

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

INARI AGRICULTURE, INC.,
Petitioner,

v.

CORTEVA AGRISCIENCE LLC,
Patent Owner.

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

**PETITION FOR INTER PARTES REVIEW
UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. § 42.1 et seq**

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1006	Non-Provisional Application No. 10/837,105 (“April 2004 Application”)
1007	Declaration of Aron Silverstone (“Silverstone”)
1008	Curriculum Vitae of Aron Silverstone
1009	U.S. Patent Publication No. 20060037095 (“Barbour”)
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I. INTRODUCTION

Claims 1-8 (“Challenged Claims”) of U.S. Patent No. 8,901,378 (EX1001, “the ’378 Patent”) are unpatentable. They recite a unique biological “event” in which foreign genes were incorporated into a corn plant’s genome to create a transgenic plant. The process entailed bombarding corn embryos with microprojectiles coated in the foreign DNA, thereby incorporating the DNA at arbitrary and uncontrollable locations within the genome. Thereafter, the inventors screened multiple different events and selected the one codenamed TC1507 as having “a superior combination of characteristics.” EX1001, 17:50-18:48.

The “transgene integration” underlying the ’378 Patent was a “random process” (EX1012, 185; EX1013, 313)—akin to “throwing a grenade into the genome” (EX1014, 311). However, the site of integration was known to have an important but unpredictable impact on transgene expression. The ’378 Patent acknowledges how “the presence of the transgene at different locations in the genome” impacts “the overall phenotype of the plant in different ways,” such that researchers typically “produce hundreds to thousands of different events and screen those events for a **single event that has desired transgene expression levels and patterns.**” EX1001, 1:52-2:13.¹

¹ All emphasis and annotations are added unless noted.

Using this method, any given transformation event such as that described in the '378 Patent incorporates the foreign DNA in a way uniquely characteristic of that event—analogous to scar tissue following a wound. Integrating transgenes triggers a “plant’s wound response”—a DNA repair process that slices and rearranges the exogenous DNA within the plant’s genome. EX1015, 250. This repair process yields “truncated or otherwise rearranged [DNA] sequences.” EX1016, 277.

The end result is a unique fingerprint that would be exceedingly difficult to reproduce independently even with gene editing technologies available today—more than twenty years after the '378 Patent’s purported priority date. In the words of PO’s expert in a separate proceeding, controlling where within the plant genome a transgene is inserted constitutes one of the “**holy grails of plant biotechnology.**” EX1017, 46:4-12. Yet the Challenged Claims require incorporating transgenes at a particular location within the corn genome—a location the inventors characterized after studying the random results of the event they had generated.

As of April 2004 (the filing date of the earliest non-provisional application to which the '378 Patent claims priority), it would have been essentially impossible to reproduce the claimed “TC1507” event without access to germplasm from the

actual event the inventors generated. Patent Owner (“PO”)² acknowledged this to the European Patent Office (EPO) in related proceedings: “[r]eproducing the event of the invention in the absence of any physical sample would be **almost impossible.**” EX1003, 520.

The Challenged Claims therefore exemplify the type of invention that requires depositing the relevant biological material to ensure public access. As the Office has explained, such deposit “may be necessary” to comply with §112³ “[w]here the invention involves a biological material and words alone cannot sufficiently describe how to make and use the invention in a reproducible manner.” Manual of Patent Examining Procedure (MPEP) §2402.

PO admitted the same in a different utility patent on a different transgenic plant. Despite claiming priority only to a provisional application filed in 2004 (as opposed to the ’378 Patent, which references a 2003 provisional), PO explained that it had made a deposit because transformations “are **random** events and generally **cannot be duplicated.**” EX1018, 4:42-47. PO likewise cited the

² Corteva Agriscience—the assignee of record—includes both Pioneer Hi-Bred International, Inc. (the assignee reflected on the ’378 Patent) and Dow AgroSciences, LLC (the EPO applicant of record). See EX1010; EX1046, 1, 5.

³ Section cites are to 35 U.S.C. or 37 C.F.R. as context indicates.

“**random**” nature of transgenic events when explaining why it had deposited seeds corresponding to a transgenic corn plant with a 2009 priority date—well **after** the purported priority date here. EX1019, 5:61-6:4.

Similarly, the Office required PO to provide a deposit for another transgenic corn utility patent claiming priority to a 2009 provisional and claiming a transgenic event that included the same two foreign genes as the '378 Patent along with two others. EX1022, 2:44-3:40, 6:34-7:6; EX1023. The Office explained that §112(a) required the transgenic seeds to be “readily available to the public”—without any restriction following patent issuance. EX1023, 5-6 (“A deposit is required for enablement purposes.”)

Here, by contrast, PO **never made such a deposit** of the transgenic TC1507 germplasm even though the '378 Patent claims priority back further in time—when the art was even less developed. PO’s April 2004 Application thus does not enable the Challenged Claims under §112(a). Yet without access to TC1507 germplasm, POSAs are deprived of necessary disclosure to make and use the claimed invention in a reproducible manner.

Given the lack of a deposit and the April 2004 Application’s resulting failure to enable the Challenged Claims, references accessible before July 6, 2006 (one year before the next application in the priority chain) constitute indisputable pre-AIA §102(b) prior art.

This includes Barbour—a U.S. patent publication corresponding to the April 2004 application. Barbour describes the TC1507 event and discloses the corresponding unique fingerprint of DNA sequences, thus rendering all Challenged Claims unpatentable.

Ground 1 concerns why Barbour anticipates claims 1-2 and 8, which cover TC1507 corn plants. **Ground 2** concerns why Barbour likewise anticipates or at minimum renders obvious claims 3-4 and 7, which cover methods of breeding TC1507 with other corn plants to produce an insect-resistant plant (like TC1507). **Ground 3** concerns why Barbour renders obvious claims 5-6, which depend from claim 3 and specify whether TC1507 is the male (claim 5) or female (claim 6) in the claimed breeding method. It was well known that corn plants have both male and female flowers. There is nothing inventive about specifying one versus the other for breeding purposes.

Barbour is enabled for prior art purposes under §102 despite the corresponding April 2004 Application failing to comply with §112(a). The statutes serve different purposes, with different corresponding standards.

For §102, the Federal Circuit and Board have held that printed publications were enabled as prior art based on the commercial availability of the relevant plant. *See infra* §VI.A.2.c. Here, PO commercialized TC1507 starting in 2003—making TC1507 germplasm accessible years before the July 2006 critical date. Persons of

ordinary skill in the art (“POSAs”) could have identified such germplasm using methods described in Barbour to screen for TC1507’s unique fingerprint.

By contrast, for §112, the Federal Circuit and Board have rejected attempts to rely on commercial availability in lieu of a proper deposit. Commercial material indeed will not necessarily be freely available. Permitting PO to rely on its commercialization of TC1507 for enablement under §112(a) would subvert the Patent Act’s underlying *quid pro quo* and wrongly permit PO to limit the public’s ability to use and improve upon the inventions of the Challenged Claims even now the ’378 Patent has expired.

II. REQUIREMENTS FOR INTER PARTES REVIEW

A. Certification of Availability

Petitioner certifies that the ’378 patent is available for *inter partes* review (IPR) and that Petitioner is not barred or estopped from such request. §42.104(a).

B. Ground for Unpatentability

The table below identifies the relevant claims and basis for each ground.

Ground Number and Reference(s)		Claims	Basis
1	Barbour	1-2, 8	§102
2	Barbour	3-4, 7	§102/103
3	Barbour in view of POSA’s knowledge	5-6	§103

Barbour constitutes pre-AIA §102(b) prior art because it was published on 2/16/06, whereas the Challenged Claims are not entitled to an effective filing date earlier

than 7/6/07 (*infra* §V). While *infra* §VI.A.2 cites PO’s commercialization of TC1507 when explaining why the Barbour publication is enabled under §102, it explains why “the **publication** has placed the claimed invention in the possession of the public before the [4/6/06] critical date.” *In re Elsner*, 381 F.3d 1125, 1130 (Fed. Cir. 2004) (upholding Board’s reliance on plant sales to assess whether printed publication was enabled). The identified grounds therefore rely “only on the basis of prior art consisting of patents or printed publications.” §311(b).

III. THE ’378 PATENT

The ’378 Patent discloses “transforming a corn cell” with “DNA construct PHI8999A (SEQ ID NO:25)” to yield a transformed “corn plant that is resistant to insects.” EX1001, 5:24-26. The resultant “transgenic” plant “contain[s] the transformed nucleic acid fragments,” which are passed down to offspring when the plant is bred. EX1001, 10:26-30; *see also id.*, 2:10-11.

As the specification acknowledges, however, transformation using the methods disclosed in the ’378 Patent involves “**random integration** of the foreign DNA” into host organisms. EX1001, 7:31-33. Any given transformation—known as a transgenic “event” (EX1001, 9:35-37)—yields “flanking regions” at either end of the foreign DNA “**unique**” for each event (EX1001, 7:31-35). Even if identical plant cells were each transformed with identical sequences of foreign DNA, each transformation event would have unique flanking regions characteristic of the

particular event, and including junction sequences where insert DNA joins genomic DNA. Silverstone, ¶¶41-42; *see also* EX1026, ¶3 (subsequent PO application acknowledging that “multiple transgenic plant events...will not be identical” even if “using the same genetic construct”).

A. Described Embodiments

The '378 Patent concerns “maize event TC1507”—that is, “plant TC1507.” EX1001, 1:26-28. TC1507 is the only ostensibly new plant variety the '378 Patent discloses. Silverstone, ¶43.

Example 1 describes generating event TC1507 using “microprojectile bombardment” to incorporate the DNA molecule designated PHI8999A as reflected in FIG. 1 and SEQ ID NO.25. EX1001, 17:50-18:48. This technique—also called “biolistics”—involves “shooting small DNA-coated metal particles...into plant tissue” to pierce “the cell wall and membrane and release the foreign DNA” to be integrated. Silverstone, ¶44 (quoting EX1027, ¶48).

The PHI8999A insert included two different “transgene expression cassettes” for delivering two different genes the inventors sought to incorporate into corn so that it resisted insects but tolerated herbicides. EX1001, 2:44-3:6. The first cassette incorporated a gene encoding “Cry1F”—a protein known to have insecticidal properties. EX1001, 2:53-63; Silverstone, ¶45. The second cassette incorporated a gene encoding phosphinothricin acetyltransferase (“PAT”), which

deactivates phosphinothricin (glufosinate)—a common herbicide. EX1001, 2:63-3:6; Silverstone, ¶45.

After coating “microscopic tungsten particles...with purified PHI8999A DNA (SEQ ID NO:25),” the inventors used a “particle gun” to shoot the gene-laced particles into “immature embryos.” EX1001, 18:13-22.

After the embryos were bombarded with these projectiles, they were transferred to cultures containing glufosinate as a “selection agent.” EX1001, 18:27. Survival of particular embryos despite this herbicide suggested the successful incorporation of the above-discussed PAT gene within the PHI8999A insert coated on the microprojectiles. Silverstone, ¶¶46-47.

While most embryos “died on the selective medium,” some survived and were “assigned unique identification codes representing putative transformation events.” EX1001, 18:29-32. POSAs would have understood that “TC1507” was simply one such code (out of many). Silverstone, ¶48.

For “each unique event,” the inventors grew plants and tested leaf samples to verify the presence of the transgene, confirm expression of the Cry1F protein, and test the plants against corn borer insects. EX1001, 18:35-39. Plants passing these screens “were crossed with inbred lines to obtain seed from the initial transformed plants,” and multiple “lines were evaluated in the field.” EX1001, 18:39-41. The inventors ultimately selected “[t]he TC1507 event from a population of

independent transgenic events” given TC1507’s “superior combination of characteristics, including insect resistance” and “agronomic performance” (EX1001, 18:42-28)—that is, productivity under real-world conditions. Silverstone, ¶49.

