

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMGEN INC.,
Petitioner,

v.

BRISTOL-MYERS SQUIBB COMPANY
Patent Owner.

Case No. IPR2025-00601
Patent No. 9,856,320

**PETITIONER'S REQUEST FOR DIRECTOR REVIEW OF DECISION
DENYING INSTITUTION OF *INTER PARTES* REVIEW**

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I. INTRODUCTION

The Interim Director's decision discretionarily denying institution of IPR2025-00601 ("Decision") overlooked the fact that essentially the same claims here were abandoned in Europe in 2022, in the face of the very art that the USPTO misapplied during prosecution. The Discretionary Denial Opposition makes this plain. DD Opp. (Paper No. 8), 12-18, 3-4, 12-16 and 61-63. This glaring "material error" in the agency's earlier work allows BMS to unduly extend its market exclusivity on the drug Opdivo® by another 6 years based on a known dosage regimen¹. Patent Owner (PO) could not possibly have had seven years of "settled expectations" in a claim scope it abandoned in Europe, *in the face of the same clinical trial protocol with a slightly later date, only four years into the term of this challenged patent*. Shielding such material error from correction in the U.S. will contribute to biosimilars being delayed in coming to market in the U.S. to the

¹ The Examiner rejected the pending claims over a post-filing version of a clinical trial protocol. That reference was overcome based on its date, which does not apply to Ground 1's Exhibit 1005, which is an earlier version of the same protocol. The '320 Patent would not have issued had the Examiner considered the prior art teachings (corresponding to, *inter alia*, EX1005). The invalidating information was already in the prior art and the Examiner failed to recognize the earlier version.

detriment of U.S. healthcare consumers. Far from Petitioner “not provid[ing] persuasive reasoning why an *inter partes* review is an appropriate use of Board resources” there could not possibly be a more compelling use of an executive agency’s resources but to align with its Chief Executive to advance the critical goal of bringing biosimilars to market in a timely manner—especially here, where the error is plain and the USPTO never should have issued the ’320 Patent. *Lowering Drug Prices by Once Again Putting Americans First*, Executive Order No. 14273, 90 Fed. Reg. 16441 (Apr. 15, 2025).

Further, changed circumstances since the discretionary denial only underscore the agency’s misapprehension of the significant public policy issues at play here. Since this Petition was discretionarily denied, *PO has disclaimed ALL claims in companion IPR2025-00603.*² The result is that PO has now abandoned similar anti-PD-1 dosage claims in *both Europe and the U.S.* when faced with prior art clearly revealing their obviousness. The disclaimer makes plain that PO had no settled expectations in these dosage cases. Much like its acknowledgement of deficiencies in its European counterpart claims to those challenged in this IPR, PO

² IPR2025-00603 of U.S. Patent No. 11,332,529 (“’529 Patent”) survived discretion and was referred to the merits panel because it was not in force as long as the ’320 Patent. Paper 9, 2-3.

is *now* attempting to insulate this additional surrogate patent (the '529 Patent) by short circuiting any USPTO analysis of art that would demonstrate its claims were mistakenly granted. PO's ongoing strategy of abandoning follow-on dosage claims in the face of art rendering them unequivocally obvious—but only when challenged—highlights a complete lack of settled expectations in such claims. IPR2025-00603, Paper No. 11 (brief on gamesmanship impact on adverse judgment assessment). The only “settled expectation” PO has here is in continuing its patent shell game. And the USPTO is unknowingly assisting in this repetitive claiming strategy by providing PO with yet another administrative pathway to avoid prior art to the detriment of the American public. Absent correction, PO will simply continue to stack materially similar claims to those abandoned and even seek to resurrect them before this very agency. Ending such patent gamesmanship on a cancer drug therapy that costs the American public billions of dollars a year is the agency's highest calling. It is hard to conceive of a more worthy case for Board review.

