

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

INARI AGRICULTURE, INC.,
Petitioner,

v.

CORTEVA AGRISCIENCE LLC,
Patent Owner.

IPR2024-01014
Patent 8,901,378 B2

Before MICHAEL J. FITZPATRICK, ZHENYU YANG, and
TIMOTHY G. MAJORS, *Administrative Patent Judges*.

Opinion for the Board filed by Administrative Patent Judge YANG.

Opinion Dissenting filed by Administrative Patent Judge FITZPATRICK.

YANG, *Administrative Patent Judge*.

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

Inari Agriculture, Inc. (“Petitioner”) filed a Petition (Paper 2, “Pet.”) seeking *inter partes* review of claims 1–8 of U.S. Patent No. 8,901,378 B2 (Ex. 1001, “the ’378 patent”). Corteva Agriscience LLC (“Patent Owner”) filed a Preliminary Response. Paper 9 (“Prelim. Resp.”). With our authorization (Ex. 3001), Petitioner filed a Reply (Paper 10), and Patent Owner filed a Sur-reply (Paper 14).

We have authority under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted “unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314(a).

For the reasons provided below, we determine Petitioner has satisfied the threshold requirement set forth in 35 U.S.C. § 314(a). We decline to deny the Petition on the basis of discretion under § 314(a) or § 325(d). We institute *inter partes* review of all challenged claims based on the grounds raised in the Petition.

A. *Real Parties in Interest*

Petitioner identifies itself as the only real party in interest. Pet. 72. Patent Owner identifies itself and Pioneer Hi-Bred International, Inc. as the real parties in interest. Paper 4, 2.¹

B. *Related Matters*

Neither party has identified any litigation related to the ’378 patent. Pet. 72; Paper 4, 2. The parties list other patents and applications in the same family as the ’378 patent. Pet. 72; Paper 4, 2.

¹ Paper 4 does not include any pagination. We assign the page number here as it is the second page of the Paper.

C. The '378 Patent

The '378 patent relates to an insect resistant corn plant TC1507, the DNA plant expression construct of corn plant TC1507, and the detection of the transgene/flanking insertion region in corn plant TC1507 and progeny thereof. Ex. 1001, 1:26–31.

Before the '378 patent, insect resistance had been genetically engineered into crops such as corn in order to control insect damage and to reduce the need for traditional chemical pesticides. *Id.* at 1:36–38. According to the '378 patent, delta-endotoxins from *Bacillus thuringiensis* (B.t.) were successfully expressed in corn and provided excellent control over insect pests. *Id.* at 1:38–44.

The '378 patent provides a DNA construct capable of introduction into and replication in a host plant cell that, when expressed, confers insect resistance. *Id.* at 2:48–51. Specifically, the '378 patent discloses a DNA molecule named PHI8999A (SEQ ID NO:25) that includes two transgene expression cassettes. *Id.* at 2:51–3:5, 17:58–18:11. The first expression cassette comprises a promoter, 5' untranslated exon, the first intron of the maize ubiquitin (Ubi-1) gene, operably connected to a DNA molecule encoding B.t. delta-endotoxin Cry1F, and operably connected to a DNA molecule comprising a 3' ORF25 transcriptional terminator isolated from *Agrobacterium tumefaciens*. *Id.* at 2:53–62, 17:59–18:1. The second transgene expression cassette comprises a DNA molecule of the cauliflower mosaic virus (CaMV) 35S promoter, operably connected to a DNA molecule encoding phosphinothricin acetyltransferase (PAT) gene, operably connected to a DNA molecule comprising a 3' transcriptional terminator from (CaMV) 35S. *Id.* at 2:63–3:5, 18:2–11.

The '378 patent discloses transforming maize with PHI8999A by particle bombardment and generating transgenic corn plants containing the Cry1F gene. *Id.* at 17:50–18:38. The expression of foreign genes in plants was known to be influenced by their location in the plant genome. *Id.* at 1:52–53. At the same time, the presence of the transgene at different locations in the genome will influence the overall phenotype of the plant in different ways. *Id.* at 1:57–59. For this reason, the '378 patent acknowledges that it is often necessary to screen a large number of events in order to identify an event characterized by optimal expression of an introduced gene of interest. *Id.* at 1:59–62.

According to the '378 patent,
it is common to produce hundreds to thousands of different events and screen those events for a single event that has desired transgene expression levels and patterns for commercial purposes. An event that has desired levels or patterns of transgene expression is useful for introgressing the transgene into other genetic backgrounds by sexual outcrossing using conventional breeding methods. Progeny of such crosses maintain the transgene expression characteristics of the original transformant.
Id. at 2:3–11.