The inventors then identified and described the flanking regions for the specific TC1507 event. For example, SEQ ID NO: 26 “represents part of the PHI8999A insert as well as flanking sequence 5' to the insert,” whereas SEQ ID NO: 27 “represents part of the PHI8999A insert as well as flanking sequence 3' to the insert.” (EX1001, 65-72.)

Despite claiming a specific insertion event, PO never deposited the claimed germplasm. By contrast, PO consistently made such deposits for other transgenic plant utility patents—even those with **later** claimed priority dates. *See, e.g.*, EX1018, 4:42-54; EX1019, 5:61-6:12; EX1021, 5:8-26; EX1022, 6:34-7:6; EX1024, 19:12-35; EX1025, 10:39-55. This includes a patent claiming priority to a 2009 provisional and disclosing an analogous event incorporating the Cry1F and PAT genes (as in TC1507) along with others. EX1022, 2:44-3:40.

Noting the lack of a corresponding deposit here, **the EPO rejected claims related to the TC1507 event and the patent owner abandoned any effort to secure EPO protection for the same claims.** *See infra* III.D.2.

B. Person of Ordinary Skill in the Art

The level of ordinary skill in the art is evidenced by the prior art. *See In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995) (affirming Board’s reliance on references of record). As evidenced in the references discussed herein and in the declaration of Dr. Aron Silverstone, 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. Silverstone, ¶¶16-19, 50.

C. Prosecution History

U.S. Application 12/914,271, which matured into the ’378 Patent, was filed on 10/28/10.

As originally filed, independent claim 1 would have covered any “plant comprising a DNA construct...comprising a first and a second expression cassette” with the “first expression cassette” including, inter alia, “a Cry1F encoding DNA molecule”; and the “second expression cassette” including, inter alia, “a *pat* encoding DNA molecule” EX1002, 90. Dependent claim 2 required a “corn plant” with the recited DNA construct, but still did not require specific

sequences—much less a specific insertion site within the corn genome. EX1002, 90.

Other claims as originally filed required one of a series of “junction” sequences reflecting the intersections between different regions specified in Table

1. *See, e.g.*, claim 6:

An insect resistant corn plant, or part thereof, wherein DNA having at least one nucleotide sequence selected from the ***group consisting of SEQ ID NO: 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, 56, and 57.***

EX1002, 90.

On 11/22/2013, the Examiner mailed a non-final Office Action rejecting all pending claims under §112(a) and (b). The Examiner cited claim 1’s reference to “(CaMV) 35S” (part of the second expression cassette) and questioned whether “the parenthetical limitation defined what 35S terminator the claim encompasses.” EX1002, 160. The Examiner also noted that the specification disclosed “only one working example of the plant of instant claims 1, and 6.” EX1002, 163. 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,” and even claims 6-17 encompassed a “vast number of ways” POSAs “might make an insect resistant corn plant”— “requir[ing] undue trial and error experimentation.” EX1002, 163.

The 11/22/2013 Office Action also rejected claims 1, 2, 4, and 5 as obvious over references constituting prior art even under the earliest claimed priority date. EX1002, 164-165 (applying EXS1028-1031).

The 11/22/2013 Office Action further rejected all pending claims for non-statutory double patenting. EX1002, 166-167.

On 2/24/2014, PO responded. Concerning the §112(b) rejection, PO “amended claim 1 to specify that CaMV 35S comprises ‘the nucleic acid sequence of positions 5843 to 6032 of SEQ ID NO: 25; 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.’” EX1002, 177.

Concerning the §112(a) rejections, PO amended the claims “to recite corn plants comprising SEQ ID NO:25” (representing insert PHI8999A, the DNA molecule used to generate the TC1507 event), along with flanking sequences SEQ ID NO: 26 at the 5' end and SEQ ID NO: 27 at the 3' end.” EX1002, 177-178.

Concerning the obviousness rejection, PO stressed that Claim 1 as amended required “a corn plant comprising a DNA construct ‘comprising the nucleic acid sequence of positions 5843 to 6032 of SEQ ID NO: 25; 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.’” EX1002, 179-180. PO maintained that “[t]he cited references, alone or in combination, do not teach a DNA construct having two

expression cassettes, *wherein each expression cassette is flanked on the 5' and 3' ends by particular novel sequences.*” EX1002, 180.

On 4/11/14, the Examiner mailed a final rejection maintaining the double-patenting rejection while withdrawing the others given PO’s amendments EX1002, 188-190. The Examiner also rejected claim 7, which was “directed to a product-by-process” and lacked “any specific structure.” EX1002, 190.

On 6/11/14, PO canceled claim 7 and stated that it would consider filing terminal disclaimers “should allowable subject matter be found.” EX1002, 218.

On 6/26/14, the Examiner mailed an Advisory Action that reiterated the double patenting rejection as to the remaining claims. PO then filed terminal disclaimers, and the Examiner allowed the claims. EX1002, 222-245.

D. Related European Prosecution Histories

1. European Patent Application No. 04751097.9 (“EP ’97.9”)

When prosecuting a related European application, PO pursued claims such as “[a]n isolated DNA molecule comprising a nucleotide sequence identified as SEQ ID NO: 21, 22, 24, 26, or 27” and “[a] kit for identifying event TC1507 in a biological sample which detects a TC1507 specific region.” EX1003, 310.

Following an examination report concluding that the pending claims lacked an inventive step over references such as “D1” (EX1032) describing TC1507, PO did not dispute that D1 concerned the TC1507 event. EX1003, 307-308.

PO instead explained that an “event” means “a specific integration of transgene into a plant at a specific, *initially unknown*, genetic locus.” EX1003, 308. PO likewise stressed that “[t]he same plant could be transformed many times with the same transgene and this would represent many different events because the transgene would incorporate in different places and orientations,” and further because particular flanking sequences “might be lost, duplicated, rearranged etc. during each transformation.” EX1003, 308 (emphasis original). Accordingly, as PO explained, “two different events with the same transgene” would yield different “‘junction’ sequences between the inserted DNA and the native genomic DNA” given that “(a) the transgene is in two different genomic locations, and possibly in different orientations, and (b) different losses, duplications, rearrangements etc. of nucleotides will have occurred.” *Id.* When “the PHI8999 construct was shot into the tissue at high velocity by microprojectile bombardment” to generate the TC1507 event, “nothing was known about, for example, the orientation of the resultant insert, whether or not and if so to what extent, it had been fragmented and/or truncated, or its location in the plant genome.” *Id.* (emphasis original).

The EPO nevertheless maintained the rejection and reasoned that claims to nucleotide sequences comprising a portion of the TC1507 event were not novel given D1’s disclosure of the event itself. EX1003, 323.

In response, PO reiterated that the TC 1507 “event” required “a specific integration of a transgene into a plant at a specific, initially unknown, genetic locus.” EX1003, 328 (emphasis original: “Put another way, an event relates to exactly what happened in a given instance of transformation.”) Accordingly, “[m]ultiple transformations with the same construct constitute multiple events because of differences in the location, orientation, degree of fragmentation/truncation etc of the insert.” *Id.*

Concerning the TC1507 event itself, PO cited Table 1 and stressed that TC1507 was “not a straightforward insertion of the PHI8999A insert neatly into the wild-type [maize] genome,” but instead featured “a lot of broken-up, complex, repeated/fragmented sequence at either end of PHI8999A.” EX1003, 329. PO thus maintained that sequencing the event and designing diagnostic kits based on the junction sequences constituted an inventive step even though D1 referenced TC1507. EX1003, 331.

The EPO in turn reasoned that in view of D1, “maize TC1507 was available to the public at the relevant date of the present invention” and could have been sequenced without undue burden. EX1003, 484-485.

In response, PO asserted that TC1507 “was not publicly available at the priority date” and D1 was therefore “not enabling.” EX1003, 519 (emphasis original). Given this purported lack of access, PO maintained that “[t]he invention

could not have been reproduced by the skilled person, let alone without undue burden, at the priority date.” *Id.* Concerning the EPO’s question whether POSAs could “reproduce without undue experimentation the DNA fragment corresponding to the event TC1507” (EX1003, 486), PO stressed that it would have required “**physical access** to TC1507 germplasm, or other suitable genetic material derived from the plant” (EX1003, 520). PO reiterated that “[r]eproducing the event in the absence of any physical sample would be **almost impossible**.” EX1003, 520. Thus, PO maintained that D1 [EX1032] was “not an enabling disclosure because to reproduce D1, the skilled person needs access to the physical plant.” *Id.*

The EPO initially maintained the rejection because PO did not “provide evidence as to when the TC1507 corn (Herculex 1) was brought to the market and thus publicly available.” EX1003, 529.

In response, PO acknowledged that “TC1507 maize of this invention is the maize known as Herculex 1” and further that TC1507 had been “commercialised for the first time in 2003.” EX1003, 542. PO asserted that it could not determine exactly when “physical control of the seed first passed from [PO] to the growers.” *Id.* But PO maintained that “[e]ven if seed was transferred to growers’ land before the 2 May 2003 priority date” it was immaterial because growers were contractually restricted in using (or transferring) seed for “**research purposes**.” EX1003, 543 (emphasis original).

The EPO subsequently allowed the claims to the TC1507 detection technologies. However, as noted below, the EPO did not allow claims to the TC1507 plants themselves, nor to methods of use.

2. European Patent Application No. 15168051.9 (“EP ’51.9”)

PO later pursued a divisional application with claims directed to TC1507 plants and related methods of use. EX1004, 150-157. Following initial amendments, claim 1 recited “[a]n insect resistant corn plant or parts thereof, or corn seed, comprising the nucleotide sequence of SEQ ID NO:24.” EX1004, 309.

The EPO rejected this claim on the ground that the specification **failed to “enable”** the claim. EX1004, 370. In particular, the EPO cited PO’s previous emphasis (during prosecution of EP ’97.9) that TC1507 had been commercialized subject to contractual restrictions and was not freely available. *Id.*

In response, PO reasoned that the specification was adequate because it disclosed the “ the 5' and 3' flanking sequences structurally defining [the] specific genomic insertion site.” EX1004, 377.

The EPO nevertheless maintained the rejection and stressed that when “assessing the patentability of living matter the reproducibility is of the foremost importance.” EX1004, 386. The EPO explained that such reproducibility could be established by (1) “a deposit of living matter” that was “publicly available” or (2) a gene sequence “together with instructions on how to repeatably obtain such an

altered sequence in a target organism (e.g. by CRISPR-Cas).” *Id.* Here, however, the EPO noted that PO’s specification was “silent as to a deposited material that would have rendered the TC1507 corn plant publicly available.” *Id.* The EPO also stressed that PO’s claimed plant reflected “a particular event resulting from a random method,” yet “genome editing technologies, such as the CRISPR-Cas technology, were not available to the public at the relevant date of the present application.” EX1004, 387 (emphasis original).

PO withdrew the application following an unsuccessful stay request. EX1004, 413. PO never rebutted the EPO’s determination that the TC1507 event was not reproducible given the lack of a deposit and without the availability of later-arising technologies such as CRISPR/Cas9.

IV. CLAIM INTERPRETATION

Claim terms are construed herein using the standard used in civil actions under 35 U.S.C. § 282(b), in accordance with the ordinary and customary meaning as understood by POSAs. 37 C.F.R. § 42.100(b).