The agency's Decision to deny this IPR as a matter of discretion overlooks or misapprehends: the discontinuity in expectations resulting from previous surrender of nearly identical claims; the material error in the agency's earlier work based, in part, on a date discrepancy; the changed circumstance of PO's most recent exhibition of its pattern of strategic retreat gamesmanship; and the expressed intent of the President's Executive Order on biosimilars (validating the settled expectations of

both PO and the American public). The Decision should be reversed and the Petition grounds referred to a merits panel of the PTAB.

II. THE DISCRETIONARY DENIAL DECISION CREDITS YEARS OF TERM WHILE OVERLOOKING PO'S SURRENDER OF CLAIM SCOPE BASED ON SIMILAR ART AND OTHER COUNTERVAILING EVIDENCE WARRANTING REVERSAL

A. The Decision's "Settled Expectations" Analysis Overlooks the Impact of and Material Error Evidenced By PO's European Surrender of Nearly Identical Claims.

The composition-of-matter patent covering Opdivo® expires in 2028, at which point BMS will have recouped nearly \$10 billion/year for its investment. DD Opp., 18-21. The '320 Patent is a follow-on patent claiming obvious dosing regimens for Opdivo® (all of which were disclosed in the prior art) to unduly extend BMS's market exclusivity. The Director's decision cited alleged "settled expectations" in the validity of the '320 Patent based on the "seven" years the '320 Patent has been in force and concluded that "the Office is disinclined to disturb" them. Decision, 3. But in September of 2022—when the '320 Patent had only been in force for *four* years—PO abandoned nearly the same claims in Europe in the face of the same art applied against the challenged claims. To the extent PO *ever* had settled expectations, those expectations were unsettled by PO's realization years before that dosing protocols similar to that submitted in this petition but for a date discrepancy meant that the dosage regimens it was trying to patent in Europe, and had already patented in the U.S., were squarely in the public domain.

The Decision reasons that “Petitioner does not provide persuasive reasoning why an *inter partes* review is an appropriate use of Board resources” and states that the Decision is “based on a holistic assessment of all the evidence and arguments presented.” Decision, 2-3. But the Decision neither discusses nor even mentions the arguments or the evidence that Petitioner provided regarding the fate of nearly identical patent claims in Europe. The Decision therefore fails to explain how PO can have “settled expectations” in U.S. patent claims that—over three years ago, and only four years into the term of the challenged patent—***it knew it had abandoned in the face of prior art similar to that presented here.*** As such, a holistic assessment of all the evidence and arguments presented—including the clear error of the USPTO in allowing claims over art that prompted abandonment of nearly identical claims in Europe, the lack of parallel proceedings, and the strong public policy interests the Administration has for biosimilars—must outweigh any settled expectations that the PO could have had in a patent with claims that PO has publicly walked away from.

As discussed in Petitioner’s Discretionary Denial Opposition at pages 3-4, 12-16 and 61-63, Patent Owner voluntarily withdrew nearly identical claims to those in the ’320 Patent based on stiff rejection of such claims in Europe. In particular, EP Application No. 17189595.6 was filed in 2017 seeking issuance of exemplary claim 1 (as amended):

An anti-PD-1 antibody for use in a method of treating a human subject afflicted with a cancer in combination with an anti-CTLA-4 antibody; comprising:

- (i) an induction dosing schedule comprising administration of the anti-PD-1 antibody and the anti-CTLA-4 antibody at a dosing frequency of once every 3 weeks, for 4 doses, followed by administration of the anti-PD-1 antibody alone at a dosing frequency of once every 3 week for 4 doses; followed by
- (ii) a maintenance dosing schedule comprising administration of the anti-PD-1 antibody and the anti-CTLA-4 antibody at a dosing frequency of once every 2 to 12 weeks for 8 doses,

wherein the anti-PD-1 antibody and anti-CTLA-4 antibody are to be administered at dosages of: (a) 1 mg/kg of anti-PD-1 antibody and 3 mg/kg of anti-CTLA-4 antibody or (b) 3 mg/kg of anti-PD1 antibody and 1 mg/kg of anti-CTLA-4 antibody.

