

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMGEN INC.,
Petitioner

v.

BRISTOL-MYERS SQUIBB COMPANY,
Patent Owner

IPR2025-00601
Patent No. 9,856,320

**PATENT OWNER'S AUTHORIZED RESPONSE TO
DIRECTOR REVIEW REQUEST**

TABLE OF CONTENTS

	Page
I. INTRODUCTION	1
II. PETITIONER PROVIDES NO CREDIBLE GROUNDS FOR DIRECTOR REVIEW	4
A. Petitioner Fails to Explain How European Patent Prosecution Unsettled PO’s Expectations in the Validity of its U.S. Patent	4
B. Petitioner’s “Changed Circumstances” Argument is Irrelevant and Wholly Without Merit	8
C. Petitioner’s Assertion That PO Should Have Expected an IPR Petition Makes No Sense.....	11
D. There is No Public Interest in Advancing Petitioner’s Facially Deficient Petition Even if Petitioner Develops Biosimilars.....	12
E. Petitioner’s Cursory and Rehashed Constitutionality Challenge Does Not Support Director Review	13
III. CONCLUSION	14

TABLE OF AUTHORITIES

Page(s)

Cases

<i>AIA Engineering, Ltd. v. Magotteaux Int’l.</i> , 657 F.3d 1264 (Fed. Cir. 2011)	5
<i>Bestway USA Inc. v. Intex Marketing Ltd.</i> , PGR2024-00036, Paper 9 (PTAB Oct. 28, 2024)	10
<i>Bose Corp. v. Koss Corp.</i> , IPR2021-00297, Paper 41 (PTAB May 31, 2022)	5
<i>Cambridge Indus. USA Inc. v. Applied Optoelectronics, Inc.</i> , IPR2025-00433, Paper 13 (Req. Dir. Rev. filed July 21, 2025).....	8
<i>Dabico Airport Sol’ns Inc. v. AXA Power APS</i> , IPR2025-00408, Paper 22 (Req. Dir. Rev. filed July 16, 2025).....	8
<i>Dabico Airport Sol’ns Inc. v. AXA Power APS</i> , IPR2025-00408, Paper 24 (PTAB Aug. 21, 2025).....	6
<i>Gillette Co. v. Energizer Holdings, Inc.</i> , 405 F.3d 1367 (Fed. Cir. 2005)	5
<i>iRhythm Techs., Inc. v. Welch Allyn, Inc.</i> , IPR2025-00376, Paper 11 (Req. Dir. Rev. filed July 3, 2025).....	8
<i>Medtronic, Inc. v. Daig Corp.</i> , 789 F.2d 903 (Fed. Cir. 1986)	5
<i>Momenta Pharms, Inc. v. Bristol-Myers Squibb Co.</i> , 915 F.3d 764 (Fed. Cir. 2019)	12
<i>Pfizer Inc. v. Ranbaxy Labs.</i> , 457 F.3d 1284 (Fed. Cir. 2006)	5
<i>Replimmune Ltd. v. Amgen, Inc.</i> , IPR2023-00106, Paper 8 (POPR filed Feb. 22, 2023).....	10

Statutes

35 U.S.C. § 282	11
-----------------------	----

Other Authorities

Director Review Process § 3.E (<i>available at</i> https://www.uspto.gov/patents/ptab/decisions/director-review- process)	4, 6
---	------

I. INTRODUCTION

In its Request for Director Review (Paper 10) (“Request”), Petitioner fails to meet its burden to identify any credible basis for upsetting the Director’s decision to discretionarily deny institution of *inter partes* review of U.S. Patent No. 9,856,320 (“the ’320 Patent”). There are no important issues of law or policy, no erroneous findings of material fact, no erroneous conclusions of law, and no alleged abuses of discretion.

Instead, Petitioner attempts to assert in its Request that Patent Owner (“PO”) had no settled expectations that the claims at issue here were patentable based on (1) conclusory arguments by Petitioner regarding different claims in different patent applications undergoing prosecution in Europe, which are necessarily subject to different laws; (2) that PO chose to disclaim claims—in a different matter involving a different patent—after PO’s FDA approval changed and many of the claims no longer covered PO’s product, claims that are not related to the patent at issue in this case; and (3) the mere existence of the BPCIA litigation framework.