A. The Challenged Claims Require the Particular Flanking Sequences Uniquely Characterizing the TC1507 Event

1. Independent Claim 1

Independent claim 1 requires a corn plant incorporating foreign DNA—including genes coding for the Cry1F and PAT proteins—at a particular location within the corn genome defined based on SEQ ID NO:26 at the 5' end and SEQ ID

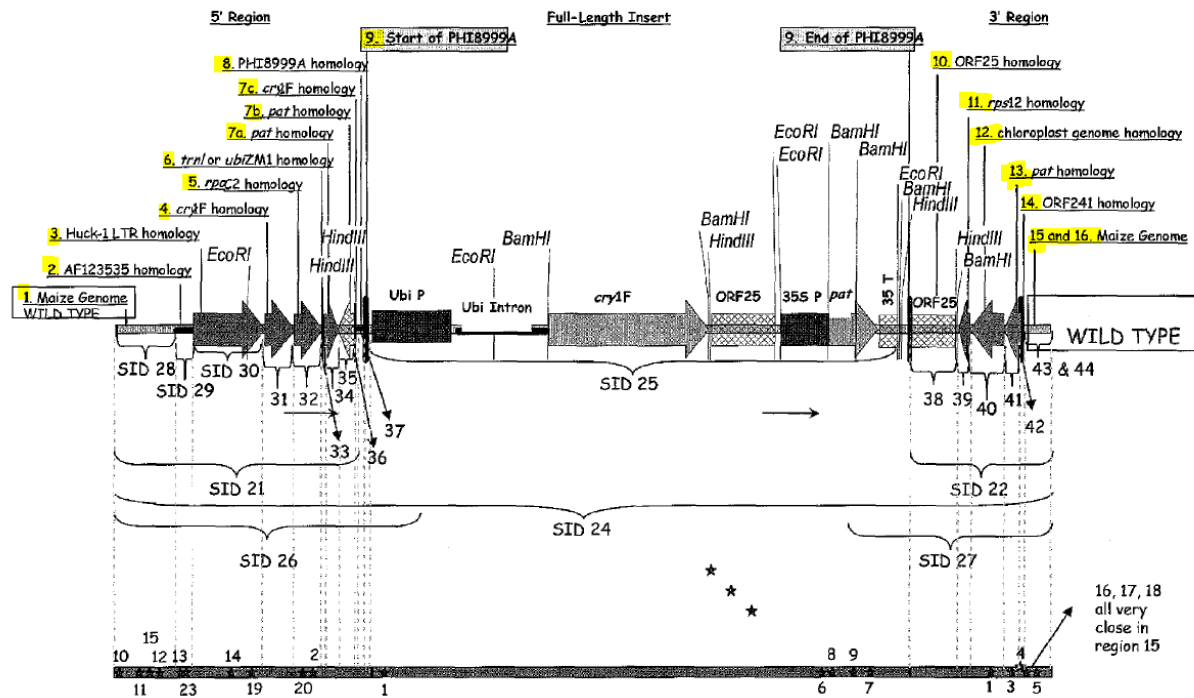
NO:27 at the 3' end. EX1001, 85:24-42; Silverstone, ¶¶54-60. Flanking sequences

SEQ ID NOs 26 and 27 incorporate various “junctions” formed during the TC1507

event and absent from natural corn DNA, as reflected in the table below and the

accompanying annotated version of Figure 1:

SEQ ID	Location	
45	junction between regions 3 and 4	<i>Included in SEQ ID NO:26</i>
46	junction between regions 4 and 5	
47	junction between regions 5 and 6	
48	junction between regions 6 and 7a	
49	junction between regions 7a and 7b	
50	junction between regions 7b and 7c	
51	junction between regions 7c and 8	
52	junction between regions 8 and 9	
53	junction between regions 9 and 10	<i>Included in SEQ ID NO: 27</i>
54	junction between regions 10 and 11	
55	junction between regions 11 and 12	
56	junction between regions 12 and 13	
57	junction between regions 13 and 14	



Silverstone, ¶56.

As the '378 Patent acknowledges, these flanking regions, including junction sequences created during the integration event, are “unique” for any given transformation event given the “random” integration of the DNA. EX1001, 4:59-61 (describing “junction sequences” as “unique” for any given transgenic event); *id.*, 7:31-35 (“Transformation procedures leading to random integration of the foreign DNA will result in transformants containing different flanking regions characteristic and unique for each transformant.”); Silverstone, ¶57; EX1066, 169-170.

PO stressed these “novel sequences” when overcoming §103 rejections during prosecution. EX1002, 180.

During European prosecution of related claims to detecting TC1507, PO

likewise stressed that “part of what distinguishes one event from another is the flanking sequence at either end of the insert.” EX1003, 294. These flanking sequences contain “partly inserted construct sequence and partly original plant sequence.” *Id.* These sequences meet at “junction” sequences, which span “the junction between heterologous DNA inserted into the genome and the DNA from the corn cell flanking the insertion site.” EX1001, 5:4-12.

Given that these “junction sequences” are “unique” for any given transgenic event (EX1001, 4:59-61), they are different for even “two different events with the same transgene” (EX1003, 294). Two different events would each place the transgene “in two different genomic locations” and cause “different losses, duplications, rearrangements etc. of nucleotide[s].” EX1003, 294.

Claim 1 accordingly requires the particular junction sequences that are unique to the TC1507 Event and reflected in flanking sequences SEQ ID NOs 26 and 27. Silverstone, ¶¶58-60.

2. Dependent Claims 2 and 8

The insertion site and related junctions unique to TC1507 are also required to practice Challenged Claims 2 and 8, which recite “[t]he corn plant of claim 1” and then specify additional requirements. Claim 2 requires that the corn plant be a “seed” (EX1001, 85:42-43) while claim 8 recites that the “DNA construct

comprises the polynucleotide of SEQ ID NO:24” (EX1001, 86:41-42). As Figure 1 reflects, SEQ ID NO:24 includes SEQ ID NO: 26 at the 5' end and SEQ ID NO:27 at the 3' end while also including SEQ ID NO:25, which is in between SEQ ID NO: 26 and SEQ ID NO:27 while overlapping both. Silverstone, ¶61.

3. Dependent Claims 3-7

Claims 3-7 depend directly or indirectly from claim 1 and concern breeding methods requiring a transgenic corn plant with the same insertion site and related junctions as that specified by claim 1 and uniquely characteristic of TC1507. Silverstone, ¶¶62-64. Claim 3 recites such a method. Claims 4-7 descend from claim 3.

Claim 3 requires a method of “breeding with an insect resistant corn plant comprising in its genome DNA *the DNA construct of claim 1.*” EX1001, 86:26-27. The “DNA construct” includes the flanking regions recited by claim 1—that is, “SEQ ID NO:26 at the 5' end and SEQ ID NO:27 at the 3' end”—and unique to TC1507 as detailed in *supra* §IV.A.1 concerning claim 1.

Dependent claim 8 confirms that construction given that it depends from claim 1 and requires that “the *DNA construct* comprises the polynucleotide of SEQ ID NO:24.” EX1001, 86:41-42. SEQ ID NO: 24 includes SEQ ID NO:26 at the 5' end and SEQ ID NO:27 at the 3' end. EX1001, Figure 1; Silverstone, ¶64. Construing “DNA construct” to exclude these flanking regions unique to TC1507

would wrongly render the Challenged Claims internally inconsistent. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005) (en banc) (“Because claim terms are normally used consistently throughout the patent, the usage of a term in one claim can often illuminate the meaning of the same term in other claims.”)

B. The Challenged Claims Encompass the TC1507 Event

Consistent with the claimed requirement of flanking sequences uniquely characterizing the TC1507 event (as explained immediately above), Challenged Claims 1-2 and 8 encompass TC1507 corn plants themselves while Challenged Claims 3-7 cover methods of using TC1507 to breed other transgenic plants. Silverstone, ¶¶65-73.

The '378 Patent discloses that the “invention...relates to the TC1507 corn plant” (5:61), and TC1507 indeed is the only event described. Silverstone, ¶¶66-67. All disclosed sequences likewise concern TC1507. *Id.* Moreover, the title of the patent is “Corn Event TC1507 and Methods for Detection Thereof.”

Construing the Challenged Claims to exclude TC1507 “would require highly persuasive evidentiary support, which is wholly absent in this case.” *Vitronics Corp. v. Conceptor, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996) (rejecting construction that would have excluded specification’s “preferred (and indeed only) embodiment”).

Considering the intrinsic evidence as a whole, POSAs would understand that Challenged Claim 1's requirement that the "first and second expression cassettes" be "*flanked by* SEQ ID NO:26 at the 5' end and SEQ ID NO: 27 at the 3' end" encompasses configurations in which SEQ ID NO:26 overlaps with the first expression cassette and SEQ ID NO: 27 overlaps with the second expression cassette. Silverstone, ¶¶71-72.

As Figure 1 illustrates, the 3' end of SEQ ID NO: 26 includes a portion of the ubiquitin promoter (Silverstone, ¶69), which the '378 Patent (including Challenged Claim 1) confirms is part of the first expression cassette. EX1001, 2:53-56, 17:58-61, 85:27-29 ("wherein said first expression cassette in operable linkage comprises (a) a maize ubiquitin promoter"). Consistent with these disclosures, the patent describes SEQ ID NO:26 as a "novel transgene/flanking insertion region" (EX1001, 3:62-64) and clarifies that SEQ ID NO: 26 "represents part of the PHI8999A insert as well as flanking sequence 5' to the insert." EX1001, 65-66.

Figure 1 likewise illustrates that SEQ ID NO: 27 includes a portion of the DNA sequence encoding for the PAT protein and a 3' transcriptional terminator from (CaMV) 35S comprising the nucleic acid sequence of positions 5843 to 6032 of SEQ ID NO:25, which the '378 Patent (including Challenged Claim 1) confirms is part of the second expression cassette. EX1001, 2:63-3:6, 18:2-12, 85:32-38;

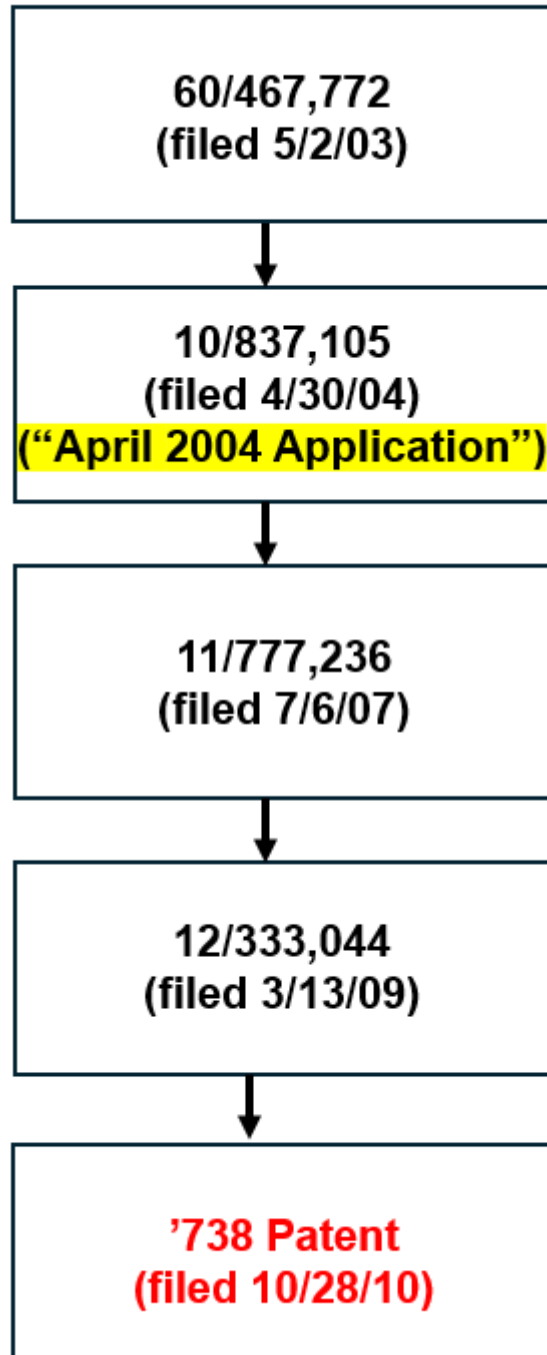
Silverstone, ¶69 The patent likewise describes SEQ ID NO:27 as a “novel transgene/flanking insertion region” (EX1001, 4:3-4) and clarifies that SEQ ID NO: 27 “represents part of the PHI8999A insert as well as flanking sequence 3' to the insert.” EX1001, 67-68.

