

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

INARI AGRICULTURE, INC.,
Petitioner,

v.

CORTEVA AGRISCIENCE LLC,
Patent Owner.

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

PATENT OWNER'S REQUEST FOR DIRECTOR REVIEW

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I. INTRODUCTION

The Board’s majority decision granting institution violated binding precedent, failed to consider admissions made by the Petitioner, made erroneous findings of fact, and improperly shifted the burden of proof to the Patent Owner as noted by the dissenting opinion. Each of these abuses of discretion favors Director review. Accordingly, Patent Owner requests Director review of the Board’s split decision granting institution based on the threshold issue of a purported lack of enablement for a failure to show a biological sample was “known and readily available.”

The Board’s majority decision is founded on an incorrect conclusion of law, requiring the “known and readily available” standard to be met *before* the filing date of the patent. In contrast, controlling precedent requires accessibility only as of the issue date. According to the Board, there is no question that the biological sample was “‘known and readily available to the public’ by 2010,” four years before the ’378 patent issued. Maj. Op., 23.

The Board also made a clearly erroneous finding of fact when it concluded that “TC1507 [the sample at issue] was commercially available and without restriction *only as of February 2006*.” Maj. Op., 14.¹ The record is replete with evidence, including Petitioner’s own admissions, that biological material was accessible before this time, including after the 2003 growing season and before the

¹ Emphasis added in *italics* or **bold** unless otherwise noted.

April 2004 filing date. Thus, the requisite biological sample was accessible even by the time dictated by the Board’s erroneous conclusion of law, i.e., by the April 2004 filing date.

The Board compounded these errors by ignoring other “information presented *in the petition*,” which it must consider in assessing whether to institute. 35 U.S.C. § 314(a). Had the Board properly considered *all* evidence presented in the Petition, and in Patent Owner’s Preliminary Response, the Board would have been forced to conclude that the biological sample was “known and readily available” by its own (incorrect) time period.

The Board further misapprehended the “known and readily available” standard by finding that Barbour—the published version of the ’378 patent—is enabled, but the issued ’378 patent is not. By adopting Petitioner’s legally flawed analysis and unsupported distinction between enablement for the purposes of §§ 112 and 102 based on the same disclosure, the Board abused its discretion by instituting the Petition based on Petitioner’s allegation of non-enablement. Neither the parties nor the Board should be forced to expend any more time or resources for a proceeding that should not have been instituted in the first place, especially for a patent that expired months ago and has not been asserted against Petitioner in any forum. Patent Owner therefore respectfully requests Director review and reversal of the majority’s institution decision.

II. LEGAL STANDARDS

A party may request Director review if the Board's institution decision presents "(a) an abuse of discretion or (b) important issues of law or policy." USPTO, *Director Review Process*, § 2.B. The Board abuses its discretion when its decision "(1) is clearly unreasonable, arbitrary, or fanciful; (2) is based on an erroneous conclusion of law; (3) rests on clearly erroneous fact findings; or (4) involves a record that contains no evidence on which the Board could rationally base its decision." *CyWee Grp. Ltd. v. ZTE (USA), Inc.*, 90 F.4th 1358, 1364 (Fed. Cir. 2024) (quoting *Ultratec, Inc. v. CaptionCall, LLC*, 872 F.3d 1267, 1272 (Fed. Cir. 2017)).

The Board must examine all evidence of record, including that which detracts from the conclusion the Board ultimately reaches. *Aqua Prods., Inc. v. Matal*, 872 F.3d 1290, 1325 (Fed. Cir. 2017). For example, a party's admission is evidence appropriately considered by a factfinder and must be evaluated by the Board to determine the impact of the admission on the balance of evidence. *Cook Grp. Inc. v. Boston Sci. Scimed, Inc.*, 809 F. App'x 990, 999-1000 (Fed. Cir. 2020) (finding the Board erred in refusing to consider a party's admission when it was weighing the evidence). Refusing to consider material evidence, including party admissions, without explanation is impermissible error. *See, e.g., Applications in Internet Time, LLC v. RPX Corp.*, 897 F.3d 1336, 1358 (Fed. Cir. 2018) (vacating the Board's decision for its failure to consider the "entirety of the evidentiary record"); *Ultratec*

872 F.3d at 1274 (“Because the Board failed to consider material evidence and failed to explain its decisions to exclude the evidence, we vacate and remand.”); *Prime Time Toys LLC v. Spin Master, Inc.*, IPR2023-01461, Paper 12 (P.T.A.B. July 9, 2024); *Weber, Inc. v. Provisur Techs., Inc.*, IPR2022-00599, Paper 74 (P.T.A.B. Nov. 29, 2023).

