

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMGEN INC.,
Petitioner

v.

BRISTOL-MYERS SQUIBB COMPANY,
Patent Owner

IPR2025-00602
Patent No. 10,174,113

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

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process](https://www.uspto.gov/patents/ptab/decisions/director-review-process)) 5, 7

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 its Petition for *inter partes* review of U.S. Patent No. 10,174,113 (“the ’113 Patent”). Petitioner’s Request does not identify any abuse of discretion, erroneous finding of fact or law, or important issue of law or policy.

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. Paper 9. Specifically, the Director made her decision based on the totality of the evidence and arguments presented, which include (1) Petitioner’s

misstatements about the substance of the prior art (Paper 6 at 10-11, 13) and (2) Petitioner's reliance on a clinical trial protocol the Examiner considered during prosecution (Paper 6 at 13-19).

Petitioner makes little mention of the merits of *its Petition* in its Request. Instead, Petitioner disagrees with one part of the Director's determination—whether PO's settled expectations in the validity of its patent here should factor in the Director's denial of institution. According to Petitioner, events during European prosecution somehow unsettled PO's settled expectations about the '113 Patent. But Petitioner fails to explain why the EPO's application of European inventive step law to foreign patents undermined PO's settled expectations in the validity of the '113 Patent, particularly where the subject matter of the '113 Patent reflects years of investment in research and clinical development. See EX2002; EX2003; EX2004; EX2005. Furthermore, Petitioner does not cite a single statement PO made during European prosecution to support this purported loss of settled expectations. Nor can it. PO maintains that the European claims are valid and has appealed the European decision. Request at 6.

Then, ignoring the Board's guidance that patent owners are encouraged to disclaim claims prior to institution in appropriate circumstances, Petitioner launches into unsubstantiated allegations of "gamesmanship" and misconduct because PO disclaimed an unrelated patent at issue in a different, unrelated IPR petition. But

after Petitioner filed its petition in that IPR, the relevant FDA indication changed and many of those claims no longer covered PO's product. PO's disclaimer of claims in that patent was appropriate and is irrelevant to whether PO had settled expectations in the validity of the unrelated '113 Patent.

Finally, Petitioner repeats the same failed policy arguments it presented in its Opposition to Discretionary Denial (Paper 8) ("Opposition") and concludes that because the Director disagreed with Petitioner, the Director must have made an error worthy of review. Request at 14. But Petitioner's dissatisfaction with the 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 and denied its 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

The Director's determination that PO had settled expectations in the validity of its '113 Patent was reasonable and is supported by the record. PO submitted a preliminary response detailing how, even at this preliminary stage, Petitioner failed to show that the '113 Patent claims are unpatentable. Paper 7. Moreover, one of the clinical trial protocols that Petitioner relies on for every ground in its Petition was already considered by the Examiner (Paper 6 at 10-11, 13), and the substance of that clinical trial is very different from how Petitioner characterizes it (Paper 6 at 13-19). In short, there is no reason to question whether the claims of the '113 Patent are valid. Furthermore, PO relied on the '113 Patent to support its extensive clinical development program resulting in improved therapies for its commercial products, OPDIVO and YERVOY. EX2004; EX2005. Nothing in PO's conduct suggests that it has any doubt in the validity of the claims of the '113 Patent.

Despite all of this, 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 '113 Patent claims and then suggests for the first time, that those events should be deemed to have "unsettled" PO's settled expectations in the '113 Patent because "[t]he only expectations that PO could have is that the claims

are unpatentable and that the USPTO clearly erred in allowing them.”¹ Request at 7. Petitioner’s argument that European prosecution disrupted PO’s settled expectations 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.

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

¹ The Director recently rejected this same argument regarding the relevance of foreign prosecution on settled expectations. See *Samsung Elecs. Co. v. OS-New Horizon Personal Coputing Sol’ns Ltd.*, IPR2025-00613, Paper 9 at 25 (Opp’n to Discretionary Denial, June 20, 2025); *id.*, Paper 10 at 2 (PTAB July 17, 2025).

concluding that European prosecution was therefore not relevant (citing *Gillette Co. v. Energizer Holdings, Inc.*, 405 F.3d 1367, 1374 (Fed. Cir. 2005)). Petitioner does not even attempt to explain why the application of European inventive step law to different claims is relevant—let alone dispositive—to PO’s understanding of the validity of the ’113 Patent’s claims. And not only does Petitioner fail to identify any “blatant admission” by PO, Petitioner does not cite even a single statement by PO in that foreign prosecution. Those omissions alone are fatal to Petitioner’s argument.

Instead, Petitioner *imagines* PO’s alleged belief based on PO’s abandonment of a European application and the revocation of a different European patent—each having different claims than those of the ’113 Patent. *Compare* EX1001 at 43:21-44:61 *with* EX1050 *and* EX1054 at 33-34. But Petitioner’s own argument demonstrates its logical fallacy—after making much of the European Patent Office’s revocation of a European patent with different claims, Petitioner notes that “[t]hat case is currently under appeal.” Request at 6 (emphasis added). Thus, despite the fact that PO is currently appealing that decision, and obviously *disagrees* that the claims are invalid, Petitioner still declares that PO has so little confidence in its European prosecution that it has tainted PO’s settled expectations in different claims in a U.S. patent. Petitioner’s argument is nonsensical. 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.").