Given these disclosures, POSAs would understand that the “ordinary meaning of “flanked by” permits overlap between the expression cassette and the DNA sequence it is flanked by. Silverstone, ¶71; *Phillips*, 415 F.3d at 1321 (“Properly viewed, the “ordinary meaning” of a claim term is its meaning to the ordinary artisan after reading the entire patent.”).

If “flanked by” were construed more narrowly to preclude overlap, it would wrongly exclude from claim 1 the TC1507 Event itself—the only disclosed embodiment and the '378 Patent's namesake. It would also contradict dependent claim 8, which depends from claim 1 and recites “SEQ ID NO: 24,” which comprises SEQ ID NO: 26 and SEQ ID NO: 27 overlapping with the first and second expression cassettes.

V. EFFECTIVE FILING DATE

The '378 Patent recites a priority claim under §120 to a 4/30/2004 utility application (“April 2004 Application,” EX1006) and under §119(e) to a 5/2/03 provisional (EX1005):



However, as detailed below, the April 2004 Application fails to enable POSAs to practice the Challenged Claims without undue experimentation. The April 2004 Application therefore does not satisfy §112(a). Yet disclosure of the invention “in

the manner provided by section 112(a)”—is required for an effective priority claim under §120. *E.g.*, *Samsung Elecs. Co. v. Acorn Semi, LLC*, IPR2020-01207, Paper 49 at 48 (PTAB Feb 9, 2022) (citing §120: “[T]he benefit of an earlier filed application requires written description and enablement support for the challenged claims in the earlier filed application.”)

The Challenged Claims are therefore not entitled to an effective filing date earlier than 7/6/07. *See, e.g.*, *US Endodontics, LLC v. Gold Standard Instruments, LLC*, PGR2015-00019, Paper 54 at 8-9, 20-30 (PTAB Dec. 28, 2016) (holding that challenged claims were not entitled to filing date of parent, which failed to enable challenged claims even though specifications were “substantively identical”); *Flex Logix Techs., Inc. v. Konda*, IPR2020-00260, Paper 55 at 19-21 (PTAB July 29, 2021) (holding that challenged claims were not entitled to parent application’s filing date because parent did not enable claimed invention); *Daiichi Sankyo Co., Ltd. v. Alethia Biotherapeutics, Inc.*, IPR2015-00291, Paper 75 at 7-15 (PTAB June 14, 2016) (same).

Petitioner does not concede that the Challenged Claims are entitled to any effective filing date earlier than the ’378 Patent’s actual 10/28/10 filing date. The applications filed on 7/6/07 and 3/13/09 fail to enable the Challenged Claims for essentially the same reasons detailed below why the 4/30/04 application fails: none identifies an available deposit of TC1507 as claimed even though the event was

random and would have been impossible for POSAs to replicate.⁴ However, the identified grounds rely exclusively on printed publications publicly available at least one year before 7/6/07. The Board therefore need not address the applications filed on 7/6/07 and/or 3/13/09. Even if the 7/6/07 application satisfied §112(a) (which it does not), Barbour and all background references discussed herein would still constitute pre-AIA §102(b) prior art.

A. The April 2004 Application Does Not Enable the Challenged Claims Under §112—It Fails to Incorporate a Deposit Even Though the Challenged Claims Concern an Event PO Admits is “Random” and Not Reproducible

The April 2004 Application (EX1006) does not enable the Challenged Claims as required by §112(a) because the disclosure does not permit POSAs to produce the claimed corn plant (claims 1-2 and 8) or practice the claimed method of producing a corn plant (claims 3-7) without undue experimentation. As explained in *supra* §IV.A, the Challenged Claims require inserting exogenous DNA at a *specific location* within the corn genome. But that location reflected *random* chance—a reality of the microprojectile bombardment technique used to generate the “TC1507 event.” *See supra* §III.A. The specification admits that

⁴ The 5/2/03 provisional likewise does not incorporate a deposit and fails to enable the Challenged Claims. However, given Barbour’s 2/16/06 publication date (EX1009), the Petition does not separately address the provisional.

such transformation events entail “*random integration* of the foreign DNA” into host organisms. EX1001, 7:31-33. Such “random insertion of transgenes” is akin to “throwing a grenade into the genome.” EX1014, 311. Even aside from the site of insertion being random, integrating transgenes using this method slices and rearranges the exogenous DNA within the plant’s genome—yielding “truncated or otherwise rearranged [DNA] sequences” unique to each insertion event. EX1015, 250; EX1016, 277.

Such random insertion of foreign transgenes into plants cannot be reproduced without undue experimentation even with current methods—much those available before modern gene editing technology such as CRISPR-Cas9. Silverstone, ¶¶78-83. As an expert for PO previously acknowledged, controlling where within the plant genome a transgene is inserted constitutes one of the “holy grails of plant biotechnology.” EX1017, 46:4-12.

Indeed, during prosecution of the EP ’97.9 Application, PO represented that “reproducing” the claimed TC1507 “event in the absence of any physical sample would be **almost impossible**.” EX1003, 520; *see also supra* §III.D.1. It would be no more likely than monkeys independently recreating the complete works of Shakespeare. Silverstone, ¶¶84-85.

Given this inability to reproduce the TC1507 event without access to the actual TC1507 germplasm, the Challenged Claims exemplify the type of invention

requiring a deposit to satisfy the statutory enablement requirement under §112. As the Office has explained, “access to” particular “biological material may be necessary” under §112 “[w]here the invention involves a biological material and words alone cannot sufficiently describe how to make and use the invention in a reproducible manner.” MPEP §2402 (citing *Ajinomoto Co. v. Archer-Daniels-Midland Co.*, 228 F.3d 1338, 1345-46 (Fed. Cir. 2000) and *In re Argoudelis*, 434 F.2d 666 (CCPA 1970)).

In particular, the Challenged Claims concern a “biological material” that is not “reproducible even when detailed procedures and a complete taxonomic description are included in the specification.” *In re Lundak*, 773 F.2d 1216, 1220 (Fed. Cir. 1985); *see also In re Wands*, 858 F.2d 731, 735 (Fed. Cir. 1988) (“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.”).

In such circumstances, “a condition of the patent grant” is that “physical samples of such materials be deposited and made available to the public, under procedures established by the PTO.” *Lundak*, 773 F.2d at 1220-21.

Indeed, when explaining why it had made a deposit for a different transgenic plant utility patent, PO explained that transgenic “‘events’ are **random** events and generally **cannot be duplicated**.” EX1018, 4:42-47. PO likewise made deposits

in connection with numerous other utility patents concerning transgenic plants.

E.g., EX1019, 5:61-6:12; EX1021, 5:8-26; EX1022, 6:34-7:6; EX1024, 19:12-35; EX1025, 10:39-55. This includes a patent claiming priority to a 2009 provisional and disclosing an analogous event incorporating the Cry1F and PAT genes (as with the above-discussed TC1507 event) along with others. EX1022, 2:44-3:40.

By contrast, the April 2004 Application fails to identify *any* deposit of biological material—much less TC1507 germplasm including the exogenous foreign DNA at the specific location required by the claims and arising randomly from the microparticle bombardment described in the specification. *Cf. Lundak*, 773 F.2d at 1223 (holding that publicly accessible deposit enabled claims to unique cell line produced via mutagenesis). For this reason, the April 2004 Application fails to enable the Challenged Claims. While it discloses the claimed flanking sequences, such “taxonomic description” (*id.* at 1220-21) does not enable the Challenged Claims given that the “sequences flanking the transgene are different in independently obtained transformants.” EX1066, 170. Without access to TC1507 germplasm, POSAs could not reproduce the event. Silverstone, ¶¶83-85.

The EPO reached a comparable conclusion concerning a claim paralleling Challenged Claim 8. *See supra* §III.D.2. Stressing the need for “reproducibility” and outlining relevant legal requirements analogous to MPEP §2402, the EPO noted that PO’s claimed plant reflected “a particular event resulting from a random

method,” yet “genome editing technologies, such as the CRISPR-Cas technology, were not available to the public at the relevant date.” EX1004, 387 (emphasis original). The EPO therefore treated the lack of a deposit as dispositive. *Id.* PO subsequently withdrew the application. EX1004, 413.

For enablement under §112(a), it is insufficient that TC1507 seed was commercially available from PO. *See White Consolidated Industries v. Vega Servo-Control, Inc.*, 713 F.2d 788, 790-791 (Fed. Cir. 1983); *Ex parte Grandics*, Appeal 2005-1337, 2005 WL 3067931, at *5 (BPAI 2005) (citing *White*: “[W]e do not find the disclosure of two commercial sources to be sufficient to enable the skilled artisan to practice the claimed invention.”); *Ex parte DeCastro*, 28 USPQ2d 1391, 1393 (BPAI 1993) (citing *White* and affirming enablement rejection despite relevant material being “commercially available”); *see also infra* §VI.A.2.c.

PO indeed commercialized TC1507 subject to contractual restrictions—including a prohibition on “research.” EX1003, 543. Such commercialization cannot substitute for a deposit under §112, as it would wrongly permit PO to “extend its exclusionary rights beyond the” ’378 Patent’s expiration date “by controlling access to” TC1507. *White*, 713 F.2d at 791. The deposit system avoids that problem by guaranteeing public access even after patents expire. 37 C.F.R. §1.806. Depositories are contractually required “to supply samples to *anyone* seeking them once the patent issues.” *Argoudelis*, 434 F.2d at 1394.

B. The *Wands* Factors Confirm the April 2004 Application Does Not Enable the Challenged Claims Under §112

Given the nature of the invention, PO's admissions, and the lack of a deposit, the Board need not individually analyze the eight *Wands* factors to determine that the April 2004 Application fails to enable POSAs to practice the Challenged Claims without undue experimentation. *See, e.g., Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1371 (Fed. Cir. 1999) (“[A]ll of the factors need not be reviewed when determining whether a disclosure is enabling.”). *Wands* itself stressed that inventions “depend[ing] on the use of living materials...may be impossible to enable...solely by means of a written disclosure.” 858 F.2d at 735.

The *Wands* factors nevertheless confirm that undue experimentation would have been required to practice the Challenged Claims given the lack of a deposit. Silverstone, ¶86.

1. Breadth of the Claims

The Challenged Claims are simultaneously broad and specific. They are broad because they read on all corn plants including the required DNA incorporated into a particular location in the plant genome. They are specific because the required location—defined by the flanking sequences in SEQ ID NO:26 at the 5' end and SEQ ID NO:27 at the 3' end—is a unique amalgamation comprising both natural corn DNA together with exogenous DNA incorporated during the transformation event. Silverstone, ¶87.

