

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 PRELIMINARY RESPONSE

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EX2001	European Patent Convention Rule 31
EX2002	JA Kemp, “Introduction to Biological Deposits at the European Patent Office under the Budapest Treaty,” https://jakemp.com/en/briefings/introduction-to-biological-deposits-at-the-european-patent-office-and-under-the-budapest-treaty/ (last accessed Sept. 15, 2024)

I. Introduction

Inari's Petition is entirely premised on the allegation that the issued claims directed to the TC1507 event in Corteva's now-expired U.S. Patent No. 8,901,378 are not enabled by their specification and are therefore not entitled to their April 2004 filing date. Petitioner then asserts that Barbour—the published version of the *very same* April 2004 specification—is enabling, anticipatory prior art because corn and seeds enabling it were commercially available. To take these diametrically opposed positions, Petitioner advocates for an unsupported distinction between enablement for the purposes of §§ 112 and 102 based on the same disclosure. Petitioner cites no controlling precedent that supports its contention. Petitioner's unsupported legal theories should be rejected, and this Petition should be denied for multiple reasons.

First, the Office expressly considered and vetted the enablement of the claims under § 112 during the prosecution of the '378 patent. Almost 10 years after the '378 patent issued and after it expired, Petitioner now seeks a redo of the work already done but offers no evidence that the Office erred in any material way related to the patentability of the issued claims. For this reason alone, the Board can use its discretion to deny institution under § 325(d).

Second, Petitioner itself demonstrates that the disclosure of the April 2004 non-provisional filing coupled with the “known and readily available” TC1507

germplasm meets U.S. enablement standards, including where biological materials are required to support enablement. Specifically, Petitioner asserts that “PO had commercialized TC1507 starting in 2003” and that skilled artisans “could have used test kits (as described in Barbour and also commercially available) to identify TC1507 germplasm—thereby possessing what the Challenged Claims cover.” Pet., 49; *see also id.*, 64, 67. This is the epitome of enablement. Because the challenged claims are enabled by their disclosure, Barbour is not prior art, and institution is precluded under the Patent Act. 35 U.S.C. §§ 311(b), 314.

And finally, the ’378 patent expired in April 2024. Accordingly, Patent Owner Corteva respectfully asks the Board to use its discretion under § 314(a) to deny institution here, where the patent has already expired and Petitioner seeks to subject the Board and Corteva to needless adjudication of issues already decided by the Office during prosecution.

Patent Owner respectfully requests that the Board deny Inari’s Petition on the merits or as an appropriate exercise of its discretion under 35 U.S.C. §§ 314(a) and 325(d).

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 (“the ’271 application”). EX1001, Cover. 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; EX1006.¹ But Petitioner then provides a different name (“Barbour”) for the publication of Application No. 10/837,105, i.e., the April 2004 Application, in an attempt to assert an allegedly enabling anticipatory disclosure. Pet., 41-67; EX1007, ¶¶ 114-166; EX1009. The disclosure in these exhibits is the same because they represent the same application.²

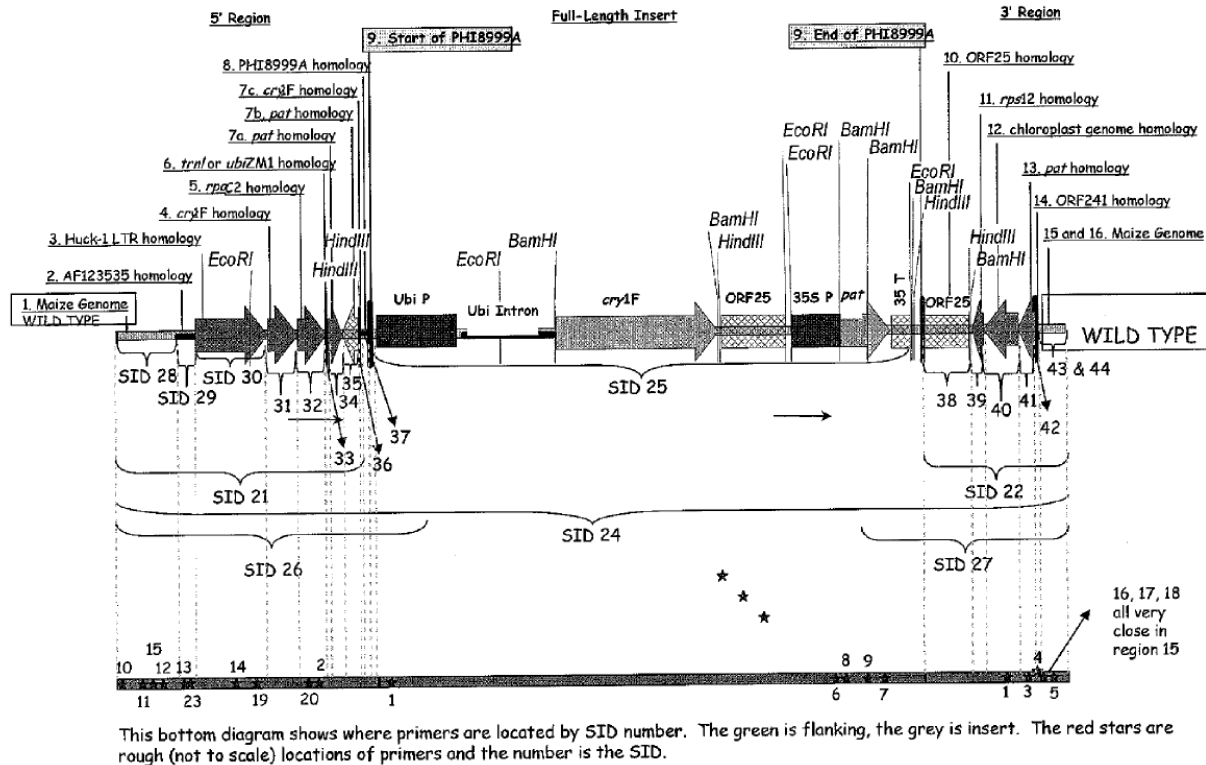
The ’378 patent is directed to a transgenic insect resistant corn plant, TC1507, and methods for detecting TC1507 based on a DNA construct inserted into the corn