III. BACKGROUND

The ’378 patent is directed to a transgenic insect resistant corn plant, TC1507, and methods for detecting TC1507 based on a DNA construct inserted into the corn plant’s genome. Paper 9, POPR, 2-7; EX1001, Abstract; EX1006, 55; Maj. Op., 3-5.

The ’378 patent issued from Application No. 12/914,271, filed on October 28, 2010, which claims priority to several earlier applications, including Application No. 10/837,105 (“the 2004 application”), filed on April 30, 2004. EX1001, Cover; POPR, 2-3.² The published version of the 2004 application is asserted reference Barbour (EX1009). Maj. Op., 9.

The Examiner addressed enablement of the ’378 claims in the context of the

² While the 2004 application claims the benefit of priority to U.S. Provisional Application No. 60/467,772, filed on May 2, 2003, neither Petitioner nor the Board address it. Pet., 26-29; Maj. Op., 9, n.4.

2004 application. POPR, 8-17. A seed deposit was never required by the Examiner during prosecution. POPR, 11, 13, 15. And the allegedly necessary biological sample, TC1507 germplasm, was “known and readily available” at the relevant time. POPR, 17-25.

The Petition is entirely premised on the allegation that the issued claims of the ’378 patent are not entitled to their April 2004 filing date because they are not enabled by their specification. Petitioner’s sole argument against enablement is that a biological deposit of TC1507 germplasm was not made and such a deposit was required for enablement despite not being required during prosecution. Pet., 4, 29-41; EX1007, ¶¶ 78-113. Petitioner asserts that because the claims are not entitled to their April 2004 filing date, they are therefore anticipated by the later publication of their own specification (Barbour), which is allegedly enabled for purposes of anticipation despite there still being no biological deposit made. *E.g.*, Pet., 4-5, 41-60; EX1007, ¶¶ 114-147.

Despite a deposit never being required during prosecution and the inconsistency in Petitioner’s arguments regarding its necessity for enablement of the application compared to the alleged prior art, in a split decision, the Board instituted *inter partes* review based on its determination that “Petitioner has shown sufficiently that the challenged claims are not entitled to the 2004 priority date because the 2004 application does not enable the full scope of the challenged claims as required by

§ 112.” Maj. Op., 10. The Board’s decision ultimately did not turn on the argument in the Petition, that because no deposit was made, the claims could not be enabled, but instead turned on the “critical issue” of “whether TC1507 was ‘known and readily available’ to the public at the relevant time [of the 2004 application].” *Id.* at 20-21. Notwithstanding the fact that the Office considered enablement and never required Patent Owner to make a deposit during prosecution, the majority adopted Petitioner’s legally flawed analysis that corn harvested from TC1507 was available to the public as of February 2006, i.e., by Barbour’s publication date, but not “as of April 30, 2004, the filing date of the 2004 application.” *Id.* at 15-16. Based on a purported lack of evidence provided by Patent Owner proving otherwise, the majority concluded that enablement did not exist at the time of filing. In contrast, the dissent pointed out the evidence in the record that the majority alleged was missing and correctly determined the Board should have denied institution.

IV. ARGUMENT

Director review of the institution decision is appropriate because the Board abused its discretion in at least two ways. Its decision is based on a fundamentally incorrect conclusion of law. And it made an unsupported and clearly erroneous finding of fact. Each of these errors fundamentally undermines the basis for institution, and for either one of these reasons, Director review should be granted, and the Board’s institution decision should be reversed.