Unable to demonstrate some material error bearing on the merits of its Petition, Petitioner vaguely accuses the Director of “misapprehending” and “overlooking” facts. The Director did no such thing. The Director necessarily considered all of the parties’ arguments and exercised her discretion to deny institution. *See* Paper 9. Specifically, the Director made her decision based on the

totality of the evidence and arguments presented, which include Petitioner's (1) failure to identify a limitation in the asserted art for Ground 2, (2) failure to show that a POSA would have combined the asserted references with a reasonable expectation of success for both grounds, (3) reliance on art considered by the Examiner during prosecution, and (4) failure to show that the Examiner made a mistake during prosecution.

Petitioner makes little mention of the merits of *its Petition* in its Request. It similarly ran away from defending the substance of its Petition in its Opposition to Discretionary Denial ("Opposition"), burying its responses to PO's Section 325(d) and merits challenges in Sections V and VI of the Opposition. Here, Petitioner disagrees that PO's long-settled expectations in its '320 Patent should factor into the Director's denial of institution. According to Petitioner, PO's *ongoing* European prosecution of a related patent somehow unsettled PO's settled expectations about the '320 Patent.¹ But Petitioner fails to explain why the EPO's application of European law in relation to different claims in different patent applications could undermine PO's settled expectations in the validity of the '320 Patent. Petitioner

¹ In FN1, Petitioner argues that PO overcame the Examiner's rejection based on NCT01024231 "based on its date." Request at 1. As discussed below, this statement blatantly mischaracterizes the prosecution history.

does not even cite a single statement made by PO during European prosecution to support its allegations. Instead, Petitioner suggests PO lost its settled expectations in the '320 Patent. Of course, Petitioner also fails to mention that the subject matter of the '320 Patent reflects years of investment research and clinical development. EX2001; EX2002; EX2003; EX2004. Petitioner's suggestion that PO lost its settled expectations in the '320 Patent because of European prosecution is absurd.

Even more absurd are Petitioner's unsubstantiated allegations of "gamesmanship" and misconduct because PO disclaimed an unrelated patent at issue in a different, unrelated IPR petition. That petition challenged a different patent with different claims and a different priority date and involved totally different asserted art. PO's disclaimer of claims in that patent is totally irrelevant here.

Finally, Petitioner repeats the same failed policy arguments it presented in its Opposition to Discretionary Denial. PO explained why those arguments are wrong in its Discretionary Denial Request. Paper 6 at 40-43. Yet Petitioner again incorrectly suggests that allowing its facially defective Petition to proceed will allegedly bring biosimilars to market sooner. The Director already considered Petitioner's policy arguments and rejected them. Petitioner's dissatisfaction with that result does not warrant Director Review.

Petitioner filed a flawed Petition challenging the patentability of a patent for which PO possesses strong settled expectations. Nothing in Petitioner's Request supports disrupting those settled expectations. The Request should be denied.

II. PETITIONER PROVIDES NO CREDIBLE GROUNDS FOR DIRECTOR REVIEW

The Director has identified four bases for which Director Review may be appropriate: (a) an abuse of discretion, (b) important issues of law or policy, (c) erroneous findings of material fact, or (d) erroneous conclusions of law. Petitioner does not meaningfully attempt to argue any of these bases. Instead, Petitioner focuses its arguments on relitigating how the Director exercised her discretion to deny the Petition. That is not sufficient for Director Review.

A. Petitioner Fails to Explain How European Patent Prosecution Unsettled PO's Expectations in the Validity of its U.S. Patent

Petitioner rehashes its argument that prosecution of related patent applications in Europe should be viewed as evidence of an error by the Examiner in allowing the claims of the '320 Patent and then suggests for the first time, that those events should be deemed to have "unsettled" PO's settled expectations in the '320 Patent. Paper 8 at 28; Request at 4. Petitioner's argument that European prosecution disrupted PO's settled expectations in the '320 Patent lacks merit, and, in any event, is waived. *See* Director Review Process § 3.E (*available at <https://www.uspto.gov/patents/ptab/decisions/director-review-process>*). Petitioner's

allegation that the European prosecution shows a clear error by the Examiner is equally without merit.