¹ In addition to the application and sequence listing, EX1006 includes transmittal pages, an application data sheet, a fee determination record, and other records. When Patent Owner refers to the application filed in 2004, it is referring to the specification and sequence listing only, not the transmittal and fee determination record.

² Application No. 10/837,105 and the included sequence listing was published as U.S. Patent Application Publication No. 2005/0039226 on February 17, 2005. Because claims 15, 20, 23, and 61 were printed incorrectly, the Patent Owner requested a corrected publication, which issued as U.S. Patent Application Publication No. 2006/0037095 on February 16, 2006, as a corrected publication. Petitioner has included this corrected publication of Application No. 10/837,105 as EX1009 and calls it “Barbour.” Despite using different names—the April 2004 Application and Barbour—those applications are the same, namely Application No. 10/837,105.

plant's genome. EX1001, Abstract; EX1006, 55.³ 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 consists of 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 specific DNA sequences at both ends.

³ Citations to the pages of EX1006 refer to the Petitioner's pagination.



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 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 Preliminary Response, Patent Owner does not dispute Petitioner's definition of the qualifications of a person of ordinary skill in the art. *See* Pet., 11; EX1007, ¶¶ 18, 50. Patent Owner reserves its right to challenge Petitioner's definition and to provide its own definition, in the event institution is granted.

IV. Claim Construction

Patent Owner notes that the Petition provides a proposed construction for the claim phrase "flanked by" recited in claim 1 of the '378 patent but then never explains why that construction has any bearing on the present proceeding. *See*

Pet., 26; EX1007, ¶¶ 71-73. Accordingly, and without acquiescing to the claim construction Petitioner sets forth, Patent Owner does not address this construction in this Preliminary Response. Patent Owner reserves the right to respond to Petitioner's proposed construction(s) in the event this proceeding is instituted.

V. The Office Addressed Enablement of the '378 Patent Claims During Prosecution

Petitioner asks the Board to reconsider the issue of enablement that the Office fully vetted during prosecution without establishing that the Office erred in any manner material to the patentability of the '378 patent claims. For at least this reason, a discretionary denial under § 325(d) is warranted. *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 8-9 (P.T.A.B. Feb. 13, 2020) (precedential) (a denial under § 325(d) is appropriate where the petition (1) includes the same or substantially the same art or arguments that were previously presented to the Office and (2) fails to demonstrate that the Office erred in a manner material to the patentability of the challenged claims); *see also Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 at 17-18 (P.T.A.B. Dec. 15, 2017).

A. The Office Expressly Addressed Enablement of the Issued Claims During Prosecution

As filed, the '271 application that led to the '378 patent included original independent claim 1:

1. A 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.

EX1002, 90.

Notably, original claim 1 does not recite any specific sequences for the claimed DNA construct. The Examiner rejected this and its dependent claims as allegedly failing to comply with the enablement requirement. *Id.*, 161-163. The Examiner stated that the specification “[did] not reasonably provide enablement for any plant comprising the recited DNA construct . . . or any insect resistant corn plant comprising any one of SEQ ID NOs 45-57.” *Id.*, 161-162. The Examiner analyzed the *Wands* factors and concluded that practicing the full scope of the claims would

allegedly require undue experimentation. *Id.*, 162-163. The Examiner nevertheless acknowledged that the specification was “enabling for a corn plant comprising SEQ ID NO: 24 and methods of using same.” *Id.*, 162.

In response, Applicants amended claim 1:

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.

Id., 182; *see also* Pet., 13.

In its remarks, Applicants stated that claim 1 had been amended “to recite corn plants comprising SEQ ID NO: 25 (the sequence representing insert PHI8999A, the DNA molecule used to transform maize line TC1507), along with flanking sequences SEQ ID NO: 26 at the 5’ end and SEQ ID NO: 27 at the 3’ end.” EX1002, 177-178. The newly added sequences are encompassed by SEQ ID NO: 24, which the Examiner acknowledged was enabled. *See* EX1001, FIG. 1, 49-72. Applicants also deleted SEQ ID NOs: 45-57 in claim 7. *Id.*, 177-178, 182-183. While not conceding the propriety of the enablement rejection, Applicants asserted that these amendments obviated the rejection. *Id.*, 178.

