

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MICROBIOTICA, LIMITED,
Petitioner

v.

BOARD OF REGENTS, THE UNIVERSITY OF TEXAS SYSTEM,
Patent Owner

Case PGR2023-00026
U.S. Patent No. 11,395,838

**PATENT OWNER'S SUR-REPLY IN SUPPORT OF
PATENT OWNER'S PRELIMINARY RESPONSE**

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I. INTRODUCTION

Nothing in the Reply rescues the Petition from its deficiencies.

First, both the Petition and the Reply fail to show that practicing the invention would have necessitated *undue* experimentation. *Amgen* did not alleviate Petitioner of its burden to show the need for undue experimentation—it merely confirmed that the legal principles for enablement have remained the same for the last 150 years. The Examiner applied these same 150-year-old legal principles in finding the claims enabled, and Petitioner remains unable to identify *any* material error on the Examiner’s part.

Second, Petitioner is unable to dispute the cumulativeness of the references and unable to identify a material error made during prosecution despite its renewed chance to do so. Instead, Petitioner asks the Board to conduct a faulty § 325(d) analysis based on the references’ *claims* (rather than their disclosures as a whole), and merely repeats the Petition’s complaint that the Examiner did not consider the exact *combination* of references relied upon in the Petition. Such treatment of the art fails to satisfy Petitioner’s burden under *Advanced Bionics*.

Third, the Reply misapplies the law on post-filing date data by myopically comparing Baruch and Davar only to the specification’s *working examples*. But Petitioner is unable to refute that Baruch and Davar demonstrated that embodiments of the claimed invention could be practiced readily with successful

results, confirming enablement. Petitioner’s unpatentability challenge is unfounded in both law and fact, and the Board should deny trial.

II. PETITIONER FAILED TO SATISFY ITS BURDEN TO DEMONSTRATE LACK OF ENABLEMENT

A. *Amgen* did not alleviate Petitioner of its burden to demonstrate that any necessary experimentation would have been “undue”

Although Petitioner implies that *Amgen v. Sanofi*, 598 U.S. 594, 610–12 (2023), provides a new basis for finding the challenged claims unpatentable, *Amgen* did not change the law. As the *Supreme Court* explained, the legal principles regarding enablement have remained “the same” “[f]or more than 150 years.” *Id.* at 616. And, under long-standing law that went unchanged by *Amgen*, Petitioner bears the burden to show that practicing the invention would necessitate *undue experimentation*.¹ 35 U.S.C. § 322(a)(3). The Petitioner failed to meet that burden.

¹*In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988) (“it is well established that enablement requires that the specification teach those in the art to make and use the invention without undue experimentation”); *Baxalta Inc. v. Genentech, Inc.*, No. 22-1461, slip op. at 2 (Fed. Cir. Sept. 20, 2023) finding *Amgen* “did not disturb the *Wands* factors” and discerning “no meaningful difference between *Wands*’ ‘undue experimentation’ and *Amgen*’s ‘unreasonable experimentation’ standards.” *Baxalta*, slip op. at 10 n.4.

B. Petitioner failed to meet the burden to show that any experimentation would have been “undue”

As an initial matter, Petitioner’s enablement ground is deficient because it merely refers back to its written description ground, leaving it to the Board and Patent Owner to guess how Petitioner’s written description and enablement challenges may or may not overlap. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1340 (Fed. Cir. 2010) (en banc) (“a written description requirement [is] separate from enablement”). Petitioner’s arguments in Ground 2 merely state, “As set forth in §VII.A” and “in view of the foregoing...” Petition, 47. The Board previously declined to institute trial when a petition left it “to the Board to ascertain what gaps to fill.” *Apple, Inc., v. Contentguard Holdings, Inc.*, No. IPR2015-00357, Paper 9, at 9 (P.T.A.B. June 29, 2015). Likewise, the Board should decline to institute trial here, where Petitioner merely invites the Board and Patent Owner to speculate regarding the basis of its enablement challenge.

