

Paper No. ____
Date Filed: September 5, 2025

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMGEN INC.,
Petitioner

v.

BRISTOL-MYERS SQUIBB COMPANY,
Patent Owner

IPR2025-00603
Patent No. 11,332,529

**REPLY TO PETITIONER'S RESPONSE TO PATENT OWNER'S
SUPPLEMENTAL PRE-INSTITUTION BRIEF**

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BMS's (PO) pre-institution disclaimer should not result in adverse judgment. In what is now established practice, the Board does not enter adverse judgment based on pre-institution disclaimer of claims. There are good reasons for this. The Board has not yet analyzed patentability **and** it encourages efficient resolution of proceedings. Indeed, PO is not aware of any case in the past 5 years entering such an opposed judgment. But in that same time the Board has declined to enter adverse judgment at least 15 times against claims disclaimed pre-institution.

In its initial cases (prior to 2016), the Board entered adverse judgment in view of such disclaimer only 3 times, without providing any reasoning. *See Hospira, Inc. v. Janssen Pharms., Inc.*, IPR2013-00365, Paper 9 (PTAB Oct. 24, 2013); *Smith & Nephew, Inc. v. Bonutti Skeletal Innovations LLC*, IPR2013-00621, Paper 9 (PTAB Jan. 17, 2014); *Glob. Tel *Link Corp. v. Howlink Glob. LLC*, IPR2014-00696, Paper 9 (PTAB Aug. 15, 2014). Then in 2016, a panel entered adverse judgment after interpreting 37 C.F.R. § 42.73(b) as merely **permitting** it to do so. *Smith & Nephew, Inc. v. Arthrex, Inc.*, IPR2016-00917, Paper 12 at 6-9 (PTAB Sept. 21, 2016), *aff'd* 880 F.3d 1345 (Fed. Cir. 2018). The Board concluded that petitioner's patentability challenge prompted the disclaimer, so it was entitled to finality on those claims. *Id.*

Since then, the Board has entered adverse judgment only once over patentee's opposition because of potential finality concerns and because the disclaimer was filed just weeks before the institution deadline. *See Google LLC v. Seven Networks*,

LLC, IPR 2018-01118, Paper 22 at 4-7 (PTAB Jan. 11, 2019). The Board entered an **unopposed** adverse judgment without discussion. *See Mmodal, LLC v. Nuance Commc's, Inc.*, IPR2018-01291, Paper 8 (PTAB Oct. 22, 2018). The Board entered adverse judgment in two IPRs (IPR2024-00564 (Paper 5); IPR2024-00288 (Paper 6)) where the patentee disclaimed pre-institution because another IPR had already been instituted against the same claims and adverse judgment was entered there. *See Microsoft Corp. v. Softex LLC*, IPR2023-01185, Paper 16 (PTAB Mar. 19, 2024).

In every other recent case, however, the Board has **not** entered adverse judgment following pre-institution disclaimer. Instead, the Board recognized its precedent and simply denied institution. *See e.g., Celltrion, Inc. v. Regeneron Pharms., Inc.*, PGR2021-00117, Paper 16 (PTAB Mar. 15, 2022). It did so where prosecution was ongoing and petitioner invested resources in its IPR, *e.g., Bestway (USA), Inc. v. Intex Mktg., Ltd.*, PGR2024-00036, Paper 9 at 6-7 (PTAB Oct. 28, 2024), and distinguished between pre- and post-institution disclaimer in the same proceeding, *e.g., Google LLC v 138 East LCD Advancements Ltd.*, IPR2024-00957, Paper 15 at 3 (PTAB June 2, 2025). This encourages patent owners to disclaim prior to institution rather than litigate every instituted AIA trial through Final Written Decision. *Bestway*, PGR2024-00036, Paper 9 at 8. *Bestway* applies here.

In April 2025, after the Petition was filed, PO's label changed to require a flat dose of OPDIVO for CRC, instead of a weight-based dose, in the combination step.

EX2005 at 2. As a result, none of the patent claims that require a specific anti-PD-1 antibody dose (claims 8-18) cover PO's label because they require a weight-based combination step. *Compare, e.g.,* EX1001 at claims 8-18 *with* EX2005 at 2. As such, those claims became irrelevant to any dispute. Thus, disclaimer shortly after the Director's discretionary denial determination, but far in advance of the Board's institution decision is sensible even where claims with specific dosages would certainly survive a challenge. Petitioner knows parties can disclaim without conceding unpatentability—it has done so itself. *See Replimmune Ltd. v. Amgen Inc.*, IPR2023-00106, Paper 8 at 1, n.2 (POPR, Feb. 22, 2023).

Petitioner misconstrues PO's continuing prosecution, which has undergone no substantive examination yet. Paper 11 at 1-3. And contrary to Petitioner's rhetoric about slipping in pending claim 43 (Paper 11 at 1-2), that claim has been pending in ***identical*** form as claim 1 since October 2024, and documents from this IPR have been filed on an IDS. Thus, prosecution will proceed in the ordinary course before a competent examiner with Petitioner's arguments considered. Petitioner only seeks adverse judgment so it can make overbroad allegations that PO is not entitled to even unrelated claims. Paper 9 at 6 (requesting disclaimer of unrelated patents); IPR2025-00601, Paper 10 at 11; IPR2025-00602, Paper 10 at 12. Adverse judgment will do nothing but force patent owners to litigate (and the Board to adjudicate) every case to a decision on institution and, if instituted, to final written decision.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of **REPLY TO PETITIONER'S RESPONSE TO PATENT OWNER'S SUPPLEMENTAL PRE-INSTITUTION BRIEF** was served on counsel of record on September 5, 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 Petitioners at the following addresses:

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