A. The Board Erred as a Matter of Law

The Board considered the question of “known and readily available” to the public “as of the *filing date* of the 2004 application, that is, April 30, 2004.” Maj. Op., 14. This analysis rests on an incorrect conclusion of law and is an abuse of discretion. While it is true that the claims of a patent must be enabled as of their filing date, the statute, controlling precedent, and USPTO regulations and practice do not require access to a biological sample for the purposes of establishing enablement *before* filing or even *during* prosecution of a patent. Rather, access to a biological sample is required only upon issuance. Had the Board considered the status as of issuance, it could not have instituted review because there is no dispute that TC1507 seeds and crops produced from them were available as of issuance.

Specifically, satisfying the enablement requirement with a biological sample “does not require such assured access to a microorganism deposit as of the filing date.”³ *Feldman v. Aunstrup*, 517 F.2d 1351, 1355 (CCPA 1975); *see also In re Lundak*, 773 F.2d 1216, 1221-22 (Fed. Cir. 1985). POPR, 18-19, 26-27. “[W]hat is required is *assurance of access* (to the microorganism culture by the public upon issuance of a patent on the application) prior to or during the pendency of the

³ Patent Owner disagrees that a seed deposit is even relevant to this proceeding since the Examiner did not require one. POPR, 11, 13, 15.

application, so that, *upon issuance* of a U.S. patent on the application, ‘the public will, in fact, receive something in return for the patent grant.’” *Feldman*, 517 F.2d at 1355 (citation omitted). “[T]he function of section 112 in ensuring *complete public disclosure* is only violated if the *disclosure* is not complete *at the time it is made public*, i.e., at the issue date.” *Lundak*, 773 F.2d at 1223 (emphasis in original). While these cases involved situations where biological deposits were made, “[b]iological material need not be deposited, *inter alia*, if it is known and readily available to the public or can be made or isolated without undue experimentation.” 37 C.F.R. § 1.802(b); *see also* M.P.E.P. § 2404.01 (“In an application where the invention required access to specific biological material, an applicant could show that the biological material is accessible because it is known and readily available to the public.”); *In re Wands*, 858 F.2d 731, 736 (Fed. Cir. 1988); POPR, 18-19.⁴

The Board abused its discretion by concluding that Patent Owner was required to show evidence of availability of the TC1507 germplasm *before* the April 30, 2004, filing date. Maj. Op., 16 (“Patent Owner does not point to any evidence that would

⁴ Contrary to the majority’s opinion, Patent Owner identified authority (cases, regulations, and USPTO practice) that extends the law on the deposit of biological material to commercial sales of such material. *Compare* Maj. Op., 18 *with* POPR, 17-25.

persuasively support a finding that [TC1507 was available to the public] as of April 30, 2004.”). The dissent similarly focuses on pre-2004. *See* Dissenting Op., 3 (Patent Owner “identifies multiple admissions by Petitioner and its declarant that TC1507 was known and publicly available in 2003 and, thus, prior to April 2004.”).

Had the Board reviewed the record at the time of issuance as controlling precedent and the USPTO’s own rules require, it could not have instituted this proceeding. The Board itself held that “it is undisputed that corn harvested from TC1507 plants was ‘known and readily available to the public’ by 2010,” which is well in advance of the issue date. Maj. Op., 23; *see also* Sur-reply, 2-3; POPR 17-25. This finding is all that was required to establish enablement as of the April 2004 filing date here, where neither the Petitioner nor Board has questioned the sufficiency of the written description. *See* Pet., 53-59, 64, 67; *see also* Maj. Op., 4-5. And, if that were not enough, Petitioner made no argument that TC1507 was not accessible after issuance and instead admitted that biological material was freely available as early as after the 2003 growing season. Pet., 52 (“[C]orn **harvested** from TC1507 plants continued to express the TC1507 event and was indisputably commercially available following the 2003, 2004, and 2005 growing seasons” and that “[s]uch corn was sold as a commodity—without any contractual restrictions.”);

see also id. at 64, 67; EX1007, ¶ 134.⁵ This too establishes the requisite accessibility well in advance of issuance that Petitioner did not assert has ever gone away.

Therefore, for at least the reason that the Board committed legal error, Director Review is appropriate, and institution should be denied.