First, European prosecution involves different law applied to different claims in a different jurisdiction and is not dispositive of patentability in the United States. *See AIA Engineering, Ltd. v. Magotteaux Int’l.*, 657 F.3d 1264, 1279 (Fed. Cir. 2011) (cautioning against reliance on foreign prosecution); *Pfizer Inc. v. Ranbaxy Labs.*, 457 F.3d 1284, 1290 (Fed. Cir. 2006); *Medtronic, Inc. v. Daig Corp.*, 789 F.2d 903, 907-08 (Fed. Cir. 1986) (cautioning against adopting validity conclusions from foreign court); *Bose Corp. v. Koss Corp.*, IPR2021-00297, Paper 41 at 45-46 (PTAB May 31, 2022) (finding that patent owner’s conduct in European prosecution did not constitute a “blatant admission” that a limitation was taught by the art and concluding that European prosecution was therefore not relevant (citing *Gillette Co. v. Energizer Holdings, Inc.*, 405 F.3d 1367, 1374 (Fed. Cir. 2005))).

Second, the rejections made during prosecution in Europe, including in a case where prosecution is ***actively ongoing***, are not sufficient to challenge the settled expectations PO has in the ’320 Patent. Those rejections apply different law and PO is continuing prosecution of the claims in the pending EP22196038 application, including claims similar to those challenged in the Petition. In no world should a patentee be presumed to forfeit settled expectations in an issued U.S. Patent because it engaged in the normal back and forth that occurs during prosecution of a related

application in a different jurisdiction. Regardless, this argument is waived because Petitioner never raised it in its Opposition.² See Director Review Process § 3.E. Director Review is not an opportunity for Petitioner to raise new challenges to PO's settled expectations, and Petitioner should have known it was required to raise its theory in the original discretionary denial briefing. *Id.*; *Dabico Airport Sol'ns Inc. v. AXA Power APS*, IPR2025-00408, Paper 24 at 3 (PTAB Aug. 21, 2025) ("The Process Memo also allowed parties to brief discretionary considerations, including settled expectations.").

Third, the EPO rejections cannot overcome Petitioner's failure to demonstrate a clear error on the part of the **United States** Patent Office ("PTO") in issuing the '320 Patent. Petitioner nevertheless argues the non-final rejections in Europe evidence that the Examiner must not have considered earlier version of the NCT01024231 protocol. As an initial matter, that argument only applies to Ground 1—Ground 2 does not include the clinical trial protocol. Thus, at best, Petitioner's alleged error only touches half of its Petition. More importantly, Petitioner's assertion of error, including that the Examiner's rejection was overcome based on

² See Paper 8, 28-29 (arguing only that PO's European prosecution "demonstrated the merits of a challenge" to the '320 Patent, but at no point suggesting that prosecution affected PO's settled expectations in the '320 Patent).

the date of the NCT01024231 protocol, is plainly contradicted by the prosecution history of the '320 Patent. As explained in the Request for Discretionary Denial, PO cited multiple versions of the NCT01024231 protocol to the Examiner during prosecution. Paper 6 at 13-19. And the Examiner did not solely rely on the 2017 version of the NCT01024231 protocol in its rejection. *Id.* at 15-24. The Examiner also relied on Ascierto, and identified several other references (including Korman) that it considered pertinent to the invention, but did not rely on to reject the claims. *Id.* The merits of the Petition were weak and thus, could not support a finding of error on the part of the Examiner during prosecution. Petitioner attempted, but failed, to sidestep the deficiencies in its Petition by pointing at PO's European prosecution in its Opposition. And by repeating the same arguments here, Petitioner fails to provide a credible basis for Director Review.

Petitioner cites a number of cases rejecting discretionary denial requests where the examiner's basis for allowance was a claim limitation that was clearly disclosed in prior art, or where a patent issued without a critical limitation—unlike the situation here. Request at 8-9. Moreover, those cases focus only on discretionary denial briefing in the first instance, not whether the party met its burden for supporting Director Review, the situation here. The Director has routinely declined to revisit her decision in the face of arguments like Petitioner's. For example, petitioners have argued that the “settled expectations” analysis will “adversely

impact consumers' access to low-cost pharmaceuticals.” *Cambridge Indus. USA Inc. v. Applied Optoelectronics, Inc.*, IPR2025-00433, Paper 13 at 12 (Req. Dir. Rev. filed July 21, 2025). Others have suggested that expectations should not be settled where patent owners should have expected IPR challenges. *See, e.g., iRhythm Techs., Inc. v. Welch Allyn, Inc.*, IPR2025-00376, Paper 11 at 10 (Req. Dir. Rev. filed July 3, 2025). Still others stressed that they filed their petition early and that it raised new prior art that allegedly directly addressed the examiner's reasons for allowance. *See Dabico Airport Sol'ns Inc. v. AXA Power APS*, IPR2025-00408, Paper 22 at 6-7 (Req. Dir. Rev. filed July 16, 2025). None of these were sufficient reasons to prompt the Director to review her discretionary denial decision.