In an embodiment of the '378 patent, plants that survived the transformation with PHI8999A and confirmed to express the Cry1F protein were

subjected to a whole plant bioassay using European corn borer insects. Positive plants were crossed with inbred lines to obtain seed from the initial transformed plants. A number of lines were evaluated in the field. The TC1507 event was selected from a population of independent transgenic events based on a superior

combination of characteristics, including insect resistance and agronomic performance.

Id. at 18:30–45.

The '378 patent describes the sequences of the transgene insert and flanking regions of TC1507 event. According to the '378 patent, SEQ ID NO: 24 “represents the transgenic insert in maize line TC1507 as well as the sequence flanking the insertion sites,” SEQ ID NO: 25 “represents insert PHI8999A,” which was “used to transform maize line TC1507,” SEQ ID NO: 26 “represents part of the PHI8999A insert as well as flanking sequence 5' to the insert,” and SEQ ID NO: 27 “represents part of the PHI8999A insert as well as flanking sequence 3' to the insert.” *Id.* at 49–50, 59–60, 65–66, 67–68, Fig. 1.

D. Illustrative Claim

Independent claim 1 is illustrative of the claimed subject matter and is reproduced below.

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; andsaid 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.

Ex. 1001, 85:24–41.

E. Relevant Prosecution History of the '378 Patent

The originally filed claim 1 differs from the issued claim 1 in three aspects: (1) it is directed to “[a] plant” generally, and not a corn plant specifically; (2) it does not include the sequence information of the 3' transcriptional terminator from (CaMV) 35S in the second expression cassette; and (3) it does not include the sequences flanking the first and second expression cassettes. Ex. 1002, 44.

During prosecution, the examiner rejected the then-pending claims for, among other reasons, failing to comply with the written-description and enablement requirements under 35 U.S.C. § 112. *Id.* at 161–62. According to the examiner, “[a]pplicant describes a transgenic corn plant comprising elite event TC1507 comprising a DNA construct essentially as show in Figure 1 and SEQ ID NO: 24,” and “does not describe the genus of corn plants as broadly claimed.” *Id.* at 161. The examiner also states that “the specification, while being enabling for a corn plant comprising SEQ ID NO: 24 and methods of using same, does not reasonably provide enablement for any plant comprising the recited DNA construct.” *Id.* at 161–62.

In response, the applicant amended pending claim 1 “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.” *Id.* at 177–78, 182. The examiner withdrew the § 112 rejections in view of the amendments. *Id.* at 188.

After the applicant later filed terminal disclaimers to overcome the double patenting rejections, the examiner allowed the claims. *Id.* at 231–32, 242–43.

F. Asserted Challenge to Patentability

Petitioner asserts the following challenge to patentability:

Claims Challenged	35 U.S.C. § ²	Reference
1, 2, 8	102	Barbour ³
3, 4, 7	102/103(a)	Barbour
5, 6	103(a)	Barbour

As support for its patentability challenge, Petitioner also relies on the Declaration of Aron Silverstone, Ph.D. Ex. 1007.

II. ANALYSIS

A. Claim Construction

In an *inter partes* review, we construe a claim term “using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. [§] 282(b).” 37 C.F.R. § 42.100(b) (2020). Under that standard, the words of a claim “are generally given their ordinary

² The Leahy-Smith America Invents Act (“AIA”), Pub. L. No. 112-29, 125 Stat. 284, 287–88 (2011), amended 35 U.S.C. §§ 102 and 103, effective March 16, 2013. AIA §§ 3(b), 3(c), and 3(n). The application that issued as the ’378 patent was filed before the effective date of AIA. Ex. 1001, code 22. Accordingly, we apply the pre-AIA version of §§ 102 and 103. We also apply the pre-AIA version of § 112 in our analysis below (*see infra* Section II.C) and deem Petitioner’s citation to AIA version of § 112 in the Petition (*see, e.g.*, Pet. 29 (citing § 112(a))) as harmless error.

³ Barbour et al., US 2006/0037095 A9, published Feb. 16, 2006 (Ex. 1009, “Barbour”).

and customary meaning,” which is “the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc).

Petitioner argues that a person of ordinary skill in the art (“POSA”) would understand that the term “‘flanked by’ permits overlap between the expression cassette and the DNA sequence it is flanked by.” Pet. 24–26. Patent Owner does not propose any claim construction. Prelim. Resp. 7–8.

On this record and for purposes of this Decision, we see no need to expressly construe any claim term.

B. Level of Ordinary Skill in the Art

Petitioner asserts that:

POSAs as of 2004 would have had a Ph.D. in biochemistry, cell biology, genetics, molecular biology, or a related field, and 3-5 years of experience in the design or development of transgenic plants including genomics, proteomics, biochemistry, plant transformation and crop science, or the equivalent. Additional graduate education could substitute for professional experience, or significant experience in the field could substitute for formal education.

