corn plants using the DNA detection technology described in the original April 2004 application. EX2003, 26:7-34:12; EX1007, ¶¶ 135-143. Specifically, he stated that “Yes, you could use some of these tools [in Barbour] to identify

TC1507 events,” and that “Yes. This was part of the original application” in April 2004. EX2003, 31:13-32:9.

At no point did Dr. Silverstone or Petitioner assert that practicing the claimed invention would require undue experimentation if a POSA had a seed in hand. Quite the contrary. *See* Pet., 49-56; EX1007, ¶¶ 130-143; *see also* EX2003, 37:6-39:5. Moreover, Petitioner and Dr. Silverstone point to no relevant changed circumstances that undermine enablement at the time the application was filed in April 2004. *See, e.g.*, EX2003, 60:14-64:4, 81:10-20.

Petitioner’s only rationale for concluding that the challenged claims were not enabled as of their April 2004 filing date is that a POSA would not have been *allowed* to practice the claimed invention, not that a POSA was incapable of doing so. *See* EX2003, 47:22-50:9. When asked “[s]o your determination as to accessibility is because a POSA was simply not permitted to do something; is that right,” Dr. Silverstone admitted that “Yes. The POSA would not be allowed to do the work.” *Id.* at 50:5-9. The “known and readily available” standard, like seed deposits, does not require unfettered right to use the biological material. *Supra*, §§ VI, VII.B.4. And in any event, Dr. Silverstone himself relied upon and admitted that TC1507 seed was available in the commodity system in 2003 and after. EX1007, ¶¶ 130-134, 140; EX2003, 50:10-52:21, 82:21-85:12. In fact, he testified that Inari itself obtained TC1507 seed. EX2003, 89:16-20. These details were not part of his enablement

analysis (EX2003, 52:22-53:13), which erroneously focused solely on whether a POSA could repeat the event itself from DNA (*id.* at 37:6-39:5)—and not from the seed. Dr. Silverstone’s enablement position in the Petition is simply not credible given his admission that “if a person were able to obtain TC1507 corn grain and had that in hand, which would have been difficult, they would have been able to reproduce a TC1507 event.” EX2003, 57:15-58:2 (“Q: If you had taken the accessibility of the TC1507 event into account in 2003, and you had a corn seed in hand with the TC1507 event and the application as it was filed in 2004, in your opinion would a [POSA] have been able to produce another TC1507 corn plant?”).

Petitioner itself has therefore established that the challenged claims were enabled as of the April 2004 filing date. The ’378 patent is thus entitled to its April 2004 filing date, and Barbour is not prior art.

D. There Is No Relevant Distinction Between the Standards for §§ 112 and 102, at Least Not As Addressed by Petitioner

The Board misapprehended the “known and readily available” standard by finding that Barbour—the published version of the ’378 patent which shares the same disclosure—is enabled, but the issued ’378 patent claims are not. *See generally* ID.

While it is true that § 112 requires *utility* of the invention and § 102 does not, that is *not* the distinction Petitioner argues here. *See* Pet., 57-60; EX2003, 86:8-

87:10; *see also Rasmusson v. SmithKline Beecham Corp.*, 413 F.3d 1318, 1325-26 (Fed. Cir. 2005); *In re Hafner*, 410 F.2d 1403, 1405 (CCPA 1969). Petitioner has not disputed the utility of the claimed invention, and Petitioner's own access to the TC1507 event and its challenge to this expired patent for a product that has been commercialized successfully for years undermines any contention that the '378 patent does not describe a useful invention. EX2003, 89:16-20. Without any relevant distinction, Petitioner's evidence and admissions regarding the enablement of Barbour are equally applicable and demonstrate enablement of the issued claims as of their April 2004 filing date.

The cases that Petitioner relies on to support its argument about an alleged distinction between the two standards do not support the distinction Petitioner wishes to make.

For example, Petitioner misconstrues the holding in *Howarth*, which does *not* address enablement as it applies to § 102. Rather, it assessed whether foreign patents, *which were not identified in the specification at issue*, could nevertheless support the enablement of the rejected claims by placing the synthesis of starting materials within the common knowledge. *Howarth*, 654 F.2d at 105-106. The court stated that “[n]ot everything that may be cited as prior art to preclude the grant of a patent in accordance with 35 U.S.C. § 102 can be equated with common knowledge for purposes of enablement under § 112.” *Id.* at 106. The court looked at what could

be expected to be common knowledge among those skilled in the art, but was skeptical that foreign patents that were not referenced in the specification placed information within the public domain for enablement purposes:

We do not exclude the possibility that foreign patents and foreign language printed publications may also be relevant to the inquiry of what is likely to be known, but we do not *ipso facto* give all patents and printed publications the same evidentiary weight for purposes of showing enablement under § 112, even though all such references are treated the same for prior art purposes under § 102.