Ex. 1023, 144-145 (cleaned up).

Every claim limitation of claim 1 of EP Application No. 17189595.6 overlaps with corresponding limitations of the '320 Patent. DD Opp. 13-14.

During prosecution of the above claim in Europe, on October 7, 2019, the EPO's Examining Division ("ED") asserted that the amended claims lacked novelty and inventive step over ***the April 30, 2012 version of NCT01024231 [D10]*** whose cohort arms recited an induction phase of concurrent anti-CTLA-4 and anti-PD-1 dosing followed by anti-PD-1 alone, followed by a maintenance phase of the two

antibodies again. The ED also asserted “*the establishment of dosage regimes is considered a matter of routine for the skilled person.*” EX1062, 2. After trying and failing to persuade the EP Examiner that the pending European claims demonstrated “superior effects” (EX1025, 1-2; EX1026, 2-3), ***PO withdrew the application*** on September 20, 2022 (five days after Third-Party Observations were filed discussing, *inter alia*, prior art reference Korman, relied on in Grounds 1 and 2 of the Petition). EX1033.

Similarly, in prosecuting EP Application 22196038.8, PO seeks claims similar to those recited above for EP App. No. 17189595.6. EX1034, 1 (reciting the dosing amount (a) only). Again, such claims have been ***rejected*** over NCT01024231, despite PO’s baseless arguments regarding alleged “superior effects.” EX1035, 2.

That the parallel claims of EP App Nos. 17189595.6 and 22196038.8 have been flatly rejected and, in the case of the former, ***withdrawn by PO***, demonstrates that PO could not possibly have “settled expectations” in the validity of the ’320 Patent. The only expectations that PO could have is that the claims are unpatentable over the prior art and that the USPTO clearly erred in allowing such claims. For the agency to decide that correcting a clear error in issuing an invalid patent is not an “efficient use of its resources” is an affront to the very mission of the USPTO. Instead, *inter partes* review proceedings provide a post-issuance ***opportunity*** to challenge issued patents granted in error. The Director’s recent decisions recognize

and give due weight to the importance of correcting material error on the part of the USPTO—including in patents that issued well before the '320 Patent.

For example, in *Anthony Inc. v. ControlTec LLC*, IPR2025-00559 and IPR2025-00636, the Director rejected requests for discretionary denial concerning patents that had “been in force for approximately eighteen and seventeen years.” IPR2025-00559, Paper No. 12, 2 (July 16, 2025). Notwithstanding this length of time, the Director determined that review was an “appropriate use of Office resources” because the petitioner had identified an apparent “material error by the Office” in “overlooking the teachings of” a prior art reference. *Id.* Similarly, in *Xencor, Inc. v. Merus N.V.*, IPR2025-00604, the Director rejected a discretionary denial request concerning a patent for producing antibodies even though it had been “in force for approximately nine years” and accordingly (in the Director’s view) “creat[ed] strong settled expectations for” the patentee. Paper No. 12, 2 (July 17, 2025). Despite those ostensible expectations, the Director concluded that review was appropriate given the petitioner’s persuasive showing that the USPTO had “materially erred during prosecution” in overlooking prior art teachings contrary to the stated reasons for allowance. *Id.*, 2-3; *see also Skullcandy, Inc. v. Earin AB*, IPR2025-00690, Paper 9, 2 (July 31, 2025) (rejecting discretionary denial request as to a patent “issued nine years ago” and “creating strong settled expectations,” as the

petitioner “appear[ed] to show a material error by the Office, and it is an appropriate use of Board resources to review the potential error.”)³

