

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

INARI AGRICULTURE, INC.,
Petitioner,

v.

CORTEVA AGRISCIENCE LLC,
Patent Owner.

PGR2023-00022
Patent 11,371,055

PATENT OWNER'S SUR-REPLY

I. Introduction

Petitioner's Reply incorrectly attempts to analogize this case to *Amgen*. That misplaced reliance is rooted in Petitioner's fundamental misunderstanding of the '055 patent claims and their structural limitations, which Petitioner fails to meaningfully address here or in the Petition. Indeed, Petitioner identifies no case finding structurally defined claims requiring a high level of sequence identity nonenabled, let alone claims that additionally recite an active site motif, as here. Petitioner also fails to address—much less rebut—recent Board decisions cited in the POPR that upheld such claims. Instead, Petitioner's challenge rests on a bare numerosity theory (e.g., alleging 10^{106} possible sequences) that the Board and other courts have repeatedly rejected, while nowhere disputing that any experimentation would have been routine as Dr. Silverstone acknowledged in earlier representations to the Office. POPR, 52. Corteva respectfully requests that the Petition be denied.

II. Petitioner's Reliance on *Amgen* Is Misplaced

In its Reply, Petitioner again fails to properly evaluate the scope of the '055 patent claims—particularly their combination of two structural limitations. Petitioner nowhere addresses, either in the Petition or Reply, the '055 patent's disclosure that the claimed levels of sequence identity (i.e., at least 85%) are “***highly identical***” within this technical field—not “vast” or a “wide range” as Petitioner asserts. Ex. 1001, 31:61-32:4 (differentiating between “highly identical (85-98%)”

and “low identity (23-32%) at the amino acid level”); Reply, 1, 3. Far from 85% being an “arbitrary number” as Petitioner contends (Reply, 1), the ’055 patent also discloses that proteins having such high similarity “*would be expected to retain similar properties*”—a disclosure Petitioner never addresses. Ex. 1001, 32:3-6. The challenged claims then further recite the active site motif of five amino acids: ***HX₁₀₉D(X)₁₁₁₋₁₃₄T(X)₁₃₆₋₂₆₁H(X)₂₆₃₋₂₇₂R***. *Id.*, 11:1-6 (these conserved motif residues comprise “the active site that is essential for catalytic activity”).

Amgen presented a distinctly different situation, as those claims recited no amino acid sequence limitations that characterized the claimed antibodies. *Amgen Inc. v. Sanofi, Aventisub LLC*, 598 U.S. 594, 615 (2023) (*Amgen*’s claims were “defined by their function”). The claims in *Amgen* thus encompassed *any antibody that works*, regardless of structure, leaving skilled artisans to experiment well beyond antibodies highly identical to those disclosed in *Amgen*’s specification.

Here, in contrast, the AAD-12 proteins within the scope of the claims are confined by the “at least 85% sequence identity” limitation—a highly identical level that the specification describes as being “expected to have similar activity.” Ex. 1001, 32:3-6. The situation here is thus unlike those in *Amgen* and *Idenix*. See *Idenix Pharms. LLC v. Gilead Sci. Inc.*, 941 F.3d 1149, 1162 (Fed. Cir. 2019) (a skilled artisan would need to search a “large number” of 2’-methyl-up nucleosides to identify the “small” number that treat HCV); *Amgen*, 598 U.S. at 611, 613 (no

“general quality” running through the genus). Indeed, against the structural disclosures of the ’055 patent, Petitioner presents only its declarant’s mere say-so that some AAD-12 proteins meeting the structural limitations of the claims would be better, worse, or similarly effective. *E.g.*, Ex. 1003, ¶¶ 82, 79 (citing no evidence). Such conclusory, unsupported testimony is insufficient to meet Petitioner’s burden at institution. 37 CFR § 42.65(a) (“Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight.”); *Sandoz Inc. v. Boehringer Ingelheim Int’l GmbH*, PGR2022-00037, Paper 11 at 28 (PTAB Nov. 7, 2022) (denying petition based on speculative, insufficient declarant testimony).¹

This case thus presents the very type of situation in which the Board and courts have required a challenger to present some identification of embodiments that are

¹ Petitioner also overstates the testimony in Dr. Silverstone’s declaration. Citing paragraphs 76-79, Petitioner contends that “many proteins otherwise satisfying claim 1 do **not** achieve the claimed functions.” Reply at 1. But that is not what Dr. Silverstone said. Without any citations (a common theme in his declaration), he more equivocally stated that “not all of these will function as an effective synthetic auxin degradative enzyme *that can be expressed well in crop plants*” and focused on a higher threshold of “similar activity.” Ex. 1003, ¶ 79.

nonenabled. But that is something Petitioner plainly failed to do. *See id.* (“[I]t is Petitioner’s burden on this issue, and we are not persuaded that the concerns raised by [Petitioner’s declarant] provide sufficient evidence of actual [nonenablement] to justify institution on this record.”) (citing *Atlas Powder Co. v. E. I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1577 (Fed. Cir. 1984)); POPR at 45-46.