Id. at 106-107. Because enablement of a reference for the purpose of § 102 was not addressed, *Howarth* is simply irrelevant to this proceeding where Petitioner itself has not challenged the written description of the '378 patent and has conceded that it fully details the claimed invention and methods to make and use it as long as one has a TC1507 seed in hand. EX2003, 10:1-12:11, 14:11-20, 38:18-39:5, 57:12-58:2; EX1007, ¶ 134.

Petitioner cites other cases as allegedly supporting its distinction between enablement under §§ 102 and 112. Pet., 57-59. But Petitioner cites those cases for what constitutes enablement of a printed publication, not whether a priority application supports the claimed invention under § 112. And none of those cases make the distinction Petitioner attempts to make between enablement under §§ 102

and 112 or holds that a priority application can simultaneously enable the claimed invention and not enable the claimed invention.

For instance, Petitioner cites *In re Wyer*, 655 F.2d 221 (CCPA 1981), which addresses whether an Australian patent application available on microfilm for inspection was a printed publication for the purposes of § 102. Pet., 58. The *Wyer* court did not address enablement at all. *Wyer* thus does not support Petitioner's argument that there is a distinction in the enablement standard between §§ 102 and 112.

Petitioner also cites “*Thomson, Meilland, Boeder, and Tickner*” as allegedly supporting the “commercial availability of plants as enabling anticipatory printed publications.” Pet., 57. But again, those cases say nothing about the enablement of the application claims at issue and do not say that a priority application can enable claims under § 102 while simultaneously not enabling those claims under § 112: Inari has not cited a single case that stands for this proposition. *See, e.g., Ex parte Thomson*, 24 U.S.P.Q.2d 1618 (BPAI 1992) (no enablement rejection of the application and agreeing that seeds, readily and commercially available in Australia, enabled prior art references); *Ex parte Meilland*, Appeal 2012-002753, 2013 WL 5408034, *1-2 (P.T.A.B. Sept. 19, 2023) (stating that French and European prior art Plant Breeder's Rights Applications were enabled by the plant's commercial availability in France and thereby affirming anticipation rejection); *Ex parte Boeder*,

Appeal 2009-003289, 2009 WL 3089031, *3-5 (BPAI Sept. 25, 2009) (affirming anticipation rejection of plant application based on a European Plant Breeder's Right application, which was enabled by the foreign sale of a plant); *Ex parte Tickner*, Appeal 2007-0317 (BPAI May 31, 2007) (affirming anticipation rejection based on a UK Plant Breeder's Grant, which was enabled by foreign sales of plant). If anything, these cases support enablement of the '378 patent claims based on Petitioner's admitted commercial availability of TC1507 and not some alleged distinction between enablement under §§ 102 and 112.

Petitioner also cites *Elsner*, stating that, “[f]or anticipation under §102, the operative question is whether POSAs ‘could obtain the information *if they wanted to.*’” Pet., 58 (citing *In re Elsner*, 381 F.3d at 1131) (emphasis in original). Petitioner argues that the *Elsner* court held “that a plant’s commercial availability sufficed to enable an otherwise non-enabled disclosure of a later-claimed plant,” suggesting that the *Elsner* court found the claimed invention non-enabled. *Id.* But the court did not. The claims in the two applications had been rejected as anticipated. *In re Elsner*, 381 F.3d at 1127. No rejection was even made for lack of enablement.