Here, by contrast, the Decision overlooks the material error of the USPTO in issuing the challenged claims even though such error is evidenced by the withdrawal of nearly identical claims in Europe as discussed above and as evidenced by the failure of the Examiner to consider the relevant prior art. As explained in the petition, the Examiner failed to consider earlier published versions of the clinical trial protocol (which are clearly prior art) after a later version of the clinical trial protocol was removed as prior art. *See* DD Opp. VI.B; *see also* *CSPC Pharmaceutical Group Ltd. v. Ipsen Biopharm Ltd.*, IPR2025-00505, Paper 11, 3 (July 16, 2025) (rejecting discretionary denial request, citing petitioner’s “persuasive evidence that the Office erred in a manner material to the patentability of the challenged claims by not considering or overlooking specific teachings in” a clinical study protocol and

³ The Director has also cited indica of “material error during patent examination” when rejecting a discretionary denial request even though the scheduled district court trial date was scheduled “to precede the expected final written decision due date.” *Microsoft Corporation v. Partec Cluster Competence Center GmbH*, IPR2025-00318, Paper No. 9, 2-3 (June 12, 2025).

related appendix). But the invalidating information was already in the prior art and the Examiner failed to recognize the earlier version.

The result of allowing such error to stand is a U.S. patent that enables BMS to unduly extend its market exclusivity *while nearly identical claims were barred in Europe*. Because the Decision misapprehended and overlooked the significance of this countervailing evidence and PO's unreasonable reliance on expectations *since 2022*, the Director should withdraw and reverse the Decision and refer the Petition to the merits panel for consideration on institution.

B. The Decision Fails to Account for Patent Owner's Recent Disclaimer and the Changed Circumstance Presented By PO's Latest Tactic In An Ongoing Strategy To Avoid Meaningful Consideration of its Obvious Follow-On Claims.

On August 18, 2025, PO statutorily disclaimed the '529 Patent in its entirety. The '529 Patent is the subject of IPR2025-00603 which was filed alongside the instant IPR but survived discretionary denial as explained above, *supra* n. 2. PO is now seeking denial of the petition without adverse judgment (which is the subject of separate briefing in IPR2025-00603). IPR2025-00603, Paper No. 11. As explained in that briefing, days before submitting its purported disclaimer of the '529 Patent to the agency, PO cancelled all claims in pending continuation (18/787,822; the "'822 Application")—a child application to the '529 Patent— and slipped in a brand new claim set of claims that are indistinct (indeed broader) than those purportedly disclaimed in the '529 Patent.

PO's willingness to abandon the '529 Patent evidences a strategic pattern that the USPTO should not facilitate. Much like its abandonment of the European counterpart to the '320 Patent discussed in § II.A., *supra*—this is just another instance in an ongoing and overt pattern of behavior to avoid merits consideration of unquestionably obvious dosing claims by sacrificing them when challenged and by pursuing indistinct *or broader* claims in different applications and/or patents. The USPTO should not be manipulated to enable such gamesmanship. This newest, blatant evidence of this shell game strategy—the disclaimer of the '529 Patent—was brought to the attention of Petitioner and this Board early last week and is being separately pursued in the '529 IPR to prevent PO from resurrecting its allegedly disclaimed claims—in addition to the '320 Patent follow-on claims—in a pending continuation application. This change in circumstance demonstrates a pattern of behavior that undermines the public confidence in the USPTO and warrants the Director's vacating of the Decision and referral of the Petition to the merits panel.

C. The Decision's "Settled Expectations" Analysis Erroneously Overlooks Evidence That PO Expected A Challenge to the '320 Patent.

As discussed at length in the Petition, the regulatory and BPCIA litigation framework applicable to development of a biosimilar for Opdivo® create expectations and timing considerations that depart from the standard assumption

that the expectations of the PO grow in step with the time that passes since issuance. DD Opp. 16-18, 28-29.

Most notably, Petitioner pointed out that *PO itself has argued* in prior litigation that where a competitor initiated an IPR too early (i.e., prior to having an approved product threatened by the challenged claims), it did not have standing to appeal an adverse decision. *Momenta Pharms, Inc. v. Bristol-Myers Squibb Co.*, 915 F.3d 764, 766 (Fed. Cir. 2019). Not only does this contradict PO's argument that Petitioner filed the instant IPR too late, it in fact demonstrates that PO *did not have any "settled expectations"* in the ongoing validity of its '320 Patent.

