

United States Patent and Trademark Office
Before the Patent Trial and Appeal Board

INARI AGRICULTURE, INC.

(Petitioner)

V.

CORTEVA AGRISCIENCE LLC

(Patent Owner)

Inter Partes Review

No. IPR2024-01014 | U.S. Patent No. 8,901,378

Petitioner's Demonstrative Exhibits

Inari Exhibit 1106
Inari v. Corteva
IPR2024-01014

August 26, 2025

Seed Deposit Regulations

37 CFR 1.802(b) Biological material need not be deposited unless access to such material is necessary for the satisfaction of the statutory requirements for patentability under 35 U.S.C. 112. If a deposit is necessary, it shall be acceptable if made in accordance with these regulations. Biological material need not be deposited, inter alia, if it is known and **readily available** to the public or can be made or isolated without undue experimentation. Once deposited in a depository complying with these regulations, a biological material will be considered to be readily available even though some requirement of law or regulation of the United States or of the country in which the depository institution is located permits access to the material only under conditions imposed for safety, public health or similar reasons.

Petitioner's Reply (Paper 28) at 3

37 CFR 1.808(a) A deposit must be made under conditions that assure that:
(1) Access to the deposit will be available during pendency of the patent application making reference to the deposit to one determined by the Director to be entitled thereto under § 1.14 and 35 U.S.C. 122, and
(2) Subject to paragraph (b) of this section, **all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of the patent.**

Petitioner's Reply at 23

Transgene Integration is a Random Process

“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).”

Petition (Paper 2) at 1

Transgene integration, mediated by either *A. tumefaciens* or direct DNA transfer, is a random process and the sites of integration are believed to correlate with (1) the positions of naturally occurring chromosome breaks³ and (2) transcriptionally active regions of the genome particularly the sub-terminal regions of the chromosomes, perhaps because the DNA is more accessible in these areas.^{4,5}

Kohli et al., Plant Signaling & Behavior (EX1012) at 185

In contrast, University of Wisconsin plant pathologist Robert Goodman (2002) likens the random insertion of transgenes by genetic engineering techniques to “throwing a grenade into the genome.”

First the Seed: The Political Economy of Plant Biotechnology
(2nd Ed.) (EX1014) at 311

PO Admits Claimed Event Near Impossible to Reproduce

The third question to be answered is whether it is possible for the skilled person to reproduce without undue burden the DNA fragment corresponding to the event TC1507 and comprising the 5'- and 3'-flanking region thereof.

Prosecution History of European Patent Application
No. 04 751 097.9 (EX1003) at 486; Petition at 17

In response to the “third question”, a skilled person would need physical access to TC1507 germplasm, or other suitable genetic material derived from the plant, to reproduce the event. This is because even if the junction sequences of the event were known (which they were not) the same event could not routinely be obtained again by transformation. Reproducing the event of the invention in the absence of any physical sample would be almost impossible.

EX1003 at 520; Petition at 17

D1 does not enable the skilled person to obtain a physical sample of a TC1507-containing plant on which to carry out the analysis the Examining Division has in mind. Rather, D1 is a mere paper disclosure of the existence of TC1507 as part of the regulatory approval process. D1 does not provide any sequence information, nor does it make the plant publicly available. In fact, actual physical samples of TC1507 were not available to the public at the priority date (due to the regulatory process). So while D1 refers to the existence of a plant, the plant itself was not publicly available and so could not have been used by the skilled person to arrive at the present invention.

EX1003 at 520; Petition at 17

Referring to the section of the Pioneer agreement headed “You Agree”, it is clear that the grower is only permitted to use the seed to raise a commercial crop, in a single season, and for no other purpose. In particular, the grower is prohibited from transmitting the seed onwards to third parties for planting, breeding, seed production or research purposes.

EX1003 at 543; Petition at 17

EPO Denied Event Patent for Lack of Deposit

According to the decision T657/10, the disclosure has to enable the skilled person to obtain the particular product resulting from the TC1507. In view of your letter dated 16.10.2014, wherein you stated that "in view of the section of Pioneer agreement headed "I agree" it is clear that the grower is only permitted to use the seed to raise a commercial crop in a single season and not for any other purpose.

these requirements are not fulfilled.