Dr. Robinson’s declaration is of no avail. Dr. Robinson merely repeats, ***verbatim***, the conclusory assertions it allegedly supports (compare Petition, 47, last paragraph, and EX1003, ¶143). Even the entirety of Dr. Robinson’s opinions on written description (¶¶110-142), which are referenced in his enablement section (¶143), are a ***verbatim*** copy of the Petition (Petition, 31-47). Dr. Robinson does not offer any evidence to support the stated conclusions. POPR, 62. Such “conclusory and unsupported” declaration testimony “is entitled to little weight.” *Xerox Corp.*

v. Bytemark, Inc., IPR2022-00624, Paper 9, at 15 (P.T.A.B. Aug. 24, 2022); 37

C.F.R. § 42.65(a).

At most, Petitioner and Dr. Robinson argue that the '838 Patent fails to teach a POSA how to make and use the claimed invention without “considerable” experimentation. Petition, 47. But a “considerable amount of experimentation is permissible, if it is merely routine.” *PPG Indus., Inc. v. Guardian Indus. Corp.*, 75 F.3d 1558, 1564 (Fed. Cir. 1996); *Falko-Gunter Falkner v. Inglis*, 448 F.3d 1357, 1365 (Fed. Cir. 2006) (agreeing with the Board that “the mere fact that the experimentation may have been difficult and time consuming does not mandate a conclusion that such experimentation would have been considered to be ‘undue’ in this art”). Petitioner does not provide any evidence that the alleged “considerable” experimentation would have been anything other than routine, particularly in view of Petitioner’s statement that a POSA would have known “how to formulate and administer [bacterial] compositions.” Petition, 61; EX1003, ¶168; POPR, 63. Indeed, Petitioner does not assess the nature of the experimentation or consider and weigh the *Wands* factors. *In re Wands*, 858 F.2d at 737 (“The key word is ‘undue,’ not ‘experimentation’”). Petitioner’s failure to establish why any necessary experimentation would have been undue renders Petitioner’s enablement ground defective.

Having failed to show a need for undue experimentation in its Petition,

Petitioner attempts to use its Reply to make up for the Petition's deficiencies.

Petitioner now alleges that courts are "finding functional genus claims, like the ones at issue here, invalid under §112." Reply, 6. But the Petitioner provides no evidence that the challenged claims are like to those in *Amgen*, *Baxalta*, or *Eli Lilly*, each of which concerned making and screening antibodies. *Amgen*, 598 U.S. at 610-12; *Baxalta*, slip op. at 3; Plaintiff's Response to Eli Lilly and Company's Notice of Supplemental Authority, *Eli Lilly & Co. v. Teva Pharmaceuticals International GmbH*, No. 1:18-cv-12029 (D. Mass, Sept. 26, 2023, ECF No. 694. As the court stated in *Amgen*, enablement "depend[s] on the nature of the invention and the underlying art." 598 U.S. at 612. Petitioner's attorney argument that the claims here are like those in *Amgen*, *Baxalta*, and *Eli Lilly* "is not evidence," and it is "not sufficient to meet Petitioner's burden" under 35 U.S.C. § 322(a)(3). *Icon Health & Fitness, Inc. v. Strava Inc.*, 849 F.3d 1034, 1043 (Fed. Cir. 2017); *Instrumentation Lab'y Co. v. HemoSonics LLC*, PGR2019-00047, Paper 8, at 22 (P.T.A.B. Oct. 24, 2019). Similarly, Petitioner's attorney argument that "a POSA is left to engage in 'painstaking experimentation,'" is a misleading use of a quote from *Amgen* that is not supported by the evidentiary record in this case. Reply, 5. Nothing in the Reply overcomes the Petition's and Dr. Robinson's failure to establish that undue experimentation is required to practice *the claimed* invention.