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. Because PO was aware of Amgen's biosimilar launch timeline with approval being years away, PO would not have expected any earlier challenge by Amgen to its '320 Patent.

D. The Decision Erroneously Overlooks the Public's Interest in the Swift Advancement of Biosimilars.

In addition to ignoring clear error, the Decision erroneously overemphasizes the "settled expectations" of PO in a suspect patent without any consideration of the interests and expectations of the public (and Amgen) in not having invalid patents keeping competitors from coming to the market. As discussed in the DD Opposition (and overlooked by the Decision), a key aspect of the ability of

biosimilar developers to bring critical products to market is the ability to challenge erroneously granted patents at around the time such biosimilar developers become aware of the technical feasibility of their biosimilar and based on their entry into the process for application for regulatory approval. DD Opp. 5-6, 26-29. The retroactive narrowing of this opportunity based on the years since a challenged patent issued is a factor that is largely irrelevant in the context of biosimilar development.

As detailed in Petitioner's DD Opposition, Amgen plays a significant role in the biosimilar market and, in particular, the development and commercialization of an affordable alternative to Opdivo®. DD Opp. 6-7. The Opposition explains that IPRs provide biosimilar developers like Amgen with the ability to identify erroneously granted patents and challenge their patentability prior to launch on a predictable timeline before an expert panel. And, as in this case, a successful challenge to obvious patent claims can help prevent the issuance of similarly unpatentable patents. DD Opp. 2, 5-6, 26-28. In addition, rendering unpatentable a method of treatment patent, like the '320 Patent, before aBLA approval helps to inform the biosimilar applicant on the swiftest path to obtain regulatory approval of an indication or dosing regimen that may be relevant to the patent or to omit that indication/dosing regimen from a carved-out label to reduce patent risk. DD Opp. 5-6. In short, the continued availability of IPR proceedings to challenge mistakenly

granted patents in advance of possible BPCIA proceedings comports with the public's interest in the accelerated approval of biosimilars.

All of this evidence was presented in the Opposition but was overlooked, or at the very least, misapprehended as such evidence clearly dwarfs any error-generated expectations PO has in claims it knows to be unpatentable. In view of the applicability of this critical public interest factor, the Decision should be reversed and the Petition referred to the merits panel.

E. Discretionary Denial Pursuant to Retroactive Application of the Interim Memo's "Settled Expectations" Factor is Unconstitutional.

Reversal of the Decision denying institution is also necessary because the Decision is based on the Acting Director's March 26, 2025 "Interim Processes for PTAB Workload Management" memorandum, which itself is unconstitutional as retroactively applied here by PO to petitions that were filed on February 28, 2025 in reliance on previous policies. The only factor cited in the Decision as favoring discretionary denial is PO's purported "settled expectations" given the length of time the '320 Patent has been in force. Decision, 3. Yet the March 26, 2025 memorandum was the first time the USPTO had suggested that the "[s]ettled expectations of the parties, such as the length of time the claims have been in force" could be a factor weighing in favor of discretionary denial. Applying this

newly introduced factor to deny Petitioner's statutory right to pursue *inter partes* review exceeded the Director's powers and ignored notice-and-comment rulemaking processes. Such a denial violated at least Petitioner's due process rights under the Fifth Amendment by retroactively applying the new factors of the March Memo in contravention of statutory authority.

III. CONCLUSION

For the foregoing reasons detailed above, the Decision denying institution should be reversed.

Respectfully submitted,

Date: August 25, 2025

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CERTIFICATE OF SERVICE UNDER 37 C.F.R. § 42.6 (e)(4)

I certify that on August 25, 2025, a copy of the foregoing document, including any exhibits filed therewith, is being served via electronic mail, as previously consented to by Patent Owner, upon the following:

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