Pet. 11. Patent Owner does not, at this point, dispute this proposed definition of the ordinarily skilled artisan. Prelim. Resp. 7. For purposes of this Decision, we adopt Petitioner’s definition of the person of ordinary skill in the art as it appears consistent with the skill level reflected in the disclosure of the ’378 patent.

C. Priority Date of the Challenged Claims

The ’378 patent application issued from application No. 12/914,271 (“the ’271 application”), filed on October 28, 2010. Ex. 1001, code 22. The ’271 application claims priority to several earlier applications, including

application No. 11/774,236 (“the 2007 application”), filed July 6, 2007, which is a division of application No. 10/837,105 (“the 2004 application”), filed April 30, 2004. Ex. 1001, code 60.⁴ It is undisputed that the 2004 application, the 2007 application, and the ’271 application share the same or substantially the same specification. It is also undisputed that Barbour, the sole alleged prior art, is the published 2004 application. Ex. 1009, code 21.

In this IPR, Petitioner bears the burden of persuasion to prove unpatentability by a preponderance of the evidence, and that burden never shifts to Patent Owner. *See Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). Petitioner also bears the initial burden of production to show the asserted reference is prior art. *See id.* at 1379. Barbour was published in 2006 (Ex. 1009, code 48), before the 2010 filing date of the ’271 application (Ex. 1001, code 22). Thus, Petitioner has satisfied its initial burden to show that Barbour is prior art.

The burden of production then shifts to Patent Owner to show that Barbour is not prior art because the challenged claims are entitled to a priority date earlier than Barbour’s 2006 publication date.⁵ *See Dynamic Drinkware*, 800 F.3d at 1379. At this stage, Patent Owner has produced only two pieces of evidence. *See* Ex. 2001 (Rule 31 of the European Patent

⁴ The ’271 application also claims priority to a 2003 provisional application. Ex. 1001, code 60. That application is not at issue in this proceeding.

⁵ At this stage of the proceeding, Patent Owner does not dispute that Barbour, if it qualifies as prior art, anticipates and/or renders obvious the challenged claims. *See generally* Prelim. Resp.

Convention); Ex. 2002 (an article published by a law firm discussing biological deposits at the European Patent Office).

Nonetheless, once Patent Owner presents argument and evidence that the challenged claims are entitled to the priority date of the 2004 application (Prelim. Resp. 17–40), Petitioner must persuade us that the challenged claims are not entitled to the benefit of the 2004 priority date. *See Dynamic Drinkware*, 800 F.3d at 1379.

“[A] patent’s claims are not entitled to an earlier priority date merely because the patentee claims priority.” *In re NTP, Inc.*, 654 F.3d 1268, 1276 (Fed. Cir. 2011). “Rather, for a patent’s claims to be entitled to an earlier priority date, the patentee must demonstrate that the claims meet the requirements of 35 U.S.C. § 120.” *Id.*; *see also Nat. Alternatives Int’l, Inc. v. Iancu*, 904 F.3d 1375, 1380 (Fed. Cir. 2018) (holding that “claims in a patent or patent application are not entitled to priority under § 120 at least until the patent owner *proves* entitlement to the PTO, the Board, or a federal court”). Under § 120, entitlement to the benefit of an earlier priority date requires that the priority application satisfies the requirements under § 112, which include, among others, the enablement requirement. *See* 35 U.S.C. §§ 112, 120.

Based on this record, we find that, for purposes of institution, Petitioner has shown sufficiently that the challenged claims are not entitled to the 2004 priority date because the 2004 application does not enable the full scope of the challenged claims as required by § 112. *See* Pet. 26–41.

1. Enablement Based on the Disclosure of the 2004 Application

Petitioner presents detailed analysis of the *Wands* factors to support its argument that the disclosure of the 2004 application “fails to enable POSAs

to practice the Challenged without undue experimentation.” Pet. 34–41; *In re Wands*, 858 F.2d 731, 735 (Fed. Cir. 1988).

Petitioner points out that the challenged claims, which are directed to a transgenic corn plant or a method of producing such a plant, require inserting exogenous DNA at a specific location within the corn genome. Pet. 29; *see also id.* at 19–20 (“Independent claim 1 requires a corn plant incorporating foreign DNA . . . at a particular location within the corn genome defined based on SEQ ID NO:26 at the 5' end and SEQ ID NO:27 at the 3' end.”). Yet, Petitioner argues that, as of April 2004, transgene integration was a random process, with exogenous DNA incorporated at “arbitrary and uncontrollable locations” within the corn genome. *Id.* at 1–4, 29–41 (citing Ex. 1012, 185; Ex. 1013, 313; Ex. 1014, 311; Ex. 1015, 250; Ex. 1016, 277; Ex. 1017, 46:4–12).