In a subsequent final Office Action, the rejection of the claims “as failing to comply with the enablement requirement [was] withdrawn in view of Applicant’s amendments to the claims.” *Id.*, 188. Claim 1 issued thereafter without further amendment.⁴ *Id.*, 214, 242.

As part of examination, the Examiner was required to consider whether a deposit was needed for § 112. *See* 37 C.F.R. § 1.809(a) (“The examiner *shall* determine pursuant to § 1.104 in each application for patent, . . . if a deposit is needed, and if needed, if a deposit actually made is acceptable for patent purposes.”)

⁴ Claims 5 and 7 were canceled in response to another rejection not at issue in this proceeding. EX1002, 214, 218.

(emphasis added). Here, the Examiner expressly and meaningfully addressed enablement of the issued claims. In making that assessment, the Examiner did not require any such deposit during the prosecution of the '378 patent. Indeed, as mentioned, the Office found the specification enabling for a corn plant comprising SEQ ID NO: 24 and methods of using same. EX1002, 161-162. The Examiner was also aware of the Herculex I product because it was included in search strings during prosecution. *Id.*, 171, 173 (November 15, 2013 search for “TC1507” or “Herculex” or “HX1”), 194 (S2, S3), 244 (S2, S3).

B. The Petition Presents the Same or Substantially the Same Arguments Previously Considered by the Office

Petitioner attempts to sidestep the first prong of *Advanced Bionics* by refocusing the Board’s attention on Barbour and §§ 102 and 103 to argue that its asserted grounds are not the same or substantially the same as arguments considered during prosecution. Pet., 68. That is a red herring. Inari’s entire Petition relies on the threshold question of whether the specification as originally filed in April 2004 enables the '378 patent claims.⁵ Pet., 28-29. That is *exactly* the question the Office considered when originally rejecting the claims for allegedly lacking enablement over its specification, i.e., the same disclosure that was filed in April 2004. *Supra*,

⁵ Petitioner does not address § 112 support in the 2003 provisional application and therefore has waived any argument that it does not enable the claims. Pet., 29, n.4.

§ V.A. Petitioner’s argument that the Examiner did not consider whether what Petitioner calls the “April 2004 Application” enables the challenged claims is simply incorrect. *See* Pet., 68.

The Office considered Petitioner’s threshold question: whether the issued claims were enabled by the specification filed in April 2004. EX1002, 161-163. Following claim amendments that led to the issued claims now being challenged, the Office found that they were enabled and did not require a deposit. *Supra*, § V.A.; 37 C.F.R. § 1.809(a). It is thus irrelevant for the purposes of § 325(d) that Barbour was not a reference of record (Pet., 68) because its 2006 publication date renders it outside the scope of prior art. *See* 35 U.S.C. § 102. Indeed, Barbour is merely the publication of the application filed in April 2004, so the Office expressly considered whether that application enables the ’378 patent claims.

Smith & Nephew v. Arthrex, Inc. is not analogous and thus cannot control. Pet., 68. There, the Office did not meaningfully consider the question of § 112 support in earlier priority applications. IPR2017-00275, Paper 7 at 11 (P.T.A.B. May 10, 2017). Instead, the Office accepted the applicant’s statements of support at face value. *Id.* And, unlike the situation here, the Board there stated that Patent Owner “does not point to, and we do not find, any submission by Patent Owner or any analysis by the Examiner during the prosecution detailing why the subject matter of

claims 1 and 16 is adequately supported by the June 2000 provisional application or any other document in the priority chain.” *Id.* at 12.

C. Petitioner Has Not Demonstrated That the Office Made a Material Error

The gist of Petitioner’s argument that the Office materially erred is that it was unaware of the random nature of a specific plant event. Pet., 69-70. That, however, does not accurately reflect the record. The specification detailing the method that led to the TC1507 event was before the Examiner, and the Examiner asserted that it enabled certain subject matter. EX1002, 161-162. Moreover, in making its enablement rejection, the Office itself acknowledged the “elite event” of TC1507 and the “random chance” associated with it. *Id.*, 162-163 (“Applicant provides limited guidance and only one working example of the plant of instant claims 1, and 6. SEQ ID NOs 45-57 were produced by random chance when Applicant transformed a corn plant with the PHI8999A plasmid.”). Petitioner itself acknowledges that the Office was aware of the random nature of the event. Pet., 12 (“The Examiner likewise stressed that ‘SEQ ID NOs 45-57 were produced by *random chance* when Applicant transformed a corn plant with the PHI8999A plasmid.’”).

Petitioner’s resort to statements from other U.S. and foreign applications and proceedings does not evidence any material error in the current record.