Without access to TC1507 germplasm, POSAs could not have practiced the Challenged Claims as of 4/30/04 based on the April 2004 Application.

Silverstone, ¶88.

2. Nature of the Invention

The Challenged Claims concern a transgenic corn plant and related methods comprising (1) a Cry1F gene encoding a bacterial endotoxin conferring insect resistance; and (2) a PAT gene encoding a bacterial enzyme deactivating glufosinate herbicides. EX1001, 85:24-41.

The claims require integration of the DNA construct comprising these genes into the corn genome at a position defined by the flanking sequences recited in the claims and reflecting one random transformation event (i.e., TC1507) following physical bombardment of corn embryos with metal microprojectiles coated with a DNA insert incorporating the desired genes. Silverstone, ¶¶89-90.

Such introduction of exogenous DNA stimulates the plant cell's "wound response" (EX1012, 186; EX1015, 250), with the associated "DNA repair mechanisms" (EX1013, 308) triggering a "panoply of enzymes" acting on the exogenous DNA itself—thereby often leading to "degradation" during the integration process (EX1015, 250; EX1016, 284) and the ultimate incorporation "of truncated and otherwise rearranged copies" (EX1016, 284). Silverstone, ¶91.

Indeed, as Table 1 reflects and PO admitted during prosecution of the EP 097.9 application, the TC1507 event was “not a straightforward insertion of the PHI8999A insert neatly into the wild-type genome.” EX1003, 329. Instead, there are “broken-up, complex, repeated/fragmented sequences[s]” at either end of PHI8999A,” including “regions 4, 5, 6, 7 and 8 at the 5' end and regions 10, 11, 12, 13, and 14 at the 3' end.” *Id.* Regions 4-8 are included in SEQ ID NO:26 at the 5' end of the DNA construct recited in Challenged Claim 1, while Regions 10-14 are included in SEQ ID NO:27 at the 3' end. Silverstone, ¶¶92. These regions and related junctions—combining corn DNA with foreign DNA—were created by “random” chance during the TC1507 event (EX1001, 7:31-35) and are required to practice the Challenged Claims (*supra* §IV.A).

3. Level of Skill in the Art

While POSAs as of 2004 were highly educated (*see supra* §III.B) and able to transform plants via techniques such as isolating bacterial genes, inserting such genes into vectors, and using the vectors to incorporate the genes into plants, the level of skill in the art was not high in relevant respect—that is, concerning the Challenged Claims’ requirement of junction sequences specific to the TC1507 event (*see supra* §VI). Available transformation technologies—for example, the “biolistics” technique of bombarding plant cells with microprojectiles as the ’378 Patent describes—did not allow POSAs to control where within the genome where

the exogenous DNA was incorporated. Silverstone, ¶¶93-97; EX1066, 170. Even today, an expert witness for PO describes the quest for such control as one of the “holy grails of plant biotechnology.” EX1017, 46:4-12. Nor did the level of skill in the art allow POSAs to control whether and how the exogenous DNA was truncated or otherwise rearranged. Silverstone, ¶94. POSAs therefore could not reproduce a given transformation event and independently create plant cells with the exact junction sequences as the original event. *Id.* PO has repeatedly admitted the same (EX1018, 4:42-48; EX1026, ¶3)—including when prosecuting a related European application (EX1003, 294, 520).

4. State of the Prior Art

As of 4/30/04, microprojectile bombardment—the method used to generate TC1507—constituted the state of the art for transforming monocot plants such as corn. Silverstone, ¶98. Modern gene editing technologies such as CRISPR-Cas9 were unknown. *Id.*; *see also Regents of Univ. of California v. Broad Inst., Inc.*, 903 F.3d 1286, 1289 (Fed. Cir. 2018) (CRISPR-Cas9 interference decision discussing foundational 2012 articles).

The literature as of 2004 reflected significant limitations and lack of understanding concerning transgenic plants in general and microprojectile bombardment in particular. Silverstone, ¶¶99-101, POSAs had a “relatively poor understanding of the mechanisms that control transgene expression, especially in

monocots” such as corn. EX1016, 284; Silverstone, ¶¶99; *see also* EX1016, 277

(noting that “little [was] known of the precise causes and mechanisms of transgene rearrangement,” and “mechanism of DNA integration in transgenic plants” was “also poorly understood”); EX1033, 107 (“little is known about the actual mechanism of DNA integration, and there is currently no convenient way to control it”). The scientific literature also included “wide misconceptions” concerning transformation technologies and transgene expression. EX1012, 186; *see also* Silverstone, ¶¶99; EX1064-1070.

5. Level of Predictability in the Art

The level of predictability in relevant respect is low; transformation of plant cells via a biolistic event is a random and unpredictable process. Silverstone, ¶¶102-106. “[P]roducing useful transgenic plants” was “often a matter of ‘pot luck.’” EX1033, 107-108; *see also* EX1066, 169 (noting “high inter-transformant variability”). Integrating foreign DNA depended on “proteins involved in DNA replication, repair and recombination,” and it was “highly unpredictable” even after 2004 as to how “such proteins interact with” the foreign DNA researchers desired to integrate. EX1012, 185; *see also* EX1015, 255 (noting that “integration of foreign DNA” depends “on host proteins involved in DNA replication, repair and recombination,” and it was “unpredictable” how “these proteins interact with exogenous DNA and the plant’s own genome”)

“Both the position of integration and the structure of the transgenic locus vary considerably among independent transformants, and both these factors have a profound effect on transgene expression.” EX1033, 107. Even “transgenic plants containing the same transgene(s) often exhibit unpredictable and to some extent unstable expression patterns” EX1012, 185; *see also id.*, 187 (“[E]ven subtle changes in the integrated transgene construct can cause unpredictable expression patterns....”)

PO stressed the unpredictability of the art when successfully arguing during prosecution of the EP '97.9 application that claims to detection of TC1507 were patentable over prior art disclosing the TC1507 event. EX1003, 294; *see also supra* §III.D.1

6. Amount of Direction Provided by the Inventor

While Example 1 in the April 2004 Application describes *how* the TC1507 event was generated—i.e., coating metal particles with PHI8999A (SEQ ID NO:25) and bombarding immature corn embryos with these microprojectiles (EX1006, 24:8-28:18)—it offers no directions for independently reproducing TC1507. Silverstone, ¶107. The application instead acknowledges that transformation led to “random integration of the foreign DNA,” with corresponding “flanking regions characteristic and *unique* for each transformant.” EX1006, 9:27-29.

The remaining examples in the application concern TC1507 and describe the extensive sequencing and verification efforts required to characterize the genetic sequence of those flanking regions. EX1006, 28:22-43:3; Silverstone, ¶108.

7. Existence of Working Examples

As noted immediately above, the April 2004 Application discloses only a single working example—TC1507. Silverstone, ¶109. Moreover, as Figure 1 reflects, the TC1507 event “was **not** a straightforward insertion of the PHI8999A insert (SEQ ID NO 25) neatly into the wild-type genome.” EX1003, 329. Figure 1 instead confirms that this single example includes many “broken-up, complex, repeated/fragmented sequence[s] at both end[s] of PHI8999A” (EX1003, 329)—consistent with the above-discussed state of the art as of 2004 concerning plant transformation. Silverstone, ¶109. It would be essentially impossible to recreate independently. *Id.*, §110.

8. Quantity of Experimentation Required

Given the April 2004 Application’s failure to identify a deposit of TC1507, 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. Silverstone, ¶¶110-113.

As PO represented to the EPO, reproducing the event and thereby recreating TC1507’s junction sequences—required in all Challenged Claims (*supra* §IV.A)—

would have required “**physical access** to TC1507 germplasm, or other suitable genetic material.” EX1003, 520. Those junction sequences are “unique” to any event and “could not routinely be obtained again by transformation.” *Id.* Instead, as PO stressed to the EPO, “[r]eproducing the event of the invention in the absence of any physical sample would be almost impossible.” *Id.*

When explaining why it had made a deposit in connection with a different transgenic plant utility patent, PO likewise explained that transgenic events are “unique” and “generally **cannot be duplicated**.” EX1018, 4:42-48; *see also* EX1066 (noting “high inter-transformant variability”).

VI. BARBOUR (EX1009) ANTICIPATES OR RENDERS OBVIOUS ALL CHALLENGED CLAIMS

Barbour (EX1009)—the corrected U.S. patent publication corresponding to PO’s April 2004 Application—discloses the claimed TC1507 event (*see infra* §VI.A.1) and is enabled under §102 because TC1507 germplasm was accessible to POSAs (*see infra* §VI.A.2). Barbour therefore anticipates product claims 1-2 and 8 (Ground 1, §VI.A) and method claims 3-4 and 7 (§VI.B). Barbour renders obvious method claims 5-6 (§VI.C).

Barbour was published on 2/16/06, which is more than one year before 7/6/2007—the earliest possible effective filing date given the April 2004

Application’s failure to enable the Challenged Claims under §112(a).⁵ Sections 102 and 112 are different statutory provisions serving different purposes. As detailed in §VI.A.2, Barbour is enabled under §102 whereas the April 2004 Application does not enable the Challenged Claims under §112, which applies when assessing priority claims. *Application of Hafner*, 410 F.2d 1403, 1406 (CCPA 1969).

A. Ground 1: Barbour Anticipates Claims 1-2 and 8

Barbour discloses the TC1507 event underlying the Challenged Claims. Silverstone, ¶114. In particular, Barbour discloses the unique flanking sequences distinguishing TC1507 from other transgenic events. EX1009, ¶28 (“Linear map showing the transgenic insert PHI8999A, as well as the sequences flanking the transgenic insert”); Silverstone, ¶117.

1. Barbour Discloses the Purported Inventions as Claimed

a. Claim 1: Corn Plant Comprising DNA Construct

Challenged Claim 1 is identical to Barbour’s Claim 20 aside from the preamble (reciting “[a] corn plant comprising a DNA construct,” whereas

⁵ While the 7/6/07 and 3/13/09 applications likewise fail to enable the Challenged Claims given the lack of a deposit, the Board need not address them given that Barbour is pre-AIA §102(b) prior art regardless.

Barbour’s Claim 20 recites “[a] DNA construct”) and the concluding language following “a 3’ transcriptional terminator from (CaMV) 35S”:

Challenged Claim 1 (EX1001, 85:24-41)	Barbour Claim 20 (EX1009, 45-46)
<i>A corn plant comprising</i> <i>a DNA construct, said DNA construct</i> 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 <i>comprising the nucleic acid sequence of positions</i>	A DNA construct comprising: a first and 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

<i>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.</i>	
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Silverstone, ¶118. Barbour’s claim 21 descends from claim 20 and discloses “[a] plant comprising the DNA construct of claim 20,” while claim 22 descends from claim 21 and specifies that “said plant is a corn plant.” Barbour’s claim 22 is therefore identical to Challenged Claim 1 aside from Challenged Claim 1’s recitation that:

- (1) the (CaMV) 35S transcriptional terminator comprises “the nucleic acid sequence of positions 5843 to 6032 of SEQ ID NO: 25; and
- (2) “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.”

Silverstone, ¶119. But these recitations merely characterize aspects of the TC1507 event disclosed identically in both Barbour and the ’378 Patent. *Id.*

Barbour indeed discloses the same “SEQ ID NO: 25,” “SEQ ID NO. 26,” and “SEQ ID NO: 27” as the corresponding sequences in the ’378 Patent while also characterizing these sequences in the same way:

- Barbour and the ’378 Patent both disclose that SEQ ID NO: 25 “represents the DNA molecule used to transform maize line TC1507,”

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and in particular that “[t]his sequence represents insert PHI8999A.”