Citing the testimony of its declarant, Petitioner argues that “[s]uch random insertion of foreign transgenes into plants cannot be reproduced without undue experimentation even with current methods.” *Id.* (citing Ex. 1007 ¶¶ 78–83); *see also* Ex. 1007 ¶ 79 (“Even as of today, it would be extraordinarily difficult to reproduce such random insertion of foreign transgenes into plants using gene editing technologies such as CRISPR-Cas9—a platform that did not exist in the 2003–2007 timeframe.”).

Despite the unpredictability of the art, Petitioner continues, the 2004 application only describes how the TC1507 event was generated, and “offers no directions for independently reproducing TC1507.” *Id.* at 39 (citing Ex. 1006, 24:8–28:18; Ex. 1007 ¶ 107). Petitioner asserts that “it would have been essentially impossible at the time even with extensive

experimentation for POSAs to make and use the inventions of the Challenged Claims.” *Id.* at 40 (citing Ex. 1007 ¶¶ 110–113).

In the Preliminary Response, Patent Owner does not refute Petitioner’s *Wands*-factors analysis. *See generally* Prelim. Resp. In fact, elsewhere, Patent Owner appears to agree with Petitioner that, in 2004, or even as late as 2009, the introduction and integration of a transgene into a plant genome were “random” and “unpredictable.” Ex. 1018, 4:28–34; Ex. 1019, 5:48–54. Indeed, the ’378 patent itself recognizes 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.” Ex. 1001, 7:31–35. Patent Owner also acknowledges that because events, such as TC1507, are “random,” they “generally cannot be duplicated.” Ex. 1018, 4:41–42.

Thus, based on the current record, and for purposes of this Decision, we find Petitioner’s *Wands*-factors analysis persuasive to support its argument that the disclosure of the 2004 application does not enable full scope of the challenged claims as of April 2004. *See* Pet. 34–41.

2. Enablement Based on Deposit of Biological Material

“Where an invention depends on use of living materials such as microorganisms or cultured cells, it may be impossible to enable the public to make the invention solely by means of a written disclosure.”

Wands, 858 F.2d at 735; *see also In re Lundak*, 773 F.2d 1216, 1220–21 (Fed. Cir. 1985) (“When an invention relates to a new biological material, the material may not be reproducible even when detailed procedures and a complete taxonomic description are included in the specification.”).

“The deposit of biological organisms for public availability satisfies the

enablement requirement for materials that are not amenable to written description or that constitute unique biological materials which can not be duplicated.” *Ajinomoto Co. v. Archer-Daniels-Midland Co.*, 228 F.3d 1338, 1345–46 (Fed. Cir. 2000).

It is undisputed that Patent Owner did not make a deposit of the transgenic TC1507 germplasm. Thus, the enablement requirement is not met by deposit of living materials.

3. Known and Readily Available to the Public

“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.” *Wands*, 858 F.2d at 736 (footnotes omitted). “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.” *Id.*; *see also* 37 C.F.R. § 1.802(b) (“Biological material need not be deposited . . . if it is known and readily available to the public or can be made or isolated without undue experimentation.”).

Patent Owner contends that “germplasm from TC1507 was known and readily available before the issuance of the ’378 patent and remains so today.” Prelim. Resp. 18–25. According to Patent Owner, “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.” *Id.* at 25. Specifically, Patent Owner argues that

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.”

Id. at 19–20 (citing Pet. 47, 49–51, 54–57, 64, 67; Ex. 1007 ¶¶ 129–143).

At this preliminary stage, we are not persuaded by Patent Owner’s argument.

To decide whether the challenged claims are entitled to the 2004 priority, we determine whether the 2004 application enables the challenged claims as of the filing date of the 2004 application, that is, April 30, 2004. *See Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1254 (Fed. Cir. 2004). Petitioner’s alleged admission that Patent Owner relies on, however, shows that TC1507 was commercially available and without restriction only as of February 2006, and thus after April 2004. *See, e.g.*, Pet. 55 (“By 2006, TC1507 was widely found in ‘food or feed products’ commercially sold without restriction.”); *see also* Ex. 1007 ¶ 131 (“By Barbour’s publication date [of February 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).”).

Patent Owner emphasizes Petitioner’s argument that “PO had commercialized TC1507 starting in 2003.” Prelim. Resp. 2 (citing Pet. 49), 20 (citing Pet. 5). Evidence of record, however, suggests that such commercial activity did not render TC1507 “readily available to the public.”

Indeed, during the prosecution of related European patent applications, Patent Owner represented to the European Patent Office (“EPO”) that “whilst [TC1507] seed did at some point during 2003 leave the physical control of [Patent Owner], important elements of legal control were

always retained.” Ex. 1003, 543. Pointing to the sales agreements, Patent Owner asserted before the EPO that

it is clear that the grower is only permitted to use the seed to raise a commercial crop, in a single season, and for no other purpose. In particular, the grower is prohibited from transmitting the seed onwards to third parties for planting, breeding, seed production or research purposes. The grower himself is also prohibited from using the seed for such purposes.

. . .