That Patent Owner may deposit transgenic plant germplasm when pursuing other applications does not demonstrate any error here where (1) the Examiner considered but did not require a deposit; and (2) where Petitioner's own admissions show seed containing TC1507 event was known and readily available at the relevant time, of which the Examiner demonstrated awareness by searching for "TC1507," "Herculex" and "HX1." EX1002, 171, 173, 194, 244; *Ex parte Ushio Sakazaki*, Appeal 2021-002993, 2021 WL 3014127, at *11-12 (P.T.A.B. July 14, 2021) ("Because a seed deposit was not required by the Examiner, we concluded that these rules are not applicable here."); *infra*, § VI.

Moreover, Patent Owner's statements and actions before the European Patent Office are simply irrelevant. *See* Pet., 69; EX1007, ¶¶ 80, 95, 112. Specifically, the statements Petitioner relies on from the prosecution of European Patent Application No. 04751097.9 (EX1003) do not raise any new issues that the Office did not already consider during prosecution. Those statements in Europe were made in the context of claims directed to isolated DNA having specific sequences that were rejected as not being novel over a general description of the TC1507 event. EX1003, 493-505, 518. That prior art disclosure did not include any sequence information, and Patent Owner simply informed the European examiner that without germplasm underlying the TC1507 event, the claimed DNA sequences could not be determined. EX1003, 518-520.

As mentioned, the U.S. Examiner was well aware of the “elite” and “random” nature of the TC1507 event. Petitioner admits this. Pet., 12. The ’378 patent specification itself details the steps and effort required to arrive at the TC1507 event. EX1001, 17:52-18:48 (Example 1); EX1006, 27:11-28:19 (Example 1). The ’378 patent also states that “[t]ransformation procedures leading to random integration of the foreign DNA will result in transformants containing different flanking regions characteristic and unique for each transformant.” EX1001, 7:31-35; EX1002, 9-10; EX1006, 12:27-29. Moreover, Patent Owner submitted the equivalent of EX1032 during prosecution, which the Examiner considered, and also discusses how transgenic TC1507 maize was produced. EX1002, 96 (Cite No. 7), 172 (“All references considered except where lined through.”); *see generally* EX1032. The Office was therefore well aware of the state of the art and the random nature of arriving at TC1507.

Petitioner’s reliance on the prosecution of European Patent Application No. 15168051.9 (EX1004) and applicant’s abandonment of subject matter there is similarly unavailing. Completely devoid from Inari’s Petition is any reference to the rules and regulations that dictate support and plant deposits in Europe. As discussed in more detail below, they are fundamentally different than those in the United States. Notably, under European rules, plant deposits *must* be made before the filing of a priority application. EX2001, European Patent Convention Rule 31,

<https://www.epo.org/en/legal/epc/2020/r31.html> (last accessed Sept. 15, 2024).

And, unlike the United States, there is no alternative procedure for otherwise making the biological material “known and readily available.” *See id.* That the patent applicant in Europe was unable to meet these different standards and abandoned similar claims there has no bearing in the United States where biological deposit rules, if even necessary, are different. *Infra*, § VI.B.

Accordingly, Petitioner has not established any material error, and the Board would be well within its discretion to deny institution under § 325(d). *See Google LLC v. Valtrus Innovations Ltd.*, IPR2022-01197, Paper 18 at 21-24 (P.T.A.B. June 13, 2023); *see also Roku, Inc. v. Universal Elecs., Inc.*, IPR2019-01619, Paper 11 at 19-20 (P.T.A.B. Apr. 2, 2020) (declining to consider merits of a patentability challenge where the petitioner did not “explain adequately how the Examiner erred in a manner material to [] patentability”).

VI. Petitioner’s Own Admissions Demonstrate That the April 2004 Application Enables the Challenged Claims Precluding Institution

Petitioner’s grounds of alleged unpatentability rest on the contention that a biological deposit of TC1507 germplasm was required to enable the claims as of the April 30, 2004, non-provisional filing date. *E.g.*, Pet., 3, 29-41; EX1007, ¶¶ 78-113. Even though the Office expressly considered the issue of enablement and did not require a deposit on the present record, exempting this proceeding from deposit

rules, *Sakazaki*, 2021 WL 3014127, at *11-12, there is no dispute that those rules were nevertheless met. Patent Owner's actions in Europe do not obviate enablement in the United States, and Petitioner's cases are inapposite.

A. Inari's Petition Establishes That TC1507 Germplasm Was "Known and Readily Available"

Under controlling precedent and USPTO rules, a deposit need not be made before the earliest filing date of a patent application. *In re Lundak*, 773 F.2d 1216, 1222 (Fed. Cir. 1985) (holding that § 112 "does not require the transfer of a sample of the invention to an independent depository prior to the filing date of the patent application"); 37 C.F.R. § 1.804(a) (deposit may be made before application is filed or "subject to § 1.809, during pendency of the application for patent"). And "[b]iological material need not be deposited, *inter alia*, 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* M.P.E.P. § 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 731, 736 (Fed. Cir. 1988) ("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 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).

By Petitioner’s own admissions, germplasm from TC1507 was known and readily available before the issuance of the ’378 patent and remains so today. It is thus entirely irrelevant to this proceeding that no biological deposit was made. 37 C.F.R. § 1.802(b); M.P.E.P. § 2404.