EX1001, columns 59-60; EX1009, 32.

- Barbour and the '378 Patent both disclose that SEQ ID NO: 26 and NO:27 constitute the “transgene/flanking insertion region” (EX1001, 3:58-59, EX1009, ¶12) with
 - SEQ ID NO. 26 the “5' flanking maize DNA sequence” (EX1001, 4:13-15; EX1009, ¶15); and
 - SEQ ID NO. 27 the “3' flanking maize DNA sequence” (EX1001, 4:23-25; EX1009, ¶16).

Silverstone, ¶120. The additional language in Challenged Claim 1 merely restates that which POSAs would understand Barbour’s claim 22 encompassed.

Silverstone, ¶121.

Indeed, Barbour separately discloses SEQ ID NO 24 as “the transgenic insert in maize line TC1507 as well as the sequence flanking the insertion sites.” EX1009, 26; *see also* Table 1 (“Sequence summary for event TC1507 insert,” delineating each region within SEQ ID NO: 24). POSAs would recognize that SEQ ID NO: 24 reflects the combination of sequences 25, 26, and 27—with 26 at the 5' end, 27 at the 3' end, and 25 in the middle. Silverstone, ¶122. Barbour and the '378 Patent include identical disclosures of “SEQ ID NO: 24.” *Id.*

The '378 Patent also includes Challenged Claim 8, which depends from Claim 1 and recites that “[t]he DNA construct comprises the polynucleotide of SEQ ID NO: 24.” Barbour anticipates Challenged Claim 8 as detailed in §VI.A below. Barbour’s anticipation of the dependent claim further confirms that Barbour also anticipates the independent claim from which claim 8 depends. *See Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 971 (Fed. Cir. 2001) (a “genus claim limitation is anticipated by, and therefore not patentably distinct from, [a] species claim”).

b. Dependent Claims 2 and 8

Barbour anticipates Challenged Claims 2 and 8, which recite the “corn plant of claim 1” while specifying additional requirements Barbour also discloses.

i. Claim 2: Corn Plant is a Seed

Challenged Claim 2—requiring that “the corn plant is a seed”—is anticipated by Barbour’s above-discussed disclosures and related teaching that “plant” includes “seeds.” EX1009, ¶50; Silverstone, ¶125; *see also* EX1009, ¶26 (disclosing “corn plant and seed TC1507” as “an aspect of the invention”); *id.*, ¶50 (“[T]he term ‘plant’ includes reference to whole plants [and] seeds....”).

ii. Claim 8: SEQ ID NO: 24

Challenged Claim 8—requiring that “the DNA construct comprises the polynucleotide of SEQ ID NO:24”—is anticipated by Barbour’s above-discussed disclosure together with Barbour’s disclosure of “SEQ ID NO 24” and related

teaching that this sequence—identical to the SEQ ID NO:24 disclosed in the '378 Patent—“represents the transgenic insert in maize line TC1507 as well as the sequence flanking the insertion sites.” EX1009, pages 26-34; Silverstone, ¶126. POSAs would understand that SEQ ID NO:24 reflects the TC1507 event and constitutes a particular species that Barbour discloses for use in connection with Barbour’s claim 22, which anticipates Challenged Claim 1 as explained in *supra* §VI.A.1.a. Silverstone, ¶127.

2. Barbour Enables Claims 1-2 and 8 Under §102

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.

The sale—even a “foreign sale”—of a “reproducible plant variety may enable an otherwise non-enabled printed publication disclosing that plant.” *Elsner*, 381 F.3d at 1128. Indeed, “[t]he proper test of a publication as a [pre-AIA] §102(b) bar is ‘whether [a POSA] could take the description of the invention in the printed publication and combine it with his own knowledge of the particular art

and from this combination be put in possession of the invention on which a patent is sought.” *Id.*

While *Elsner* concerned a plant patent application, the Board has applied the same principle for utility claims. *Ex parte Thomson* affirmed an anticipation rejection based on publications describing the claimed plant even though the publication did not disclose breeding processes. 24 USPQ2d 1618, 1619-21 (BPAI 1992). The Board instead stressed that POSAs could grow the claimed plant from seeds commercially available over a year before the filing date. *Id.* at 1620.

The MPEP cites both *Elsner* and *Thomson* when explaining that when claims are “drawn to plants, the [prior art] reference, ***combined with knowledge in the prior art***, must enable one of ordinary skill in the art to reproduce the plant.” MPEP §2123.03. The Board has repeatedly cited *Elsner* for this same principle when holding that claims to plants were unpatentable as anticipated by printed publications enabled by commercial sales of the relevant plants. *Ex parte Meilland*, Appeal 2012-002753, 2013 WL 5408034, at *2 (PTAB Sept. 19, 2013) (citing sale of rose plant in France); *Ex parte Boeder*, Appeal 2009-003289, 2009 WL 3089031, at *3 (BPAI Sept. 25, 2009) (citing “sale of flowers at [a] Dutch flower auction”); *Ex parte Tickner*, Appeal 2007-0317 (BPAI May 31, 2007) (citing *Elsner* for proposition that “evidence of a foreign sale of a claimed

reproducible plant variety may enable an otherwise non-enabled printed publication disclosing that plant”).

Here, PO had commercialized TC1507 starting in 2003—years before Barbour’s February 2006 publication. *See infra* §VI.2.a. POSAs could have used test kits (as described in Barbour and also commercially available) to identify TC1507 germplasm—thereby possessing what the Challenged Claims cover. *See infra* §VI.2.b. And it is consistent to conclude that Barbour is enabled for §102 purposes despite the corresponding April 2004 Application not satisfying §112(a). *See infra* §VI.2.c.

a. TC1507 Germplasm Was Publicly Available Given PO’s Commercialization

Barbour is enabling prior art because POSAs could have taken Barbour’s “description of the invention” as of Barbour’s 2/16/06 publication date and “combine[d] it with [their] own knowledge of the particular art” as of that date “and from this combination be put in possession of the invention” of the Challenged Claims. *Elsner*, 381 F.3d at 1128.

By Barbour’s publication date, TC1507 corn had been commercialized under PO’s “Herculex” trademark for three growing seasons—2003, 2004, and 2005. PO admitted to the EPO that “Herculex 1” corresponded to TC1507 and had been “commercialised for the first time in 2003.” EX1003, 542 (“TC1507 (Herculex 1) maize of this invention was sold by both Pioneer/Du Pont and Dow in

2003.”); *see also* EX1011, 1127 (USDA report that PO had “commercialized” Herculex in FY2003”); EX1040, 30 (February 2004 PO SEC filing referencing “strong growth” in “new products” such as “Herculex I insect protection”); EX1041, 33 (February 2005 PO SEC filing stating that “sales” of “HERCULEX I....continued to grow”); EX1042, 34 (February 2006 PO SEC filing stating that “sales” of “HERCULEXTM I” had “continued to ramp up”); EX1043, 33-34.⁶

Multiple reports and articles distributed publicly prior to 2006 likewise taught that “Herculex” was TC1507. *E.g.*, EX1011, 1128 (USDA report: “corn event TC1507 (HerculexTM)”; EX1032; EX1034, 104; EX1035, 936; EX1036, 1347; EX1037; Silverstone, ¶¶130-133.

Consistent with these reports and PO’s admission, a third-party patent application filed in April 2003 noted that PO had commercialized Herculex I. EX1038, ¶119; *see also* EX1039, 119:11 (June 2005 PCT filed by another third party noting that Herculex I was “commercially available”). Similar reports abounded in the agricultural trade press. *E.g.*, EX1047 (11/02 article noting that “[c]orn growers” had “option of purchasing” PO’s “Herculex I”); EX1048, (2/2003 article noting availability of “Herculex I”); EX1049, 8 (identifying “TC1507” among the “seed products available for the 2004 planting season”);

⁶ PO includes both Pioneer and Dow. *See supra* note 2.

EX1050 (2005 article noting “wider availability of Herculex I insect-resistant corn hybrids”).

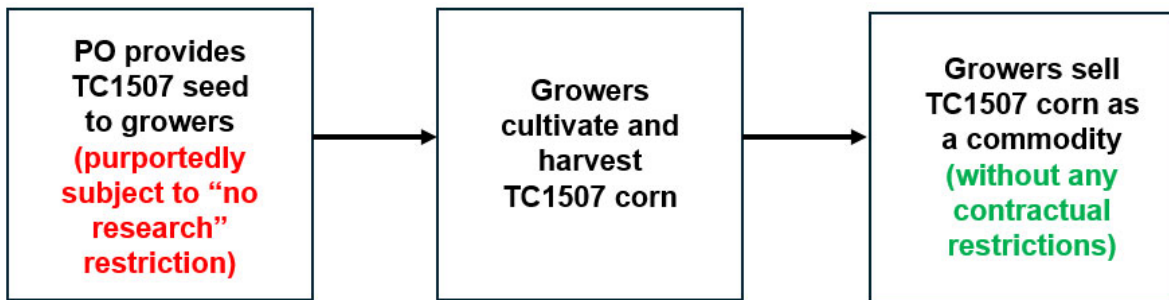
These references were available over a year before the earliest conceivable 7/6/07 priority date (*see supra* §V) and are thus probative in demonstrating Barbour’s enablement. *See Bristol-Myers Squibb Co. v. Ben Venue Lab’ys, Inc.*, 246 F.3d 1368, 1379 (Fed. Cir. 2001). They confirm that TC1507’s commercialization 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. *Elsner*, 381 F.3d at 1130.

During prosecution of the EP ’97.9 application (*supra* §III.D), PO sidestepped TC1507’s commercial availability by citing contractual provisions purportedly barring farmers from using TC1507 seed for “research purposes.” EX1003, 543 (emphasis original). Such theories fail under U.S. law for multiple reasons.

For one, the Challenged Claims are not limited to using TC1507 for “research” purposes. They instead purport to prevent the public from using TC1507 for *any* purpose—notwithstanding that Barbour discloses TC1507 and enables POSAs to practice that event when combined with their own knowledge, including TC1507’s commercialization.

Moreover, PO’s argument would wrongly permit applicants to circumvent the Federal Circuit’s binding *Elsner* caselaw and the Board’s corresponding consistent approach (as reflected in *Thomson*, *Meilland*, *Boeder*, and *Tickner*) merely by commercializing plants subject to “no research” boilerplate. But contractual terms cannot override disclosures that were in fact public. *Weber, Inc. v. Provisur Techs., Inc.*, 92 F.4th 1059, 1069 (Fed. Cir. 2024) (reversing Board’s determination that operating manuals did not qualify as printed publications).

The Board need not even address this issue, however, 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. Silverstone, ¶¶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. This is a separate and independent reason why PO cannot evade the Federal Circuit’s *Elsner* holding by imposing contractual terms on growers.

b. POSAs Could Have Detected the Presence of TC1507 in Commercially Available Corn Without Undue Experimentation

As disclosed in Barbour (*infra* §VI.A.2.b.i) and corroborated by the availability of commercial test kits (*infra* §VI.A.2.b.ii), 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. Silverstone, ¶135.

**i. Barbour Discloses Methods and Related Kits For
Detecting TC1507 in Food or Feed Products**

Aside from disclosing “corn plant TC1507” (*supra* §VI.A), 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. EX1009, ¶¶2-3; Silverstone, ¶136. Given Barbour’s teaching of such “methods for identifying [the] novel corn plant designated TC1507” using “primers or probes which specifically recognize the 5' and/or 3' flanking sequence of TC1507” (EX1009, ¶9), POSAs could have readily performed such assays on commercially available bulk corn and thereby identified kernels (i.e., corn seed) from TC1507 corn plants. Silverstone, ¶¶136-137.