B. Petitioner's “Changed Circumstances” Argument is Irrelevant and Wholly Without Merit

In an effort to identify gamesmanship where none exists, Petitioner seizes on PO's disclaimer of the claims in unrelated Patent No. 11,332,529 (“the '529 Patent”) as “changed circumstances” that allegedly affect the Director's decision here. There is no relationship between the '320 Patent at issue here and the '529 Patent. The patents have distinct priority dates, distinct issue dates, distinct claims, and distinct inventors. Notably, despite filing petitions challenging both patents on the same day, Petitioner never identified the petitions as related, nor did Petitioner rely on the '320 Patent as prior art in any asserted ground challenging the '529 Patent. And there is

no evidence that PO's disclaimer was part of a complex conspiracy to further some "shell game." Request at 3, 11.

On the contrary, the colorectal cancer (CRC) indication on PO's label changed after Petitioner filed its Petition and many of the issued claims in the '529 Patent no longer covered labeled indications. By way of background, the '529 Patent at issue in IPR2025-00603 was specific to a treatment of a form of CRC. When Petitioner filed its Petition for the '529 Patent, many of the dependent claims included limitations that matched the specific dosing required on Opdivo's label for the treatment of CRC. In April 2025, the FDA revised PO's CRC indication to require a flat dose of OPDIVO in the combination portion of the CRC treatment. *See* EX2004 at 2 (5/2025 revision) (requiring 240 mg OPDIVO followed by 1mg/kg of Yervoy in combination step for CRC treatment). After the label changed, the specific dosing claims of the '529 Patent no longer covered PO's label, thus limiting the value of that patent. Disclaimer in this circumstance is not only appropriate; it is encouraged by the Board:

[T]he efficient administration of the Office weighs against entering adverse judgment because such an action would have the effect of discouraging other similarly situated patent owners from filing disclaimers prior to institution in appropriate cases and also encourage patent owners to continue to litigate every AIA trial proceeding through Final Written Decision in such cases.

Bestway USA Inc. v. Intex Marketing Ltd., PGR2024-00036, Paper 9 at 8 (PTAB Oct. 28, 2024).

As Petitioner notes, a continuation application is pending (Request at 10), but that application has not yet undergone any substantive examination. Petitioner accuses PO of pursuing in that application “brand new . . . claims that are indistinct (indeed broader) than those purportedly disclaimed in the ’529 Patent.” Request at 10. But Petitioner neglected to tell the panel in that “separate briefing,” and neglects to tell the Director here, that the primary focus of its argument (claim 43) is not “brand new”; it has existed in identical form as claim 1 in that application since October 2024—long before Petitioner challenged the ’529 Patent. The documents from IPR2025-00603 have since been filed on an IDS in the file of that pending child application and the claims will be amended during the ordinary course of prosecution. The Examiner is competent and will consider the appropriate scope of claims in view of all relevant information. Petitioner’s allegations of gamesmanship are entirely untrue.

Indeed, Petitioner knows that there are circumstances where a party should disclaim patentable claims prior to institution—it has done so itself. *Replimmune Ltd. v. Amgen, Inc.*, IPR2023-00106, Paper 8 at n.2 (POPR filed Feb. 22, 2023) (“Without making any concession regarding their patentability, ***PO has disclaimed claims 2, 10, 14, and 17-19***” (emphasis in original)). PO similarly made no

concessions regarding the patentability of the claims of the '529 Patent and disclaimer of those claims has no bearing on the '320 Patent at issue here.

**C. Petitioner's Assertion That PO Should Have Expected an IPR
Petition Makes No Sense**

Petitioner argues, without support, that PO must have expected Petitioner to file a Petition *after* its biosimilar of OPDIVO® received FDA approval, and therefore, should not have had any settled expectations in its patent. Request at 12. That argument is ridiculous. There is no mandatory requirement for a party developing a biosimilar to file a petition for *inter partes* review. Nor should a patentee be presumed to doubt the validity of its issued patents because its competition may seek to challenge it. On the contrary, issued patents are presumed valid. 35 U.S.C. § 282. While that presumption may not apply during an *inter partes* review proceeding, a patentee cannot lose its entitlement to that presumption and the expectations it instills merely because the patent may be challenged in the future. Petitioner's suggestion to the contrary—that a patentee subject to competition should have no confidence in its issued patents—undermines the U.S. patent system.