To meet the “known and readily available” standard, “the biological material must be both known and readily available – neither concept alone is sufficient.” M.P.E.P. § 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.*

Inari’s own Petition demonstrates that germplasm for TC1507 met the known and readily available standard before the issuance of the ’378 patent. For instance, Petitioner argues for pages and pages, citing numerous exhibits and its own expert,

that TC1507 was widely commercially available starting in 2003, that the source of TC1507—Herculex I—was well known and available from multiple sources, and that detection kits were identified in the application and were well known as commercially available such that one of ordinary skill in the art “could thus screen commercially available corn to identify germplasm expressing the TC1507 event, thereby possessing the claimed invention.” Pet., 47, 49-51, 54-57; *see also id.*, 64, 67; EX1007, ¶¶ 129-143. Petitioner therefore asserts that the disclosure of Barbour—and thus the same disclosure in the April 2004 Application—enables the claims because of this known availability. Pet., 47-57; EX1007, ¶¶ 128-143. In fact, Petitioner includes the following heading in its Petition: “Barbour *Enables* Claims 1-2 and 8 Under § 102.” Pet., 47 (emphasis added); *see also id.*, 64 (“Barbour Enables Claims 3-4 and 7 Under § 102”); 67 (“Barbour Enables Claims 5-6 Under § 102”). In this case, there is no distinction between the standard for enablement under §§ 112 and 102. *Infra*, § VII. Thus, these are express admissions by Petitioner that the challenged claims are enabled.

Petitioner’s own evidence also establishes that the known and readily available standard was met, demonstrating enablement. Regarding commercial availability, Petitioner asserts that “PO commercialized TC1507 starting in 2003—making TC1507 germplasm accessible.” Pet., 5, 47, 49-53; *see also id.*, 64, 67; EX1007, ¶¶ 131-134. Petitioner and its expert also assert 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; *see also id.*, 64, 67; EX1007, ¶ 134. Petitioner asserts that buyers of corn produced from TC1507 seeds “lack any contractual relationship with PO and are thus not bound by any purported restrictions.” Pet., 53; *see also id.*, 64, 67; EX1007, ¶ 134. And Petitioner has not argued that cost is prohibitive or that once in the hands of a skilled artisan, one could not practice the claimed invention. To the contrary, Petitioner concedes that “POSAs could have identified TC1507 in bulk corn (i.e., following harvest) sold commercially prior to July 6, 2006—confirming that POSAs were in possession of the invention as disclosed in Barbour [the April 2004 non-provisional application].” Pet., 53; *see also id.*, 64, 67; EX1007, ¶ 135.

Inari’s Petition also establishes that other publications referred to the availability of TC1507, rendering it known. Pet., 50; EX1007, ¶¶ 132-133. For example, Petitioner cites a published third-party patent application that states, “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).” EX1038, ¶ [0119].⁶ Another third-party published PCT application from 2005 similarly states, “Examples of crops that have been rendered tolerant to

⁶ Herculex® I is not referenced in the third-party patent application’s underlying provisional application filed in May 2002.

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®.” EX1039, 119:9-12. Petitioner’s evidence thus demonstrates that according to this factor the “known and readily available” standard was met. M.P.E.P. § 2404.01 (referring to references in printed publications as one factor to assess “known and readily available”).

Dr. Silverstone’s declaration (EX1007) reflects a declaration of accessibility by one working in the field, which further supports that the known and readily available standard was met. Dr. Silverstone states that “Patent Owner had commercialized TC1507 corn more than a year before July 6, 2007.” EX1007, ¶ 129; *see also id.*, ¶¶ 131-134. Dr. Silverstone states that by 2006, “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).” *Id.*, ¶ 131. Dr. Silverstone echoes the Petition and notes that multiple reports and articles described the known availability of the TC1507 corn event. *Id.*, ¶¶ 132-133. Dr. Silverstone is one “working in the field” and is at least a person of ordinary skill in the art under Petitioner’s own definition. *Id.*, ¶¶ 6-15, 19. This factor thus strongly supports that the “known and readily available” standard

was met. M.P.E.P. § 2404.01 (identifying declarations for those working in the field as one factor to consider).

Finally, Petitioner demonstrates that the biological material necessary to practice the claimed inventions could be made and isolated without undue experimentation. 37 C.F.R. § 1.802(b); M.P.E.P. § 2404.01. In particular, Petitioner asserts that a person of ordinary skill in the art “could have identified such germplasm [from the commercially available TC1507] using methods described in Barbour [and thus in the April 2004 Application] to screen for TC1507’s unique fingerprint.” Pet., 5-6, 47, 49; *see also id.*, 64, 67; EX1007, ¶¶ 129, 135-143. Petitioner admits that one of skill in the art could have detected the presence of TC1507 in commercially available corn without undue experimentation, “confirming that POSAs were in possession of the invention as disclosed in” the Barbour application. Pet., 53; *see also id.*, 64, 67; EX1007, ¶ 135. Petitioner argues:

Aside from disclosing “corn plant TC1507”, Barbour discloses “assays for detecting the presence of corn plant TC1507 DNA in a sample” and in particular “detection of the transgene/flanking insertion region” underlying the Challenged Claims. Given Barbour’s teaching of such “methods for identifying [the] novel corn plant designated TC1507” . . . , POSAs could have readily performed such assays on commercially available bulk corn and thereby

identified kernels (i.e., corn seed) from TC1507 corn plants.