Moreover . . . merely providing seed to growers as part of a licensed commercial package does not render publicly available the invention in the sense that it can be freely handled or reproduced by third parties: this would require physical access to the germplasm in contravention of the technology agreement. Nor are the seed/plants of the invention ever present “in public”; they are either within the physical control of the Applicants or held on the grower’s private land.

Id.

Patent Owner contends that representations before the EPO have no bearing in the United States due to different legal standards. Prelim. Resp. 25–27. Patent Owner’s argument is, at present, unavailing. Even though the legal standards for enablement may differ in the two jurisdictions, the facts surrounding the TC1507 seed sales agreements remain the same. We find the Patent Owner’s representations to the EPO suggest that the TC1507 seeds sold by Patent Owner in 2003 do not meet the “readily available to the public” standard under *Wands* or 37 C.F.R. § 1.802(b).

Patent Owner also points to Petitioner’s statements 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.” Prelim. Resp. 29 (quoting Pet. 52); Sur-reply 2–3. But Petitioner’s arguments and supporting evidence only suggest that corn harvested from TC1507 was available to the public by February 2006, Barbour’s publication date. Patent Owner does not point to any evidence that would persuasively support a finding that the same was true as of April 30, 2004, the filing date of the 2004 application.

In fact, when responding to Petitioner’s argument that Patent Owner has not bridged any alleged gap between the filing date of the 2004 application and the 2006 publication date of Barbour, Patent Owner contends that “[t]here is no gap to bridge.” Sur-reply 4 (citing Reply 1, 3). Instead, Patent Owner relies on the enablement of Barbour in 2006, asserting that “Petitioner’s own evidence of enablement of Barbour in 2006 for the purposes of § 102 establishes enablement *as of the April 2004 filing date.*” *Id.* As support, Patent Owner relies on case law and the USPTO Rules. Prelim. Resp. 18 (citing *Lundak*, 773 F.2d at 1222; 37 C.F.R. § 1.804(a)), 26–27 (citing *Ajinomoto*, 228 F.3d at 1346; *Lundak*, 773 F.2d at 1220–22; *Feldman v. Aunstrup*, 517 F.2d 1351, 1355 (C.C.P.A. 1975)).

The authorities Patent Owner relies on are inapposite because they address the deposit, and not commercial availability, of biological material. For example, in *Ajinomoto*, the court stated that

[w]hen an invention relates to a new biological material, the material may not be reproducible even when detailed procedures and a complete taxonomic description are included in the specification. It 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.*

228 F.3d at 1346 (emphasis added).

Similarly, in *Lundak*, the court held that “35 U.S.C. § 112, first paragraph, does not require the transfer of a sample of the invention *to an independent depository* prior to the filing date of the patent application.” 773 F.2d at 1222 (emphasis added); *see also Feldman*, 517 F.2d at 1352–53, 1355 (holding that a “‘restricted culture’ *deposit*” made before the filing date, with the restrictions removed during pendency of the application rendered the deposit “open to the public”) (emphasis added);⁶ 37 C.F.R. § 1.804(a) (permitting an applicant to make an “*original deposit*” of a biological material “at any time before filing the application for patent or, subject to § 1.809, during pendency of the application for patent”) (emphasis added).

Patent Owner, however, never made a deposit of the transgenic TC1507 germplasm. Instead, Patent Owner argues that TC1507 was “known and readily available,” and thus, a deposit was not necessary. *See* Prelim. Resp. 17–25. Patent Owner does not point to any authority to show, or otherwise persuasively argue, that case law and Rules addressing the deposit of biological material would apply to commercial sales of the material as presented on the record here.

As Patent Owner recognizes, the court requires that, when the enablement requirement is satisfied via the deposit of biological material,

⁶ The facts in *Feldman* are further distinguishable from those in this case. In *Feldman*, at the time the application-at-issue was filed, the claimed invention as “described in the application was fully capable of being reduced to practice (i.e., no technological problems, the resolution of which would require more than ordinary skill and reasonable time, remained in order to obtain an operative, useful process).” 517 F.2d at 1355. Such is not the case here. *See supra* Section II.C.1.

such materials be deposited “under procedures established by the PTO and by international treaty.” Prelim. Resp. 26–27 (quoting *Ajinomoto*, 228 F.3d at 1346). And the Office indeed has established specific procedures governing the deposit of biological material. For example, the Rule requires that

[w]hen the original deposit is made after the effective filing date of an application for patent, the applicant must promptly submit a statement from a person in a position to corroborate the fact, stating that the biological material which is deposited is a biological material specifically identified in the application as filed.

37 C.F.R. § 1.804(b).

We decline to hold that the commercial availability of biological material during the pendency of the application but after the application’s filing date (for which the priority benefit is sought) retroactively meets the enablement requirement as of the filing date because (1) Patent Owner points to no authority that directs us to extend the law applicable to the deposit of biological material to commercial sales of such material, and (2) commercial sales lack safeguards provided by, for example, 37 C.F.R. § 1.804(b).