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.” EX1009, ¶24; *see also id.*, ¶58 (describing use of a “‘specific probe’ for identifying event TC1507 in biological samples”); *id.*, ¶60 (disclosing “kit” for “identification of the event TC1507 in biological samples”).

Barbour also discloses detailed procedures for developing such kits and performing such assays using polymerase chain reaction (PCR) or “or other

conventional nucleic acid amplification methods.” EX1009, ¶56; *see also id.*, ¶¶75-76, ¶¶106-108; Silverstone, ¶138.

Given 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. Silverstone, ¶¶139-140. Barbour emphasizes that the “methods and kits encompassed by the present invention could be used “to identify event TC1507 in plants, plant material or in products such as, but not limited to, food or feed products (fresh or processed) comprising, or derived from plant material.” EX1009, ¶25. By 2006, TC1507 was widely found in “food or feed products” commercially sold without restriction. *See supra* §VI.A.2.a

ii. TC1507 Detection Kits Were Commercially Available

While not necessary to determine that Barbour is enabling for §102 purposes, the commercial availability of TC1507 detection kits further confirms that POSAs would have had “possession of the invention” of the Challenged Claims in view of Barbour before the 7/6/06 critical date. *Elsner*, 381 F.3d at 1128. *E.g.*, EX1045 (August 2003 SEC filing noting availability of test “able to detect, in only 10 minutes, one Cry1F Herculex™ I corn kernel in 600 non-Cry1F Herculex™ corn kernels”); *see also* EX1011, 1128 (USDA report that Grain Inspection, Packers and Stockyards Administration had approved “test for the

Cry1F protein produced by the corn event TC1507 (Herculex™)”; EX1044, 14-15 (August 2003 SEC filing noting USDA approval of kit for “detection of Cry1F Herculex™”); EX1051; EX1052; EX1053.

Such testing kits underlay PO’s regulatory strategy for commercializing TC1507. For example, the European Commission published a 2/15/05 “Validation Report” disclosing the results of a collaborative study involving fourteen laboratories across eleven countries “to assess the performance of a quantitative event-specific method to detect and quantify the TC1507 transformation event in maize flour (also known as Herculex™ 1).” EX1054. The European Commission determined that the method complied with European “labeling requirements.” EX1054, 10. *See also* EX1055, 9 (10/02 Canadian notice citing PO’s “method for detection and identification of corn specifically containing the Cry1F protein”); EX1056 (2004 article describing “multiplex PCR method” to detect “TC1507” and method’s utility for monitoring “the labeling system of GM Maize in the Korean market”); EX1036, 1348 (2006 article describing “quantitative detection of...maize event TC-1507” as alternative to PO’s previously validated “TC-1507-specific QPCR assay”).

Given such disclosures, POSAs in February 2006 would have been aware that kits were available to determine whether commercially available corn contained TC1507 germplasm. Silverstone, ¶¶141-143. The exact form of that

commercially available corn is immaterial. As defined in the '378 Patent, “plant” (as in the “corn plant” of Challenged Claim 1) encompasses even individual “plant cells.” EX1001, 10:8-10.

c. The Standard for Enablement Under §102 Differs From That Under §112, Such That TC1507’s Commercial Availability is Dispositive Under §102 But Insufficient Under §112

Barbour is enabled under §102 (as explained immediately above) even though the April 2004 Application does not enable the Challenged Claims under §112(a) (as explained in *supra* §V). As numerous past Board decisions reflect, the standard for whether a printed publication is enabled under §102 differs from the standard for whether a patent specification satisfies §112. The Board has consistently cited the commercial availability of plants as enabling anticipatory printed publications (as in *Thomson*, *Meilland*, *Boeder*, and *Tickner*—see *supra* §VI.A.2) while also consistently finding claims unpatentable for lack of enablement despite the commercial availability of corresponding plants or other biological material (as in *Grandics* and *Decastro*—see *supra* §V).

Sections 102 and 112 “serve distinctly different purposes,” with §112 demanding “full value for the patent granted,” whereas printed publications under §102 can preclude patentability “whether or not the information is commonly known.” *In re Howarth*, 654 F.2d 103, 106 (CCPA 1981). Accordingly, “[n]ot

everything that may be cited as prior art” under §102 “can be equated with common knowledge for purposes of enablement under s 112.” *Id.*

For anticipation under §102, the operative question is whether POSAs “could obtain the information *if they wanted to.*” *Elsner*, 381 F.3d at 1131 (quoting *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 1569 (Fed. Cir. 1988); *see also* *Silverstone*, ¶¶144-146. The printed publication standard—to which the Federal Circuit expressly analogized in *Elsner* when holding that a plant’s commercial availability sufficed to enable an otherwise non-enabled disclosure of a later-claimed plant—assumes that the hypothetical POSA would exercise diligence beyond that of typical real-world researchers. This law ensures that patents do not “withdraw...subject matter... already in the possession of the public.” *In re Wyer*, 655 F.2d 221, 226 (CCPA 1981). For example, an Australian patent application constituted an anticipatory printed publication even though it was only available on seven microfilm copies that were not publicly circulated and instead held for “inspection” only “within the [Australian] patent office and its branches.” *Id.* at 224-225. The application anticipated the claims despite the lack of any evidence “respecting actual viewing or dissemination.” *Id.* at 226; *see also* *In re Hall*, 781 F.2d 897, 899-900 (Fed. Cir. 1986) (holding that dissertation shelved in a single German library constituted a printed publication).

By contrast, the enablement requirement under §112(a) polices the Patent Act’s *quid pro quo* and ensures the public’s ability to practice the full scope of the claimed invention once the patent expires. The operative question is whether the necessary materials are “***readily available*** to the public.” *Wands*, 858 F.2d at 735.

For example, *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. *Howarth*, 654 F.2d at 104-106. While such filings would have been “treated the same” as domestic filings or “[w]ell known text books ...***for prior art purposes under s. 102***,” the CCPA declined to afford all references “the same evidentiary weight for purposes of showing enablement under s. 112.” *Id.* at 106-107.

Likewise, the possibility of isolating TC1507 germplasm from commercially available corn (*see supra* §VI.A.a) using kits such as those disclosed in Barbour (*see supra* §VI.A.b) was plainly ***known*** in the art for purposes of the printed publication standard under §102. Possessing TC1507 germplasm as of February 2006 (when Barbour was published) was thus indisputably an ***option*** for POSAs—just like a possibility of locating a printed publication such a university dissertation (as in *Hall*) or abstracts on microfilm in the Australian patent office (as in *Wyer*).

For purposes of §112, however, 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. *Wands*, 858 F.2d at 735. Relying on such “general knowledge” for §112 purposes carries a “great risk”—one that applicants can avoid merely by incorporating by reference “a reasonably accessible source.” *Howarth*, 654 F.2d at 107. But PO failed to incorporate a deposit into the April 2004 Application (or for that matter any other priority application)—notwithstanding PO’s otherwise consistent practice of including deposits in transgenic plant utility patents. *E.g.*, EX1018, 4:42-54; EX1019, 5:61-6:12; EX1021, 5:8-26; EX1022, 6:34-7:6; EX1024, 19:12-35; EX1025, 10:39-55.

PO indeed maintains that TC1507 was *not* readily available (EX1003, 519-520, 542-543)—leading the EPO to reject subsequent claims to TC1507 for lack of enablement given the lack of a deposit (EX1004, 370, 386-87).

B. Ground 2: Barbour Anticipates or Renders Obvious Claims 3-4 & 7

Barbour also anticipates or at minimum renders obvious Challenged Claims 3-4 and 7, which depend from Challenged Claim 1 and recite methods of “producing an insect resistant corn plant.” EX1001, 86:24-25.

1. Barbour Discloses or Renders Obvious the Purported Inventions as Claimed

a. Claim 3: Breeding Method

Claim 3 requires “a method of producing an insect resistant corn plant comprising:

- (a) breeding with an insect resistant corn plant comprising in its genome DNA the DNA construct of claim 1 and
- (b) selecting a progeny of (a) by analyzing the genome of the progeny for the presence of the DNA construct of claim 1.”

EX1001, 86:26-30.

Barbour’s paragraph 22 discloses such “methods of producing an insect resistant corn plant that comprise the steps of: (a) sexually crossing a first parental corn line comprising the expression cassettes of the present invention, which confers resistance to insects, and a second parental corn line that lacks insect resistance, thereby producing a plurality of progeny plants; and (b) selecting a progeny plant that is insect resistant.” EX1009, ¶22; *see also id.*, ¶49 (similar); Silverstone, ¶150.

Barbour likewise discloses that “one aspect of the invention” includes incorporating a “DNA construct” with the “two transgene expression cassettes” of PHI8999A. EX1009, ¶8; Silverstone, ¶151. Barbour further discloses that these

expression cassettes are associated with TC1507. EX1009, ¶¶84-87; Silverstone, ¶151.

POSAs would therefore understand that Barbour’s paragraph 22 discloses methods of breeding involving an insect resistant corn plant comprising the DNA construct of claim 1 as detailed above in §VI.A.1.a (explaining that “DNA construct” of Barbour’s claim 20 is the same as that in Challenged Claim 1). Silverstone, ¶152.

Barbour also discloses selecting particular plants from the initial breeding process by analyzing their DNA as required by claim 3’s element (b). Barbour’s claim 54 concerns a method of “producing an insect resistant corn plant comprising breeding with a plant of claim 51 or 52, and selecting progeny by analyzing for at least one nucleotide sequence selected from the group consisting of SEQID NO: [45-57].” EX1009, p. 47; Silverstone, ¶153. As explained in *supra* §IV.A, sequence IDS 45-57 are unique to TC1507. Moreover, POSAs would understand that Barbour’s claim 54 was applicable for use with paragraph 22’s method. Silverstone, ¶153.

At minimum, it would have been obvious to practice Barbour’s paragraph 22 with the technique disclosed in Barbour’s claim 54—that is, screening progeny for TC1507’s unique DNA construct. Silverstone, ¶154. Such screening techniques

were standard by 2006. *Id.* For the same reasons, POSAs would have had a reasonable expectation of success when incorporating such screens. *Id.*

b. Claim 4: Using Second Plant

Claim 4 depends from claim 3 and specifies that the breeding be “with a second plant” (EX1001, 86:31-33)—as opposed to self-pollination (i.e., male flowers pollinating female flowers in the same plant). Silverstone, ¶155. Barbour’s paragraph 22 discloses or at minimum renders obvious the method of claim 3 (as discussed immediately above) and further discloses that the “second parental corn line...lacks insect resistance,” thus distinguishing it from the “first parental corn line comprising the expression cassettes of the present invention, which confers resistance to insects.” EX1009, ¶22; *see also id.*, ¶23 (noting that disclosed insect resistant plant can be “crossed with compatible corn varieties” rather than “self pollinated”); *id.*, ¶49; Silverstone, ¶155.

Barbour therefore discloses the requirement distinguishing claim 4 from claim 3 and therefore anticipates claim 4 or at minimum renders it obvious for the same reasons Barbour anticipates and at minimum renders obvious claim 3. Silverstone, ¶156.

c. Claim 7: Yielding Insect Resistant Corn Plant

Claim 7 depends from claim 3 and requires that the “progeny comprises the insect resistance of the insect resistant corn plant of (a).” EX1001, 86:38-39.