Finally, Petitioner cites cases where other petitioners prevailed—in their initial discretionary denial brief—by showing that there was a material error during prosecution that outweighed the patent owner's settled expectations. Request at 7-8. But in those cases, the petitioner identified a clear disclosure of a claimed element in the prior art or demonstrated that the Office inadvertently left a claim limitation out of the challenged claims. This case is nothing like that. Again, the substance of Petitioner's art was in front of the Examiner and Petitioner failed to show any material error. Paper 6 at 13-27. There is no clear disclosure in the prior art of the claim limitations here—Petitioner cobbles its argument together using expert

² See Paper 8 at 4, 8-10 (arguing only that European prosecution "[d]emonstrat[es] USPTO error," but never suggesting that prosecution affected PO's settled expectations in the '113 Patent).

testimony that is contrary to the express teachings of the prior art. Paper 7 at 31-38. And there is no argument that a limitation was inadvertently left out of the claims as issued. Petitioner identifies no material error during prosecution of the '113 Patent.

Moreover, Petitioner does not address any case where the Director determined that a party met the standard for 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 arguments were sufficient reasons to prompt the Director to review her discretionary denial decision.

The only conclusion that can be drawn from the totality of the facts here is that there is no reason to doubt the validity of the '113 Patent—Petitioner's

suggestions that PO's settled expectations in the '113 Patent changed because of European prosecution is without merit. Put simply, Petitioner fails to show that the Director abused her discretion in denying institution.

B. There are No Changed Circumstances Relevant to this IPR

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. Request at 9-12. But the '529 Patent has different inventors, a different priority date (more than a year after than the '113 Patent's date), issued more than three years after the '113 Patent, and covers a different method of treatment for a different type of cancer than the '113 Patent. Notably, despite filing petitions challenging both patents on the same day, Petitioner never identified them as related. And there is no evidence, nor could there be, that PO's disclaimer was part of a complex conspiracy to further some "shell game." *Id.* at 12. As described below, the indication for PO's commercial product changed and many existing claims (including all that required a specific dose of an anti-PD-1 antibody) no longer covered PO's product, meaning they would also no longer cover Petitioner's planned biosimilar product. PO's pre-institution disclaimer of the '529 Patent was proper and is irrelevant to the '113 Patent.

The '529 Patent at issue in IPR2025-00603 was specific to a treatment of a form of colorectal cancer (CRC). Request at 11. When Petitioner filed its petition for the '529 Patent, many of the dependent claims included limitations that matched the specific anti-PD-1 antibody dosing required on Opdivo's then-current label for the treatment of CRC—a combination treatment defined by weight-based (not flat) doses. The Request reproduces claims 12 and 16 (*id.* at 10), which ultimately depend from claim 11 (not depicted in the Request). But claim 11 of the '529 Patent requires combination treatment with **a weight-based dose** (not a flat dose) of 3 mg/kg of an anti-PD-1 antibody and 1 mg/kg of an anti-CTLA-4 antibody. 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 EX2005 at 2 (5/2025 revision).

'529 Patent Claims (Disclaimed)	OPDIVO Label (5/2025 version, EX2005 at 2 (MSI-H CRC indication))
Claim 11: The method of claim 1, wherein the anti-PD-1 antibody is administered at a dose of about 3 mg/kg body weight and the anti-CTLA-4 antibody is administered at a dose of about 1 mg/kg body weight once about every 3 weeks for a total of 12 weeks.	Adult and pediatric patients weighing 40 kg or greater: 240 mg [OPDIVO] followed by ipilimumab 1 mg/kg on the same day every 3 weeks for a maximum of 4 doses, then 240 mg every 2 weeks or 480 mg every 4 weeks.

Claim 12: The method of claim 11, wherein the administration of the anti-PD-1 antibody and the anti-CTLA-4 antibody is followed by an anti-PD-1 antibody monotherapy.	
Claim 16: The method of claim 12, wherein the anti-PD-1 antibody monotherapy is administered at a flat dose of about 240 mg once about every 2 weeks.	

Thus, after OPDIVO's label changed, the existing claims in the '529 Patent that require a specific anti-PD-1 antibody dose (claims 8-18, which include all claims that recite a flat dose (the basis of Petitioner's argument)) became **irrelevant** to PO's product and Petitioner's future biosimilar product that will copy some or all of PO's product's label. Disclaimer in this circumstance is appropriate and 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 11), but that application has not yet undergone any substantive examination. Petitioner accuses PO of pursuing in that application “brand new continuation claims that are indistinct (indeed broader) than those purportedly disclaimed in the ’529 Patent.” *Id.* at 11. Petitioner neglected to tell the panel in that “separate briefing,” and neglects to tell the Director here, that the claim it primarily focuses on (claim 43) is not “brand new”; it has existed in identical form as claim 1 in that application since October 2024—long before Petitioner filed its petition for 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 did not make

any concession regarding the patentability of the claims of the '529 Patent and disclaimer of those claims has no bearing on the '113 Patent at issue here.

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

Petitioner then argues, without support, that PO must have expected it 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 12-13. That argument is entirely without merit. A patentee should not be presumed to doubt the validity of its issued patents because its competition may challenge them. On the contrary, issued patents are presumed valid. 35 U.S.C. § 282. 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.

D. Petitioner Provides No Reason For the Director to Revisit Its Rejected Policy Arguments

Finally, Petitioner *admits* that its Request merely reiterates the same policy arguments that it raised in its Opposition. Request at 14-15. According to Petitioner, because it did not win, its evidence must have been overlooked or at least misapprehended. *See id.* at 14. First, the fact that the Director disagreed with Petitioner does not mean that its evidence and argument were overlooked. To the contrary, the Director found that both parties' arguments about the BPCIA regulatory and litigation framework "not persuasive." Paper 9 at 3. Second, Petitioner's

argument is based on its mistaken belief that PO “knows” its claims are unpatentable.

As explained here and in PO’s preliminary response, Petitioner failed to provide a reasonable basis to doubt the validity of any claim of the ’113 Patent.

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 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.

IPR2025-00602
U.S. Patent No. 10,174,113

Respectfully submitted,

Date: September 3, 2025

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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:

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