Therefore, on this record, we disagree with Patent Owner that Petitioner’s evidence showing TC1507 was commercially available without restriction by 2006 would show that the 2004 application enables the challenged claims as of April 2004.

4. Summary

In sum, based on the current record, and for purposes of this Decision, Petitioner has shown sufficiently that the disclosure of the 2004 application, by itself, fails to enable POSAs to practice the challenged claims without

undue experimentation. In addition, Patent Owner has not shown that TC1507 was “known and readily available to the public” as of the filing date of the 2004 application. Therefore, the 2004 application does not enable the challenged claims, and the challenged claims are not entitled to the 2004 priority date. The earliest possible priority date for the challenged claims is, thus, July 6, 2007, which is the filing date of the 2007 application.

D. Barbour’s Prior-Art Status

Barbour was published in 2006 (Ex. 1009, code 48), before the putative 2007 priority date for the challenged claims. Petitioner argues that Barbour is enabled because “[b]y Barbour’s publication date, TC1507 corn had been commercialized under PO’s ‘Herculex’ trademark for three growing seasons—2003, 2004, and 2005.” Pet. 49. Petitioner further contends 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.” *Id.* at 52 (citing Ex. 1007 ¶ 134). According to Petitioner, “[s]uch corn was sold as a commodity—without any contractual restrictions.” *Id.*

Petitioner argues that Barbour discloses methods and related kits for detecting TC1507 in food or feed products. *Id.* at 54–55 (citing Ex. 1007 ¶¶ 136–138; Ex. 1009 ¶¶ 2, 3, 9, 24, 56, 58, 60, 75, 76, 106–108). “Given Barbour’s disclosures,” Petitioner continues, “POSAs could have screened commercially available bulk corn from the 2003, 2004, or 2005 growing seasons and thereby gained possession of TC1507 as claimed.” *Id.* at 55 (citing Ex. 1007 ¶¶ 139–140).

Patent Owner does not dispute any of these assertions. To the contrary, Patent Owner cites them with apparent agreement. *See Prelim.*

Resp. 17–25, 29, 35. Patent Owner, however, emphasizes that the disclosures of Barbour and the 2004 application are the same. *Id.* at 1, 3 & n.2, 32. As such, Patent Owner protests that Petitioner “provides no legal support for its position that the same application can be simultaneously enabling and not enabling.” *Id.* at 32.

Petitioner, however, does not argue that the disclosure of Barbour, by itself, would satisfy the enablement requirement, in 2004 or in 2006. Pet. 34–41, 47–57. Instead, relying on the fact that Patent Owner commercialized TC1507, Petitioner asserts that “POSAs could thus screen commercially available corn to identify germplasm expressing the TC1507 event, thereby possessing the claimed invention” by Barbour’s publication date in 2006. *Id.*; *see also* Reply 3 (“To address Barbour’s enablement under §102, Petitioner presented evidence that ‘[b]y 2006’ POSAs could have obtained bulk corn on the open market after harvest (a new generation of seeds—not subject to PO’s contractual restriction) and then used PCR-based DNA detection to identify TC1507 germplasm.”).

For that matter, Patent Owner also does not argue that the disclosure of the 2004 application, which is the same as Barbour, by itself, would satisfy the enablement requirement. *See generally* Prelim. Resp. Instead, Patent Owner also relies on the commercial availability of TC1507 to argue that the 2004 application was enabled. *See* Prelim. Resp. 1–2 (arguing that the disclosure of the 2004 application “coupled with the ‘known and readily available’ TC1507 germplasm meets U.S. enablement standards”), 25, 28.

Thus, the critical issue is not, as Patent Owner asserts, whether “the same application can be simultaneously enabling and not enabling.” *Id.* at 32. It is whether TC1507 was “known and readily available” to the public

at the relevant time. As explained above, for the priority determination, the relevant time is April 30, 2004, the filing date of the 2004 application. Patent Owner has not produced or pointed to any evidence to show TC1507 corn “readily available” to the public without restrictions as of the filing date of the 2004 application.

On the other hand, for prior-art status determination, the relevant time is February 16, 2006, the publication date of Barbour. Petitioner has presented sufficient evidence, which Patent Owner does not challenge, to show that, by 2006, corn harvested from TC1507 plants was “commercially available following the 2003, 2004, and 2005 growing seasons” and “[s]uch corn was sold as a commodity—without any contractual restrictions” Pet. 52 (citing Ex. 1007 ¶ 134). As a result, based on the current record, we find Petitioner has established sufficiently that, as of its publication date in February 2006, Barbour is prior art that would have enabled practice of the subject matter encompassed by the challenged claims.