The court instead looked at whether a prior art reference is enabling for the purposes of § 102—not whether an application enabled its claims. *Id.* More specifically, the court considered whether the foreign sale of a plant could enable an otherwise non-enabled prior art publication. *Id.* at 1128. Thus, the *Elsner* court

considered whether a prior art reference was enabled and did not consider whether the applications were supported under § 112 or identify a distinction between enablement under §§ 102 and 112. To the contrary, the court equated the standards, stating that its holding that evidence of a foreign sale of a claimed reproducible plant could enable a printed publication “is *consistent* with the treatment of § 112 enablement in utility patent applications.” *Id.* at 1130. As a result, *Elsner* in no way supports Petitioner’s argument that the Barbour application is both enabling and not enabling.¹⁹

Two of the cases, briefly discussed above, that Petitioner cites address enablement under § 112 but not enablement under § 102 and thus make no distinction between enablement under §§ 102 and 112. For instance, in *Ex parte Grandics*, 2005 WL 3067931, claims had been rejected under § 112 because the specification failed to teach “what the ‘plant Soma’ is actually defining with respect to a particular botanical plant and, thus, also fails to teach how to make the essential recited anti-cancer ingredient,” and the Examiner cited several references showing

¹⁹ It is also worth noting that *Elsner* is not relevant or applicable because it relates to *plant patents*. As the *Elsner* court noted: “What sets this case apart is that it deals with plant patents.” *In re Elsner*, 381 F.3d at 1128.

that there is great confusion and controversy as to what constitutes the “plant Soma.” *Id.* at *2. The Board found “that the disclosure [did] not enable the skilled artisan to identify the plant Soma.” *Id.* at *5. *Grandics* is not analogous at all to the situation here where the specification plainly identifies the TC1507 event leading to the claimed subject matter, which Petitioner itself argues was well known in the art to be Herculex I, and identifies detection kits that were readily available to characterize it. Pet., 49-51, 54-57; *see also id.* at 64, 67; EX1007, ¶¶ 130-134, 136-143.

Petitioner also cites *Ex parte DeCastro*, 28 U.S.P.Q.2d 1391 (BPAI 1993), but that is equally inapposite. Pet., 57. In that case, the applicant had deposited microorganisms, but the Examiner had found that insufficient because the applicant “did not disclose or describe the microorganisms in any manner in the original disclosure of this application,” and the Board agreed. *DeCastro*, 28 U.S.P.Q.2d at 1393. The Board’s decision hinged on the extremely limited disclosure about the microorganism in the specification. *Id.* at 1393-94. Here, in contrast, there is no dispute that TC1507 is fully described in the present specification, including the various sequences of the DNA construct and methods of making and using the TC1507 event, which Petitioner itself acknowledged. Pet., 53-57; *see also id.*, 64, 67; EX1007, ¶¶ 135-143. Indeed, as mentioned above, Petitioner has not challenged the sufficiency of the description of the April 2004 non-provisional application.

As Petitioner itself recognizes, under § 112, the “operative question is whether

the necessary materials are ‘*readily available* to the public.’” Pet., 59 (quoting *Wands*, 858 F.2d at 735) (emphasis in original). Here, Petitioner provided evidence and argued repeatedly that TC1507, as well as detection kits, are readily available to the public. Nothing more is required for enablement under § 112.

E. All of Petitioner’s Grounds Fail Because the Challenged Claims Are Enabled by the April 2004 Application

Each and every one of Petitioner’s grounds relies upon Barbour as the primary reference. Pet., 6. Because the issued claims are enabled by their originally-filed 2004 application, Barbour, which published in 2006 and contains the same disclosure as the 2004 application, is not prior art under § 102. Accordingly, Petitioner’s Grounds 1-3 fail.

VIII. Real Party in Interest

As noted in the concurrently filed Patent Owner’s Updated Mandatory Notices, Inari Agriculture Inc. and Inari Agriculture NV asserted a counterclaim of invalidity under § 112 against the ’378 patent in the district court for the District of Delaware. Inari Agriculture NV has not been named, however, as a real party in interest in this proceeding. Given the overlap in allegations between the two proceedings, Patent Owner asserts that Inari Agriculture NV should be named as a real party in interest in this proceeding. Patent Owner “should not be forced to defend against later judicial or administrative attacks on the same or related grounds

by a party that is so closely related to the original petitioner as to qualify as a real party in interest.” *Applications in Internet Time, LLC v. RPX Corp.*, 897 F.3d 1336, 1350 (Fed. Cir. 2018).

IX. 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: March 24, 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 Response complies with the type-volume limits of 37 C.F.R. § 42.24(b)(2), because it contains 10,840 words, according to the word-processing system used to prepare this Patent Owner's Response, 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(a)(1).

Respectfully submitted,

Dated: March 24, 2025

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing **Patent Owner's Response** was served on March 24, 2025, via e-mail directed to counsel of record for the Petitioner at the following:

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