The structural limitations of the challenged claims are also not a “loophole” as Petitioner asserts (Reply at 4)—their proper consideration is a necessary aspect of analyzing enablement. *See* POPR at 47-48; *Amgen*, 598 U.S. at 611; *Sandoz*, PGR2022-00037, Paper 13 at 7 (denying institution for failure to analyze enablement of the claimed subject matter “as a whole”). Neither the Petition nor the Reply cites any case finding lack of enablement for claims limited to high sequence identities, let alone when paired with an additional active site motif limitation.

In *Lifescan*, for example, the Board declined to adopt a Petitioner’s enablement arguments where the claims required 90% sequence identity and six particular amino acids were “necessary” to the claimed function. *Lifescan Glob. Corp. v. Ikeda Food Rsch., Ltd.*, PGR2019-00032, Paper 11 at 18-24, 29 (PTAB Aug. 15, 2019) (finding that “it was routine to obtain homologues and variants” and a skilled artisan “would have an understanding of which portions of the claimed sequence were critical to its function”). In *Campbell*, the Board similarly reversed a written description rejection of claims requiring 90% sequence identity. *Ex parte*

Campbell, No. 2021-000865, Decision on Appeal at 4-5 (PTAB July 20, 2021).

Petitioner's Reply fails to address—much less distinguish—either *Lifescan* or *Campbell*, which are far more analogous than *Amgen* or *Idenix*.

III. Petitioner's Numerosity Theory Should Be Rejected

The Reply continues to rehash the same type of numerosity theory that the Board has previously rejected, and Petitioner's repetition of that argument renders it no stronger. Reply, 1, 2, 4, 5 (alleging 10^{106} possible protein sequences); *Lifescan*, PGR2019-00032, Paper 11 at 18-24 (declining to adopt enablement argument based on 10^{76} possible sequences); *Sandoz Inc.*, PGR2022-00037, Paper 11 at 19, 25, 28; *see also Ex parte Campbell*, No. 2021-000865, Decision on Appeal at 14-15 (rejecting written-description argument based on two quadrillion possible sequences). These analogous Board decisions stand in good company with other decisions that likewise rejected numerosity-based theories in enablement challenges. *See* POPR at 48-49; *In re Depomed Pat. Litig.*, No. 13-4507 (CCC-MF), 2016 WL 7163647, at *44 (D.N.J. Sept. 30, 2016) (holding that enablement does not require “the making and testing of every one of the 11 million species”), *aff'd*, 919 F.3d 1333 (Fed. Cir. 2019). Petitioner addresses none of these cases in its Reply.

Petitioner's reliance on *Idenix* fails to remedy the deficiencies of its numerosity theory. The record in *Idenix* was replete with evidence illustrating nonenabled embodiments, including “toxic” 2'-methyl up nucleosides. *Idenix*

Pharms. LLC v. Gilead Sci., Inc., 2018 WL 922125, at *11, 14 (D. Del. Feb. 16, 2018). Here, Petitioner presented no such evidence. Moreover, even with its unsupported necessary-but-not-sufficient theory that focuses on the AAD-12 motif in isolation (i.e., divorced from the at least 85% sequence identity limitation), Petitioner nowhere disputes that Dr. Silverstone’s conclusory analysis was directed to *unclaimed* enzymes and failed to analyze the AAD-12 proteins within the scope of the challenged claims. POPR, 38-39.

IV. Petitioner Failed to Establish PGR Eligibility

The threshold issue of PGR eligibility—which Petitioner never sought authorization to address—is not about what could be enabled in 2017 versus an earlier date. Petitioner had the burden of establishing PGR eligibility by addressing § 112 compliance as of the ’055 patent’s pre-AIA filing dates but failed to meet that burden. POPR, 21-26. It is insufficient to merely *assume* that the ’055 patent is PGR eligible, as Petitioner did. *Id.*, 23; Reply at 3 n.2 (acknowledging Petitioner only analyzed Corteva’s disclosure “as of 2017”). Binding precedent requires analyzing § 112 compliance as of the relevant filing dates—not against later developments in the art as of 2017—which alone justifies denying the Petition. POPR, 22 (citing *Ariad* and *Union Carbide*); *In re Hogan*, 559 F.2d 595, 606-07 (CCPA 1977) (criticizing the “erroneous use of a later state of the art in determining enablement”).

Corteva thus respectfully requests that the Board deny institution.

Dated: August 25, 2023

/Pier D. DeRoo/
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CERTIFICATE OF SERVICE

The undersigned certifies that a copy of the foregoing **Patent Owner's Sur-Reply** was served electronically via email on August 25, 2023, in its entirety on the following:

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Dated: August 25, 2023

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