B. The Board Made Clearly Erroneous Fact Findings

Even if the Board’s erroneous view of the law controlled, which it does not, it made a clearly erroneous factual finding. The cornerstone of the majority’s institution decision is an alleged absence of any showing of commercial availability of TC1507 “without restriction” before April 2004. *See* Maj. Op., 14. Specifically, the Board contended that “Patent Owner has not produced or pointed to *any evidence* to show TC1507 corn [was] ‘readily available’ to the public without restrictions as of the filing date of the 2004 application.” Maj. Op., 21. The Board’s statement contradicts the record before it.

Patent Owner pointed to numerous pieces of evidence that establish (1) TC1507 seed was sold in 2003, and (2) Petitioner admitted corn harvested from the 2003 growing season “was sold as a commodity—without any contractual

⁵ As Petitioner argued, the availability of the crop without contractual restrictions obviates any need to address Patent Owner’s statements made during European prosecution. Pet., 52.

restrictions” before the April 2004 filing date. Pet., 52. Specifically, Patent Owner identified admissions made by Petitioner and Petitioner’s expert and also pointed to their reliance on numerous documents that Petitioner cited:

- Admissions by Petitioner and Petitioner’s expert that “the TC1507 event had been commercialized under Patent Owner’s ‘Herculex’ trademark and widely planted in the United States over the course of three growing seasons (i.e., **2003**, 2004, and 2005). *E.g.*, POPR, 22 (citing EX1007, ¶¶ 131-134).
- Admissions by Petitioner that “PO had commercialized TC1507 starting in **2003**—making TC1507 germplasm accessible.” POPR, 20 (citing Pet., 5, 49).
- Admissions by Petitioner and Petitioner’s expert that TC1507 was available without restriction. POPR, 20-21 (citing Pet., 52-53 (stating that “corn *harvested* from TC1507 plants continued to express the TC1507 event and was indisputably commercially available following the **2003**, 2004, and 2005 growing seasons” and that “[s]uch corn was sold as a commodity—without any contractual restrictions”); EX1007, ¶ 134).
- Admissions by Petitioner and Petitioner’s expert that “POSAs could have identified TC1507 in bulk corn (i.e., following harvest) sold commercially prior to July 6, 2006.” POPR, 21 (citing Pet., 53; EX1007, ¶ 135); *see also* POPR, 28 (citing Pet., 53-55, 64, 67; EX1007, ¶¶ 135-140).

- Admissions by Petitioner’s expert that “a POSA could have screened commercially available bulk corn from the **2003**, 2004, or 2005 growing season ... and thereby gained possession of TC1507 as claimed.” POPR, 24 (citing Pet., 55; EX1007, ¶¶ 140, 146); *see also* POPR, 23.
- Petitioner’s arguments that “the TC1507 event embodying the claimed DNA sequences was commercially available” and “cites numerous publications reporting that TC1507 had been commercialized” even in 2003. POPR, 35 (citing Pet., 49-51; EX1007, ¶¶ 131-133).
- Petitioner’s reliance on evidence “of this common knowledge in **2003**.” POPR, 35 (citing Pet., 50).
- Petitioner’s reliance on “other publications [that] referred to the availability of TC1507, rendering it known,” including in 2003. *E.g.*, POPR, 21 (citing Pet., 50 (referring to, *e.g.*, EX1011, 1127 USDA report noting that Patent Owner had “commercialized” Herculex in FY**2003**)).
- Record evidence in the form of a third-party patent application filed in **April 2003** noting that Patent Owner had commercialized Herculex I (*i.e.*, TC1507 event). POPR, 21 (quoting EX1038, ¶ 119).