Furthermore, Petitioner's suggestion that "PO knows full well that initiation of an IPR challenge against a patent prior to having an approved product allegedly leaves a challenger without standing to appeal" does not support its argument. Request at 12. Petitioner's own conduct—filing its Petition *before applying* for FDA

approval—shows that experienced biosimilar developers are seeking *inter partes* review in advance of FDA approval regardless of whether that party may eventually be able to establish standing in an appeal. Moreover, the BPCIA’s Patent Dance is triggered ***before*** a biosimilar is approved. There is no reason to think a biosimilar applicant would wait until after approval to file a petition for *inter partes* review when BPCIA proceedings begin sooner. *Momenta Pharms, Inc. v. Bristol-Myers Squibb Co.*, a case in which the biosimilar developer abandoned its development program after failing a Phase 1 clinical trial does not show otherwise. 915 F.3d 764, 766 (Fed. Cir. 2019).

D. There is No Public Interest in Advancing Petitioner’s Facially Deficient Petition Even if Petitioner Develops Biosimilars

Despite arguing that innovative biologics developers like PO must expect biosimilar developers to wait until after FDA approval to bring *inter partes* review challenges, Petitioner immediately contradicts itself and contends that there is a strong public interest in allowing its Petition to proceed “***in advance*** of possible BPCIA proceedings.” Request at 13-14. More specifically, Petitioner argues that it is critical for biosimilar applicants to be able to challenge the patentability of claims ***during biosimilar development*** through *inter partes* review. The Director already considered this argument and found it unpersuasive. There is no reason to reconsider it here.

Moreover, neither the Director’s Decision nor the process created by the Director’s Memo foreclosed Petitioner’s ability to challenge the validity of the ’320 Patent. The Petition was accepted and considered. And Petitioner can still challenge the validity of the ’320 Patent through more efficient, streamlined BPCIA proceedings. Petitioner’s real complaint is not that it was precluded from challenging the ’320 Patent—its real complaint is that it lost that challenge. But Petitioner did not lose that challenge because of PO’s settled expectations. Rather, Petitioner lost its challenge because it did “not provide persuasive reasoning why an *inter partes* review is an appropriate use of Board resources.” Paper 9 at 3.

E. Petitioner’s Cursory and Rehashed Constitutionality Challenge Does Not Support Director Review

Petitioner’s challenge to the constitutionality of the Director’s Review Process should be rejected. Petitioner repeats the exact same cursory argument it raised in its Opposition without identifying any grounds for reconsideration. In its Request, Petitioner generically refers to “previous policies” and “statutory authority” as the foundation of its as-applied due process challenge. At no point, however, does Petitioner cite a single policy, statute, regulation, or case to support its argument, much less a particular basis for its challenge other than an expressed dislike for the Director’s acknowledgement of settled expectations. Thus, even assuming

IPR2025-00601

U.S. Patent No. 9,856,320

Petitioner's constitutionality argument *could* serve as a basis for Director Review, Petitioner failed to provide an adequate basis here.

III. CONCLUSION

For all of the above reasons, Petitioner's Request for Director Review should be denied.

Respectfully submitted,

Date: September 3, 2025

By: /Steven D. Maslowski/
Steven D. Maslowski
USPTO Registration No. 46,905
Lead Counsel for Patent Owner

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing **PATENT OWNER'S AUTHORIZED RESPONSE TO DIRECTOR REVIEW REQUEST** was served on counsel of record on September 3, 2025, by filing this document through the Patent Trial and Appeal Case Tracking System (P-TACTS), as well as delivering a copy via electronic mail to the counsel of record for the Petitioner at the following addresses:

WOLF, GREENFIELD & SACKS, P.C.

Scott A. McKeown (SMcKeown-PTAB@wolfgreenfield.com)

Oona M. Johnstone (OJohnstone-PTAB@WolfGreenfield.com)

Chelsea A. Loughran (Chelsea.Loughran@WolfGreenfield.com)

Charles T. Steenburg (Charles.Steenburg@WolfGreenfield.com)

Respectfully submitted,

Date: September 3, 2025

By: /Steven D. Maslowski/

Steven D. Maslowski

USPTO Registration No. 46,905

Counsel for Patent Owner

Bristol-Myers Squibb Company