Pet., 54 (internal citations omitted); EX1007, ¶ 136; *see also* Pet., 64, 67. According to Petitioner, “Barbour discloses a ‘DNA detection kit for identifying maize event TC1507 in biological samples,’ with the kit including a probe that preferably includes a sequence that ‘corresponds to a specific region comprising part of the 5’ or 3’ flanking region of event TC1507’” and that “Barbour also discloses detailed procedures for developing such kits and performing such assays using polymerase chain reaction (PCR) ‘or other conventional nucleic acid amplification methods.’” Pet., 54-55; *see also id.*, 64, 67; EX1007, ¶¶ 137-138. Petitioner further concluded that, “[g]iven Barbour’s disclosures, 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; *see also id.*, 64, 67; EX1007, ¶ 140.

This factor therefore also establishes that germplasm of TC1507 was known and readily available at the relevant time. Indeed, Dr. Silverstone applies an “if they wanted to” standard and concludes that “a POSA could have used Barbour’s disclosures [i.e., the same disclosure as filed in April 2004] and/or commercially available TC1507 detection kits to screen bulk corn as of [2006] and thereby obtain

possession of TC1507 (as reflected in claims 1-2 and 8) if the POSA wanted to.”
EX1007, ¶ 146.

In sum, there is no dispute on the present record that the disclosure originally filed in April 2004, coupled with Petitioner’s admissions about the known and readily available TC1507 germplasm, enables the challenged claims under § 112. 35 U.S.C. § 112; 37 C.F.R. § 1.802(b); M.P.E.P. § 2404.01. Petitioner has not challenged the sufficiency of the written description of the April 2004 Application and, in fact, has explained in detail how it would have put a person of ordinary skill in the art in possession of the claimed subject matter if germplasm was available. *E.g.*, Pet., 53-59, 64, 67; EX1007, ¶¶ 135-143. Petitioner never addresses the USPTO’s “known and readily available” standard in 37 C.F.R. § 1.802(b). But its own statements and evidence demonstrate that the “known and readily available” standard was met, contravening any need for a biological deposit—if one had even been required in the first place. Accordingly, Petitioner fails to establish that Patent Owner is not entitled to its April 30, 2004, filing date.

B. Patent Owner’s Actions in Europe Have No Bearing in the United States Where Different Law Applies

Petitioner’s reliance on the rejection of “corresponding claims” for allegedly lacking enablement during the prosecution of European Patent Application No. 15168051.9 (EX1004) (Pet., 69) does not affect the enablement of the U.S.

claims. In Europe, under different legal standards, the examiner concluded that a deposit would have been necessary. EX1004, 386. 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.**”). In the United States, 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 (stating that a deposit can be made after the filing date of an application); *Feldman*, 517 F.2d at 1355 (stating that the “enablement requirement of § 112, first paragraph, does not require such assured access to a microorganism deposit as of the *filing* date; 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.”) (citation omitted); *Ajinomoto Co. v. Archer-Daniels-Midland Co.*, 228 F.3d 1338, 1346 (Fed. Cir. 2000) (stating that when new biological material may not be reproducible, even with detailed procedures and a complete taxonomic description, “[i]t is then a condition of the patent grant that physical samples of such materials be deposited and made available to the public, under

procedures established by the PTO and by international treaty”) (citing *Lundak*, 773 F.2d at 1220-21); M.P.E.P. § 2402 (“Courts have recognized the necessity and desirability of permitting an applicant for a patent to supplement the written disclosure in an application with a deposit of biological material which is essential to meet some requirement of the statute with respect to the claimed invention,” including enablement and written description.).

Additionally, there is not a “known and readily available” alternative to a biological deposit in Europe. *See* European Patent Convention Rule 31 (EX2001). Thus, to the extent access to biological material is necessary to meet the enablement standard in Europe, the only way to do so appears to be with a biological deposit made “not later than the date of filing of the application.” *See* European Patent Convention Rule 31(1)(a) (EX2001). That the patent applicant in Europe abandoned claims where a deposit had not been made is simply not relevant in the United States, where the law is different.

C. Petitioner’s Cases Are Inapposite

Petitioner argues that, “[f]or purposes of §112, [] the commercial availability of TC1507 from PO cannot substitute for a proper deposit identified in the patent and ‘*readily available*’ to the public without restriction,” purporting to cite *Wands*, 858 F.2d at 735. Pet., 60. But *Wands* does not hold that a deposit is required in this situation. On the contrary, *Wands* states: “*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.” *Wands*, 858 F.2d at 736 (emphasis added).