C. Petitioner failed to show that the Examiner erred in finding the claims enabled

Petitioner failed to meet its burden under 35 U.S.C. § 325(d) for Ground 2. Prosecution of the '838 Patent concluded after publication of the Federal Circuit's 2021 *Amgen* decision that the Supreme Court subsequently affirmed. *Amgen*, 598 U.S. at 610-12. Thus, the Examiner resolved any issues of enablement by applying the same legal principles that remain in effect today. POPR, 22-23. Petitioner certainly has not identified any holding in *Amgen* that is different from the legal framework that the Examiner used to assess enablement during prosecution.

Moreover, Petitioner failed to show that the Examiner made any error material to patentability. *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6, at 8-9 (P.T.A.B. Feb. 13, 2020) (precedential). Petitioner merely alleged that “[i]n failing to identify and consider these Section 112 issues [presented in the Petition], the Examiner materially erred.” Petition, 87-88; POPR, 23-24. But a general allegation that the Examiner failed to identify and consider Petitioner's arguments and evidence is insufficient to show material error. *Pharmacosmos A/S v. American Regent, Inc.*, PGR2020-0009, Paper 17, at 26 (P.T.A.B. Aug. 14, 2020); POPR, 23-24.

D. Petitioner failed to show that the claimed genus is missing a “general quality” under *Amgen*

Petitioner argues that the specification failed to disclose any “general

quality” because “bacteria from the family Ruminococcaceae were found to be ... not significantly enriched in either the ‘responder’ or ‘non-responder’ fecal samples.” Reply, 5. But data in the specification belie Petitioner’s allegation. POPR, 54; EX2001, ¶¶65. Dr. Garrett’s unrefuted testimony explains that the data demonstrate that “Ruminococcaceae were consistently the most differentially-abundant gut bacteria in responder patients, which was shown with a high degree of statistical significance ($p < 0.001$) and effect size.” EX2001, ¶¶65; POPR, 55. Dr. Robinson does not, and cannot, dispute this fact. At most, Dr. Robinson testified that “bacteria from the family Ruminococcaceae were found in both the ‘responder’ and ‘non-responder’ fecal samples.” EX1003, ¶¶115, 132-133; Petition, 34. But the presence of some Ruminococcaceae species in non-responders does not undermine the finding that the gut microbiome from responders was “significantly enriched” with Ruminococcaceae. EX2001, ¶¶65-66; POPR, 55. It is thus the abundance of Ruminococcaceae that is the “general quality” that gives the claimed population of bacteria belonging to the family Ruminococcaceae “a peculiar fitness for the particular purpose”—reducing or delaying a skin cancer tumor growth. EX2001, ¶¶58, 61-63, 65-66, 72-74; POPR, 50, 64-66. And Petitioner failed to show otherwise.

The remainder of Petitioner’s Reply arguments do not resuscitate the enablement ground. For example, Petitioner argues that the examples in the patent

do not disclose “what bacteria were administered” (Reply, 4). But as Dr. Garrett’s unrefuted testimony demonstrates, the administered FMT samples “were clearly enriched for Ruminococcaceae on all taxonomic levels.” EX2001, ¶¶58, 65; POPR, 55. Petitioner characterized the challenged claims as “near limitless” (Reply, 3), but they are not. Petitioner’s only support for its argument is Dr. Robinson’s verbatim reiteration of the Petition’s argument, which is inadequate under *Xerox*. Petition, 1-3, 31-32, 36-38 (citing to EX1003, ¶¶ 57-59, 110-111, 118, 124). And Petitioner’s recycled “Ruminococcaceae ... was a moving target” argument (Reply, 4, n.2) again fails to show any ambiguity regarding the scope of Ruminococcaceae as of the actual filing date of the ’838 Patent. POPR, 69; EX2001, ¶78.