As a result, Patent Owner pointed out ample evidence showing that seeds embodying the TC1507 event were sold in 2003 and led to crops that Petitioner admits were sold as a commodity without restriction, including after the 2003

growing season. The dissent agreed stating that, “the Preliminary Response identifies multiple admissions by Petitioner and its declarant that TC1507 was known and publicly available in 2003 and, thus, prior to April 2004.” Dissenting Op., 3. Accordingly, the majority’s finding “that TC1507 was commercially available and without restriction *only as of February 2006*” is clearly erroneous. Maj. Op., 14; *Donner Tech., LLC v. Pro Stage Gear, LLC*, 979 F.3d 1353, 1359 (Fed. Cir. 2020) (reasoning that the Board erred by mistakenly concluding that Petitioner did not provide evidence when the record showed the contrary). Indeed, Petitioner itself never asserted that TC1507 germplasm became accessible *only* as of February 2006. In fact, Petitioner asserted that “PO commercialized TC1507 starting in 2003—making TC1507 germplasm accessible *years before* the July 2006 critical date.” Pet., 5. The Board’s inexplicable conclusion to the contrary without providing any rationale or support to contradict TC1507’s availability in 2003 is therefore clearly erroneous.

Compounding that error, which supports Director review and a reversal of institution on its own, the Board impermissibly ignored Petitioner’s evidence that supports non-institution under its own reasoning. Specifically, the Board did not consider or cite in its institution decision:

- Petitioner’s evidence that “TC1507” was among the “seed products available for the 2004 planting season.” EX1049, 8; Pet., 50; EX1007, ¶ 133.

- Petitioner’s evidence in the form of SEC filings from **August 2003** noting availability of a test kit able to detect “Cry1F Herculex™.” EX1044, 14-15; EX1045; Pet., 55-56; EX1007, ¶ 141.
- Petitioner’s evidence in the form of reports from **February 2003** (EX1048), **October 2003** (EX1051), **November 2003** (EX1052), and **December 2003** (EX1053) noting the availability of TC1507/Herculex I and a kit able to detect Cry1F (Herculex). Pet., 50-51, 56; EX1007, ¶¶ 133, 141.
- Petitioner’s evidence in the form of SEC filing from February 2004 that referenced “strong growth” in “new products” such as “Herculex I insect protection.” EX1040, 30; Pet., 50.

While the “Board is not required to discuss every piece of evidence,” it cannot “disregard [evidence] without explanation” or “short-cut its consideration of the factual record before it.” *Princeton Vanguard, LLC v. Frito-Lay N. Am., Inc.*, 786 F.3d 960, 970 (Fed. Cir. 2015). The majority also ignored Petitioner’s admission that corn sold as a commodity after the 2003 growing season, i.e., before April 2004, was available “without any contractual restrictions.” Pet., 52. The majority offers no explanation for ignoring this admission. *Cook Grp.*, 809 F. App’x at 999-1000 (holding that a party admission “is evidence appropriately considered by a factfinder”); *Princeton Vanguard*, 786 F.3d at 970 (remanding to the Board to properly consider “all of the evidence of record”).

If the majority had considered this evidence and Petitioner’s admissions, it could have reached only one conclusion, Patent Owner has sufficiently “demonstrate[d] enablement of the 2004 application” because “TC1507 became publicly available ... certainly before the end of 2003,” and therefore institution should be denied. *See* Dissenting Op., 1-3.

By overlooking Petitioner’s admissions and failing to address all record evidence, the Board committed legal error that violates both the Administrative Procedure Act and Federal Circuit precedent. *See Aqua Prods.*, 872 F.3d at 1325; *see also* 5 U.S.C. § 554(c)(1). Here, the Board did precisely what it is precluded from doing—it failed to consider material evidence in the Petition and the Preliminary Response without providing an explanation for ignoring it. The Board’s finding therefore lacks adequate reasoning or bases and is an abuse of discretion. *See, e.g., Ultratec*, 872 F.3d at 1275 (finding the Board’s refusal to consider material evidence and failure to explain its decision to exclude the evidence an abuse of discretion); *Weber, Inc.*, IPR2022-00599, Paper 74 at 5-6 (Director finding the Board should have considered Patent Owner’s evidence in support of its patentability arguments or excluded the evidence).

V. CONCLUSION

Patent Owner respectfully requests Director review of the Board’s decision, reversal of it, and remand to the Board with instructions to deny institution.

Respectfully submitted,

Dated: December 30, 2024

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing **Patent Owner's Request for Director Review** was served on December 30, 2024, via e-mail directed to counsel of record for the Petitioner at the following:

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