Referring to “living materials,” the *Wands* court states that, “[o]ne means that has been developed for complying with the enablement requirement is to deposit the living materials in cell depositories which will distribute samples to the public who wish to practice the invention after the patent issues.” *Id.* at 735. *Wands* explains that a “deposit has been held necessary for enablement where the starting materials (i.e., the living cells used to practice the invention, or cells from which the required cells can be produced) are not readily available to the public.” *Id.* But the court also recognized the requirement “may be met in ways other than by making a deposit.” *Id.* at 736. And the court expressly stated that, “[n]o deposit is necessary if the biological organisms can be obtained from readily available sources.” *Id.* (emphasis added).

Here, Petitioner has argued with supporting evidence and expert testimony that one of ordinary skill in the art could have obtained the claimed inventions without undue experimentation based on the commercial availability of TC1507. Pet., 53-55; *see also id.*, 64, 67; EX1007, ¶¶ 135-140. That, coupled with the description in the specification—which Petitioner does not challenge—is all that is required to enable to claimed invention. And while Petitioner suggests that *Wands*

holds that the sample must be available “without restriction,” it nowhere says that.

And 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 LLC, et al. v. Inari Agric., Inc., C.A. No. 23-1059, slip op. at 22-23 (D. Del. Aug. 2, 2024) (denying Inari’s Rule 12(b)(6) motion to dismiss).

In any event, Petitioner itself argues that TC1507 was available without restriction, so that argument is irrelevant. *See, e.g.*, Pet., 52 (stating that “as 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”); *see also id.*, 64, 67; EX1007, ¶ 134. Thus, because Petitioner has argued TC1507 was commercially available without restriction before the ’378 patent issued, it has no basis to argue that the application filed in 2004 does not enable the claimed invention.

Petitioner also relies on *White Consolidated Industries, Inc. v. Vega Servo-Control, Inc.*, 713 F.2d 788, 790-91 (Fed. Cir. 1983). *White* is distinguishable

and does not control. First and foremost, it does not relate to the deposit of biological material. Rather, it is 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.

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 tradename was sufficient for the purposes of identifying and enabling a “theophylline utilizing enzyme.” 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.

Petitioner also relies heavily on *In re Elsner*, 381 F.3d 1125 (Fed. Cir. 2004), throughout its Petition. *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. 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. The case was decided in the context of *plant patents*: “What sets this case apart is that it deals with plant patents.” *Id.* It also did not hold that the foreign sales were enabling but instead remanded for additional factual findings. *Id.* at 1131.

Finally, Petitioner cites to three 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).

VII. Petitioner’s Distinction Between Enablement Under §§ 112 and 102 Is Unavailing on This Record

Petitioner attempts to create a distinction between enablement for the purposes of 35 U.S.C. §§ 102 and 112 (*e.g.*, Pet., 57-60), but no such distinction exists here. Indeed, Petitioner is referring to the same application, namely Application No. 10/837,105, whether it calls it the April 2004 Application or Barbour, when it argues that it is enabling for purposes of § 102 but not for purposes of § 112. Petitioner, however, provides no legal support for its position that the same application can be simultaneously enabling and not enabling.

A. Petitioner’s Primary Case, *In re Howarth*, Does Not Support Finding the Barbour Application Both Enabling and Not Enabling

Petitioner posits an unsupported distinction between enablement under §§ 102 and 112. While the Federal Circuit has held that for the purposes of § 102, “a prior art reference need not demonstrate utility in order to serve as an anticipating reference,” that is *not* the distinction with § 112 that Petitioner argues. *See* Pet., 57-60; *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 challenge to this expired patent for a product that has been commercialized for years undermines any contention that the ’378 patent does not describe a useful invention.

Rather, Petitioner relies on *In re Howarth*, 654 F.2d 103, 104-05 (CCPA 1981), to argue that the application filed in 2004 does not enable the claims under § 112 even though the same application when published, i.e., what Petitioner calls Barbour, enables the same claims for the purposes of § 102. Pet., 59. 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.* 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 106-07. 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.

In *Howarth*, the claimed invention was directed to derivatives of clavulanic acid. *Id.* at 104. While the preparation of the claimed derivatives was disclosed, no method was disclosed for making the starting material to derive clavulanic acid nor was “a source named” for such a method. *Id.* The question before the court was whether some foreign patents, which were not identified in the specification at issue, placed the synthesis of starting materials within the common knowledge. *Id.* at 105-06. 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 were 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 106-07.

The *Howarth* court concluded that if an applicant “chooses to rely upon general knowledge in the art to render his disclosure enabling, then the burden rests upon him to establish that those of *ordinary* skill in the art can be expected to possess or know where to obtain this knowledge.” *Id.* at 107 (emphasis added).