Barbour’s paragraph 22 discloses or at minimum renders obvious the method of claim 3 (as discussed in §VI.A.1.b.ii(1)) and further discloses that the method yields “an insect resistant corn plant.” EX1009, ¶22; ; Silverstone, ¶157. Indeed, transgenes (e.g., the Cry1F gene disclosed in Barbour for insect resistance) “are genetically dominant,” such that only one parent “needs to contain the transgene” for it to be passed down. EX1049, 4.

Barbour therefore discloses the requirement distinguishing claim 7 from claim 3 and therefore anticipates claim 7 or at minimum renders it obvious for the same reasons Barbour anticipates and at minimum renders obvious claim 3.

Silverstone, ¶158.

2. Barbour Enables Claims 3-4 and 7 Under §102

Barbour enables Challenged Claims 3-4 and 7 under §102 for the same reasons Barbour enables Challenged Claims 1-2 and 8 under §102. As explained in *supra* VI.A.2, POSAs could have obtained TC1507 germplasm as of Barbour’s February 2006 publication date given that PO had previously commercialized TC1507. POSAs could likewise have used that TC1507 germplasm to breed additional insect resistant corn plants as recited in claims 3-4 and 7. Silverstone, ¶159.

**C. Ground 3: Barbour in View of a POSA's Knowledge
Renders Obvious Claims 5-6**

Barbour in view of a POSA's knowledge renders obvious claims 5-6, which depend from claim 3 and specify which plant in the breeding process serves as the "pollen parent." Any given corn plant has separate male and female flowers, with the male flowers located on the tassel and the female flowers located on the ear, which contains numerous ovules. EX1049, 1; EX1058, 1:29-31; EX1059, 737; EX1060, 131; Silverstone, ¶160. Each ovule represents a potential kernel, which develops if the ovule receives pollen from a tassel. Silverstone, ¶159.

POSAs likewise would have known that when breeding a transgenic corn plant with another corn plant (per method claim 3), the transgenic plant can serve as "either the female or male parent." EX1061, 1409; *see also* EX1062, 207-208; EX1063, 24:7-14; Silverstone, ¶161. POSAs indeed could control pollination mechanically. EX1049, 1 (discussing treatment of "plant that is to be used as a female").

Given the competitive nature of the corn market, POSAs would also have recognized a commercial need to continue developing new corn lines by cross-breeding existing lines with desirable properties. Silverstone, ¶162; EX1049. This need was particularly pronounced with transgenic lines such as TC1507 given that transgenes are typically inserted initially into corn varieties selected specifically to

promote “successful transformation events” despite being “inferior” for agricultural purposes. EX1049, 3; Silverstone, ¶162.

In sum, there was “market pressure to solve a problem” (i.e., the need to develop new transgenic corn lines from an existing one) and two “identified, predictable solutions” (i.e., using the transgenic line as either the male or the female). *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 402-03 (2007). POSAs therefore had “good reason to pursue [both] known options within [their] technical grasp.” *Id.* POSAs also had a reasonable expectation of success given Barbour’s confirmation that TC1507 included both “pollen” and “ovules.” EX1009, ¶26; Silverstone, ¶162.

1. Barbour Renders Obvious the Purported Inventions as Claimed

a. Claim 5: Insect Resistant Corn Plant as Pollen Parent

Claim 5 depends from claim 3 and specifies that the “insect resistant corn plant” used in the crossing is the “pollen parent” (EX1001, 86:34-35)—that is, the “male” parent, providing pollen to fertilize ovules in the female flower (Silverstone, ¶164). Claim 5 merely recites one of the two above-discussed “identified, predictable solutions” and therefore is obvious over Barbour in view of “ordinary skill and common sense.” *KSR*, 550 U.S. at 403. Silverstone, ¶164.

b. Claim 6: Second Plant as Pollen Parent

Claim 6 depends from claim 3 and requires that the “second plant” be the “pollen parent”—meaning that the “insect resistant corn plant” is the “female” parent into which the pollen is deposited (Silverstone, ¶164). Claim 6 merely recites the other of the two above-discussed “identified, predictable solutions” and therefore is obvious over Barbour in view of “ordinary skill and common sense.” *KSR*, 550 U.S. at 403. Silverstone, ¶165.

2. Barbour Enables Claims 5-6 Under §102

Barbour enables Challenged Claims 5-6 under §102 for the same reasons Barbour enables Challenged Claim 3 under §102. *See supra* §VI.B.2.

VII. NO BASIS EXISTS FOR DISCRETIONARY DENIAL

A. §314(a)

There is no previous petition concerning the ’378 Patent that would warrant discretionary denial based on the factors in *General Plastic Industrial Co., Ltd. v. Canon Kabushiki Kaisha*, IPR2016-01357, Paper 19 (PTAB Sept. 6, 2017) (precedential).

B. §324(a)

There is no co-pending litigation involving the ’378 Patent that would warrant discretionary denial based on the factors in *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 (PTAB Mar. 20, 2020) (precedential).

C. §325(d)

Considering the two-part framework discussed in *Advanced Bionics, LLC v. Med-El Elektromedizinische Gerate GMBH*, IPR2019-01469, Paper 6 (PTAB Feb. 13, 2020) (precedential), the Board should not exercise its §325(d) discretion to deny institution. As the Director recently noted in a notice of proposed rulemaking, “application of section 325(d) should be limited to situations in which the prior art or arguments were meaningfully addressed by the Office”—meaning that the Office “articulated its consideration of the art or arguments in the record.” 89 Fed. Reg. 28,693, 28,700 (Apr. 19, 2024). The record here lacks any such articulation. See EX1002.

All three grounds turn on Barbour—a reference not of record during prosecution. **The anticipation arguments in Grounds 1-2 and the obviousness arguments in Grounds 2-3 are accordingly not the same or substantially the same as arguments considered during prosecution.** For this reason, the *Advanced Bionics* inquiry ends at the first step. Indeed, the Examiner never made *any* anticipation rejection of *any* challenged claim based on *any* prior art.

Nor is there any indication the Examiner considered whether the April 2004 Application enables the Challenged Claims to remove Barbour as prior art. *Smith & Nephew, Inc. v. Arthrex, Inc.*, IPR2017-00275, Paper 7 at 11 (PTAB May 10, 2017) (instituting IPR based on priority challenge: “[W]e 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.”).

Moreover, while the Examiner stated that the specification was “enabling for a corn plant comprising SEQ ID NO: 24 and methods of using same,” the record does not reflect any consideration of the underlying facts detailed in *supra* §V.

Even if the Board reached part two of *Advanced Bionics*, Petitioner presents ample evidence that the Examiner erred in failing to recognize the Challenged Claims’ lack of entitlement to the 4/30/04 filing date, including but not limited to:

- PO’s representation to the EPO (but not disclosed to the Examiner) that “[r]eproducing the event of the invention in the absence of any physical sample would be **almost impossible**” (EX1003, 520);
- the EPO’s rejection of corresponding claims to the “**random**” event for lack of enablement given the lack of a deposit (EX1004, 386-387);
- PO’s subsequent abandonment of the EP application (*id.*, 413);
- the acknowledgment by PO’s expert witness that controlling the location of transgene insertion—as required by the Challenged Claims—constitutes one of “the **holy grails of plant biotechnology**” (EX1017, 46:4-12);

- PO's otherwise consistent practice of depositing transgenic plant germplasm when pursuing patent protection (e.g., EX1019, 5:61-6:12; EX1021, 5:8-26; EX1022, 6:34-7:6; EX1024, 19:12-35; EX1025, 10:39-55); and
- PO's acknowledgment that it made such deposits because transgenic “events’ are **random** events and generally **cannot be duplicated**” (EX1018, 4:42-47).

Indeed, in connection with one of PO's other transgenic plant utility patents (EX1019), the Examiner rejected the claims for lack of enablement given that “[t]he specification does not disclose a repeatable process to obtain the plants and it is not apparent whether the plants are readily available to the public” (EX1020, 5-6). While PO's specification referenced a deposit, the Examiner required “an affirmative statement as to irrevocable public availability” (*id.*, 6).

Here, by contrast, neither the April 2004 Application nor any other application in the '378 Patent's priority chain references any deposit to the unique TC1507 germplasm—much less ensures irrevocable public access. The Examiner erred in failing to recognize that Barbour thus constitutes §102(b) prior art.

VIII. CONCLUSION

IPR of claims 1-8 of the '378 Patent is requested.

U.S. Patent No. 8,901,378
Petition for Inter Partes Review – IPR2024-01014

Dated: June 13, 2024

Respectfully submitted,
Inari Agriculture, Inc.

By: /Scott A. McKeown/
Scott A. McKeown, Reg. No. 42,866
WOLF, GREENFIELD & SACKS, P.C.

IX. MANDATORY NOTICES

A. Real Party-In-Interest

Pursuant to §42.8(b)(1), Petitioner identifies Inari Agriculture, Inc. as real party-in-interest. No other party had access to or control over the present Petition, and no other party funded or participated in preparation of the present Petition.

B. Related Matters

A decision in this proceeding could affect or be affected by the following:

1. United States Patent & Trademark Office

The application from which U.S. Patent No. 8,901,378 issued is a division of U.S. Patent Application No. 12/333,044 (U.S. Patent No. 7,989,607), filed March 13, 2009, which is a continuation of U.S. Patent Application No. 11/774,236 (U.S. Patent No. 7,514,544), filed July 6, 2007, which is a division of U.S. Patent Application No. 10/837,105 (U.S. Patent No. 7,288,643), filed April 30, 2004, which claims priority to provisional application 60/467,772, filed May, 2, 2003.

The following U.S. patent applications claim the benefit of priority to U.S. Patent 8,901,378:

- (i) U.S. Patent Application No. 14/547,589 (U.S. Patent No. 10,023,921), filed November 19, 2014;
- (ii) U.S. Patent Application No. 16/011,908, filed June 19, 2018;
- (iii) U.S. Patent Application No. 17/064,439, filed October 06, 2020.

C. Counsel and Service Information - § 42.8(b)(3) and (4)

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A power of attorney is submitted with the Petition. Counsel for Petitioner consents to service of all documents via electronic mail.

X. CLAIM LISTING

Claim 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 promotor;
- (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 40 NO: 27 at the 3' end.

Claim 2
The corn plant of claim 1, wherein the corn plant is a seed.
Claim 3
A method of producing an insect resistant corn plant comprising: (a) breeding with an insect resistant corn plant comprising in its genome DNA the DNA construct of claim 1 and (b) selecting a progeny of (a) by analyzing the genome of the progeny for the presence of the DNA construct of claim 1.
Claim 4
The method of claim 3, wherein breeding comprises crossing the insect resistant corn plant of (a) with a second plant.
Claim 5
The method of claim 3, wherein the insect resistant corn plant of (a) is the pollen parent for the crossing.
Claim 6
The method of claim 4, wherein the second plant is the pollen parent for the cross
Claim 7
The method of claim 3, wherein the progeny comprises the insect resistance of the insect resistant corn plant of (a).
Claim 8
The corn plant of claim 1, wherein the DNA construct comprises the polynucleotide of SEQ ID NO: 24.

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

I certify that on June 13, 2024, I will cause a copy of the foregoing document, including any exhibits or appendices filed therewith, to be served via Overnight FedEx at the following correspondence address of record for the patent:

DuPont Pioneer
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Date: June 13, 2024

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

CERTIFICATE OF WORD COUNT

Pursuant to 37 C.F.R. § 42.24, the undersigned certifies that the foregoing Petition for *Inter Partes* Review contains 13,994 words excluding a table of contents, a table of authorities, Mandatory Notices under § 42.8, a certificate of service or word count, or appendix of exhibits or claim listing. Petitioner has relied on the word count feature of the word processing system used to create this paper in making this certification.

Date: June 13, 2024

/MacAulay Rush/
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