E. Anticipation by or Obviousness over Barbour

Petitioner asserts that Barbour anticipates and/or renders obvious all challenged claims. Pet. 6, 41–67. Patent Owner does not dispute these assertions.

Barbour is the published 2004 application and shares the same disclosure as the ’378 patent. Based on this record, we find Petitioner’s arguments on anticipation and/or obviousness persuasive. Thus, we determine Petitioner has established a reasonable likelihood that it would prevail in showing the unpatentability of the challenged claims. We institute *inter partes* review of all challenged claims on all of the grounds in the Petition.

III. DISCRETIONARY DENIAL

Institution of an *inter partes* review is discretionary. *See Cuozzo Speed Techs., LLC v. Lee*, 579 U.S. 261, 273 (2016) (explaining that because 35 U.S.C. § 314 includes no mandate to institute review, “the agency’s decision to deny a petition is a matter committed to the Patent Office’s discretion”); *see also Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1367 (Fed. Cir. 2016) (stating that under § 314(a), “the PTO is permitted, but never compelled, to institute an IPR proceeding”).

A. § 325(d)

Under 35 U.S.C. § 325(d), in determining whether to institute an *inter partes* review, “the Director may take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office.” Our § 325(d) analysis employs a two-prong framework: (1) whether the arguments presented in the petition are the same or substantially the same as those previously presented to the Office; and (2) if so, whether the petitioner has demonstrated a material error by the Office in its prior consideration of those arguments. *Advanced Bionics, LLC v. Med-El Electromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 (“*Advanced Bionics*”), 8 (PTAB Feb. 13, 2020) (precedential).

Patent Owner argues that we should exercise our discretion to deny institution under § 325(d). Prelim. Resp. 8–17. Patent Owner points out that, during the prosecution of the ’378 patent, the examiner rejected the original claim 1 and its dependent claims as “allegedly failing to comply with the enablement requirement.” *Id.* at 9 (citing Ex. 1002, 161–63).

As explained above, original claim 1 is directed to “[a] plant” generally, and not a corn plant specifically. *See supra* Section I.E. It also does not include certain sequence information recited in the issued claim 1. *Id.* Patent Owner emphasizes that the examiner “nevertheless acknowledged that the specification was ‘enabling for a corn plant comprising SEQ ID NO: 24 and methods of using same.’” Prelim. Resp. 10 (citing Ex. 1002, 162). After the applicant amended the claim to recite a corn plant and adding the sequence information as recited in the issued claim 1, the examiner withdrew the enablement rejection. *Id.* at 11 (citing Ex. 1002, 177–78, 188). According to Patent Owner, this shows the examiner considered “whether the issued claims were enabled by the specification filed in April 2004.” *Id.* at 13 (citing Ex. 1002, 161–63).

Patent Owner’s statement is not incorrect; it is, however, incomplete. The examiner addressed the patentability question: whether the specification enabled the challenged claims as of October 28, 2010, the filing date of the ’271 application, which matured into the ’378 patent. Because it is undisputed that corn harvested from TC1507 plants was “known and readily available to the public” by 2010, we see no error on this record with the examiner’s assessment of the enablement issue that was previously considered during prosecution.

The Petition, however, is directed to the priority issue: whether the same specification enabled the challenged claims as of April 2004, the filing date of the 2004 application, so that the claims are entitled to the 2004 priority date. The examiner never addressed this question, because “the PTO does not need to make a determination as to whether the 35 U.S.C. § 112(a) requirement of 35 U.S.C. § 120 is met unless the filing date of the earlier

nonprovisional application is relied upon in a proceeding before the PTO.”
Nat. Alternatives, 904 F.3d at 1380 (brackets and quotation marks omitted).

Thus, we disagree with Patent Owner that the Petition presents the same or substantially the same arguments previously considered by the examiner. As a result, we will not exercise our discretion to deny the Petition under § 325(d).

B. § 314(a)

Patent Owner represents that the ’378 patent expired in April 2024, before the Petition was filed on June 13, 2024. Prelim. Resp. 2, 41. According to Patent Owner, “Petitioner has identified no litigation related to the ’378 patent.” *Id.* at 41. Patent Owner asks us to exercise our discretion to deny the Petition under § 314(a) to preserve administrative efficiency. *Id.* at 40–41.

“Inter partes review is ‘a second look at an earlier administrative grant of a patent.’” *Oil States Energy Servs., LLC v. Greene’s Energy Grp., LLC*, 584 U.S. 325, 336 (2018) (quoting *Cuozzo*, 579 U.S. at 279). The statutes and our Rules governing *inter partes* review do not exclude expired patents or those not subject to civil actions. *See, e.g.*, 35 U.S.C. §§ 311, 315; 37 C.F.R. § 42.100(b). On this record, we see no good reason to exercise our discretion to deny the Petition under § 314(a), and thus, decline to do so.