The present facts are simply not analogous—the ’378 patent’s enablement support is not predicated on an unidentified foreign publication. The present specification describes how the TC1507 event was achieved. There is no dispute that it provides specific DNA sequences characterizing the event and also provides methods for detecting whether the event occurred. Pet., 53-57; *see also id.*, 64, 67;

EX1007, ¶¶ 135-143. Petitioner also argues that the TC1507 event embodying the claimed DNA sequences was commercially available and cites numerous publications reporting that TC1507 had been commercialized, showing the common knowledge of its availability at the applicable time. Pet., 49-51; *see also* EX1007, ¶¶ 131-133. Petitioner admits this common knowledge when it argues “that TC1507’s commercialization was ‘within the knowledge of the skilled artisan’ prior to 7/6/06 and would have ‘provide[d] the public with access to’ the Challenged Claims as disclosed in Barbour.” Pet., 51. Petitioner even cites evidence of this common knowledge in 2003. *Id.*, 50. Petitioner further argues that “corn *harvested* from TC1507 plants continued to express the TC1507 event” and was available without restriction starting in 2003. *Id.*, 52.

Petitioner’s evidence and argument regarding the common knowledge of one of ordinary skill in the art for the purposes of asserting that Barbour is enabled under § 102 applies equally for enablement under § 112 in view of the April 2004 Application’s identical disclosure. *Supra*, § VI. Indeed, Petitioner cites no case indicating that what is common knowledge in the art differs for enablement under either section. Thus, Petitioner’s alleged distinction between enablement under §§ 102 and 112 does not supporting finding the Barbour application both enabling and not enabling.

B. The Other Cases That Petitioner Cites for An Alleged Distinction Between Enablement Under §§ 102 and 112 Are Inapposite

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. *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). 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 (emphasis added). As a result, *Elsner* in no way supports Petitioner’s argument that the Barbour application is both enabling and not enabling.⁷

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*

⁷ 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.

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 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.*, 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 *3. The Board’s decision hinged on the extremely limited disclosure about the microorganism in the specification. *Id.* at *3-4. 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. *Supra*, § VI.A.

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). 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.

VIII. Grounds 1-3 Should Not Be Instituted

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, is not prior art under § 102. Accordingly, the Board should not institute Inari’s Petition on any grounds. *See* 35 U.S.C. § 311(b).

IX. The Board Should Exercise Its Discretion to Deny Institution Under § 314(a) Because the ’378 Patent Is Expired

The Board has discretion to deny the Petition under § 314(a) because Petitioner asks the Board to waste administrative resources and consider whether an expired patent is unpatentable. The purpose of *inter partes* review is to resolve

“patent-related disputes among parties” and “protect the public’s ‘paramount interest in seeing that patent monopolies . . . are kept within their legitimate scope.’” *Cuozzo Speed Techs., LLC v. Lee*, 579 U.S. 261, 279-80 (2016) (quoting *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 816 (1945)). Here, Petitioner has identified no litigation related to the ’378 patent. Pet., 72. Further, the Board has discretion to deny the Petition based on administrative efficiency alone. *See, e.g., Mylan Lab’ys Ltd. v. Janssen Pharmaceutica, N.V.*, 989 F.3d 1375, 1382 (Fed. Cir. 2021) (explaining that a petitioner has no right to institution and “the Director is free . . . to determine that for reasons of administrative efficiency an IPR will not be instituted”); *see also BioDelivery Scis. Int’l, Inc. v. Aquestive Therapeutics, Inc.*, 935 F.3d 1362, 1364-65 (Fed. Cir. 2019); 35 U.S.C. § 316(b). Because the Office already squarely addressed the enablement issue at the crux of this Petition, the Board would be well within its discretion to preserve its resources and deny institution.

X. The Board Does Not Have Jurisdiction to Adjudicate Expired Patents

The ’378 patent expired before the Petition was filed on June 13, 2024. The issue of whether the Board has jurisdiction over expired patents is currently before the Federal Circuit on appeal. *Apple, Inc. et al. v. Gesture Tech. Partners, LLC*, IPR2021-00922, Paper 26, at 25-27 (P.T.A.B. Nov. 28, 2022); *see Gesture Tech. Partners, LLC v. Apple Inc. et al.*, No. 23-1463, D.I. 19, at 31-33 (Fed. Cir. July 17,

2023) (Br. Of Appellants). Patent Owner thus reserves its right to address the Board's threshold jurisdiction, depending on the outcome of this Federal Circuit appeal.

XI. Conclusion

For the reasons set forth above, Petitioner has not shown that it has a reasonable likelihood of prevailing on its proposed challenge to claims 1-8 of the '378 patent, and the Board should exercise its discretion to deny institution.

Respectfully submitted,

Dated: September 17, 2024

By: /Erin M. Sommers/

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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 Preliminary Response complies with the type-volume limits of 37 C.F.R. § 42.24(b)(1), because it contains 9,379 words, according to the word-processing system used to prepare this Preliminary Response, excluding the words in the Table of Contents, Table of Authorities, List of Exhibits, Certification Under § 42.24(d), and Certificate of Service, as set forth in 37 C.F.R. § 42.24(a)(1).

Respectfully submitted,

Dated: September 17, 2024

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CERTIFICATE OF SERVICE

The undersigned certifies that a copy of the foregoing **Patent Owner's Preliminary Response and Patent Owner's Exhibits 2001 and 2002** were served on September 17, 2024, via e-mail directed to counsel of record for the Petitioner at the following:

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