Prosecution History of European Patent Application No. 15 168 051.9 (EX1004) at 370;
Petition at 18

In the present case, the present application is silent as to a deposited material that would have rendered the TC1507 corn plant publicly available. The Applicant fails as well in his letter dated January, 4th 2019, to provide such deposit evidence.

EX1004 at 386; Petition at 18

The Examining Division respectfully disagrees with the Applicant's contention. Thus, the claimed subject-matter includes a particular event resulting from a random method and having one surprising and advantageous property, i.e. insect resistance. However, genome editing technologies, such as the CRISPR-Cas technology, were not available to the public at the relevant date of the present application.

EX1004 at 387; Petition at 19

Patent Owner's argument is, at present, unavailing. Even though the legal standards for enablement may differ in the two jurisdictions, the facts surrounding the TC1507 seed sales agreements remain the same. We find the Patent Owner's representations to the EPO suggest that the TC1507 seeds sold by Patent Owner in 2003 do not meet the "readily available to the public" standard under *Wands* or 37 C.F.R. § 1.802(b).

Institution Decision (Paper 15) at 15;
Petitioner's Reply (Paper 28) at 19-20

Commercial Availability is an Exacting Standard

“The Office will accept commercial availability as evidence that a biological material is known and readily available only when the evidence is **clear and convincing** that the public has access to the material.”

MPEP 2404.01;
Petitioner's Reply at 6

Extreme Difficulty in Obtaining TC1507

22 A. The availability of TC1507-event corn in
23 that time period would have been extremely
24 difficult to get in hand based on the low
1 planting acreage. I would not have considered a
2 POSA having availability of the TC1507 event in
3 hand in that timeframe.

EX2003 at 53:22-54:3;
Petitioner's Reply at 10

7 Q. I am going to go back to the original
8 question I asked at the beginning. I understand
9 you believe that the availability of TC1507 may
10 have been somewhat limited in 2003, right?

11 A. That is correct.

12 Q. I would like you to put aside how
13 available it was at the moment and answer a
14 question.

EX2003 at 57:7-14;
Petitioner's Reply at 10

Research Prohibited Unless There is a Deposit

Pioneer Hi-Bred Technology Agreement

YOU AGREE:

- To use the seed containing the subject technology for planting a commercial crop only in a single season.
- To not supply any of this seed to any other person or entity for planting, and not to save any crop produced from this seed for replanting, or supply saved seed to anyone for replanting.
- To not use this seed or its progeny or provide it to anyone for crop breeding, seed production or research (other than to make agronomic comparisons and conduct yield testing).

EX1003 at 545;
Petitioner's Reply (Paper 28) at 1, 19

MATERIAL TRANSFER AGREEMENT ("MTA")

Last updated: November 15, 2011



Scope of Use

ATCC Material and Progeny: ATCC Material and Progeny may only be used by Purchaser's Investigator for research purposes and only in Investigator's laboratory.

Inari Agriculture N.V./S.A. Material Transfer Agreement with ATCC (EX2007) at 1;
Petitioner's Reply (Paper 28) at 1, 19

Patent Owner's Shifting Theories (& Waiver)

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

Patent Owner Response (Paper 24) at 29

the public could buy TC1507 corn from corn growers

Thus, purchasers of corn at grain

elevators knew exactly where to look for downstream access to TC1507 corn

Patent Owner's Sur-Reply at 8

Put together, the evidence demonstrates that, even if a person of ordinary skill were the appropriate target, they would have known (1) where to access the corn seed embodying TC1507, from at least Dow AgroSciences and Pioneer; and (2) would have been able to obtain it pursuant to a TUA.

Patent Owner's Sur-Reply at 10

Patent Owner's Continued Credibility Problem

409. Corteva first learned of Inari's conversion of seeds containing the DP-004114-3 and TC-1507 events in September 2021, but did not learn that Inari had converted hundreds of Corteva's protected seeds until December 2022, which is when ATCC first informed Corteva of Inari's actions.

Second Amended Complaint in *Corteva Agriscience LLC et al. v. Inari Agriculture, Inc. et al.* (EX1072) at 105

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

Patent Owner's Sur-Reply (Paper 34) at 19