IV. CONCLUSION

Based on the current record, and for the reasons explained above, we find Petitioner has demonstrated a reasonable likelihood that it would prevail with respect to at least one claim challenged in the Petition. We therefore institute an *inter partes* review of all challenged claims on all asserted grounds.

ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314(a), *inter partes* review is hereby instituted on all challenged claims of the '378 patent based on the assert ground set forth in the Petition; and

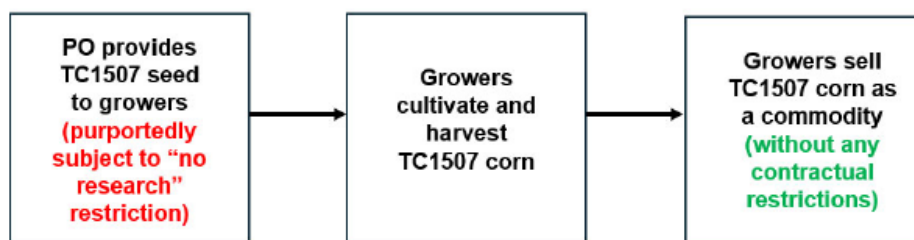
FURTHER ORDERED, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4(b), notice is hereby given of the institution of a trial commencing on the entry date of this decision.

FITZPATRICK, *Administrative Patent Judge*, dissenting.

I would deny institution.

Petitioner asserts the following in its Petition:

[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. Silverstone [Ex. 1007], ¶¶134–134. Such corn was sold as a commodity—without any contractual restrictions:



Buyers of corn from growers lack any contractual relationship with PO and are thus not bound by any purported restrictions.

Pet. 52–53. Petitioner relies on these asserted facts to argue that Barbour is enabling for purposes of anticipation of the challenged claims. Pet. 47. In Petitioner’s words:

Barbour enables Challenged Claims 1–2 and 8 for anticipation purposes because PO had commercialized TC1507 more than a year before July 6, 2007 (*infra* §VI.A.2.a) and POSAs could thus screen commercially available corn to identify germplasm expressing the TC1507 event, thereby possessing the claimed invention (*infra* §VI.A.2.b). Barbour itself discloses such screening methods and related kits.

Pet. 47.

Patent Owner argues that these same facts likewise demonstrate enablement of the 2004 application (which was published in February 2006 as Barbour). *See* Prelim. Resp. 19–20 (“Petitioner argues . . . that TC1507 was widely commercially available starting in 2003. . . . 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.”). I agree with Patent Owner.

Although the Petition does not provide a precise date within 2003 that TC1507 became publicly available, the Petition implies that it was by autumn of 2003 and certainly before the end of 2003. *See* Pet. 52 (“following the 2003 . . . growing season[.]”); *see also id.* at 5 (“PO commercialized TC1507 starting in 2003—making TC1507 germplasm accessible years before the July 2006 critical date.”). The testimony of Petitioner’s declarant, Dr. Silverstone, further supports that TC1507 was known and readily available in 2003. First, Dr. Silverstone testifies 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).” Ex. 1007 ¶131. Second, Dr. Silverstone testified that corn harvested from these growing seasons, including the 2003 growing season, was commercially available to third parties whose use of the corn was unrestricted. Specifically, Dr. Silverstone testified:

I understand that in European patent office proceedings, Patent Owner cited contractual provisions purportedly barring farmers from using TC1507 seed for “research purposes” or “transmitting the seed onwards to third parties” for such purposes. EX1003, 543 (emphasis original). However, I have been informed that such alleged restrictions would not apply to

bulk corn harvested (and then sold into commerce, making it commercially available) from the TC1507 seed that farmers planted. Such corn kernels would continue to express the TC1507 event. *See* EX1003, 294 (noting that “[a]ny given event can be transmitted by breeding from the original transformant plant, thereby to create descendent plants with the same event.”).

Ex. 1007 ¶134.

In its Preliminary Reply, Petitioner correctly argues that, based on the facts presented, enablement must be determined as of two separate dates—(1) whether the 2004 application enables the challenged claims must be determined as of April 30, 2004, and (2) whether Barbour enables the challenged claims must be determined as of February 16, 2006. Prelim. Reply. 3. Thereafter, however, Petitioner incorrectly argues that Patent Owner “offers no counter-evidence or argument attempting to bridge the twenty-two-month gap between April 2004 and February 2006” and “instead ignores the issue entirely.” *Id.* Petitioner is mistaken.

As discussed above, the Preliminary Response identifies multiple admissions by Petitioner and its declarant that TC1507 was known and publicly available in 2003 and, thus, prior to April 2004. *See* Prelim Resp. 20 (citing, *inter alia*, Pet. 5, 47, 49–53; Ex. 1007 ¶¶131–134).

It is Petitioner, not Patent Owner, that has avoided rebutting an issue. I would deny the Petition.

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