III. PETITIONER’S REPLY UNDERSCORES PETITIONER’S FAILURE TO MEET ITS BURDEN UNDER *ADVANCED BIONICS*

Petitioner alleges that Patent Owner mischaracterized Honda and Tokyo because i) the two references are not related and ii) the claims of Honda are different from those of Tokyo. Reply, 7-8. Petitioner’s allegations only highlight Petitioner’s failure to meet its burden under *Advanced Bionics*. *Advanced Bionics, LLC*, Paper 6, at 7-8.

First, the absence of a priority relationship between Honda and Tokyo is inapposite to whether the references are the same or substantially the same under *Advanced Bionics*, and Petitioner cites to no legal authority in support. Reply, 7.

The correct inquiry includes assessing “the cumulative nature of the asserted art and the prior art evaluated during examination.” *Advanced Bionics, LLC*, Paper 6, at 9 n.10. Neither Petitioner nor Dr. Robinson performed this assessment. POPR, 38-39; Reply, 7. Dr. Garrett’s testimony that Honda is cumulative to Tokyo remains unrefuted. POPR, 30-32, EX2001, ¶¶91-93.

Second, Petitioner erroneously limits its analysis to the disclosure of Tokyo’s and Honda’s *claims*. Reply, 7-8. Because “[i]t is presumed that public officials do their assigned jobs,” the Examiner is presumed to have considered Tokyo “in its entirety, i.e., as a whole.” *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1568 (Fed. Cir. 1987); *Northern Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 939 (Fed Cir. 1990). Petitioner provides no evidentiary support for its assumption that the Examiner myopically considered only the claims of Tokyo. On this record, Dr. Garrett’s testimony stands unrefuted: Tokyo’s disclosure, *as a whole*, teaches treating *cancer* using its bacterial compositions; Petitioner relies on Honda for the same teaching. EX2001, ¶¶65-66; EX2012, ¶¶97, 132.

Petitioner also shows no material error, arguing only that the Examiner “could not have considered Honda in combination with the teachings of Gajewski and Miquel.” Reply, 8. The Board has repeatedly rejected arguments of an alleged error based on a particular combination of references. *Dorco Co. v. The Gillette Co.*, IPR2017-00500, Paper 7, at 15-16 (P.T.A.B. June 21, 2017) (denying

institution where Petitioner merely “substituted” references for their obviousness argument); POPR, 33-34.

IV. PETITIONER FAILS TO DEMONSTRATE THAT PATENT OWNER MISUSED POST-FILING ART TO SUPPORT ENABLEMENT

Petitioner alleges that Patent Owner’s use of post-filing art to evidence enablement is “factually and legally incorrect.” Reply, 8. But it is Petitioner who misapplies the law. Petitioner does not dispute that Baruch/Davar’s methods fall within the claims’ scope or yield positive results, but instead argues that the methods “are not ‘commensurate in scope’ with those in the ’838 Patent” because they differ from “the mouse experiments.” Reply, 9. Petitioner thereby improperly limits its analysis to the mouse experiments. As such, Dr. Garrett’s testimony that both Baruch and Davar successfully followed the FMT procedure “described and claimed” in the ’838 Patent remains unrefuted. POPR, 65-66; EX2001, ¶¶73-74.

Petitioner also argues that neither Baruch nor Davar “is sufficient to enable the full scope of the Claims.” Reply, 10. Petitioner misapprehends Patent Owner’s reliance on the post-filing art: Patent Owner properly used Baruch and Davar “to prove that the [’838 Patent] disclosure was in fact enabling when filed,” not to show that Baruch or Davar enabled the claims. *In re Brana*, 51 F.3d 1560, 1566–67 n.19 (Fed. Cir. 1995); POPR, 64-66; EX2001, ¶¶73-74. Petitioner’s arguments are misplaced and must be rejected. And the Board should deny trial in view of the Petition’s multiple defects.

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that the foregoing **PATENT OWNER'S
SUR-REPLY IN SUPPORT OF PATENT OWNER'S PRELIMINARY
RESPONSE** was served electronically via e-mail on October 12, 2023, in its
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