

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. IPR2025-00603
Patent No. 11,332,529

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

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I. Introduction

Patent Owner (“PO”) statutorily disclaimed U.S. Patent No. 11,332,529 (“’529 Patent”) in its entirety. PO now seeks denial of this petition without adverse judgment, asserting that the Board has granted such denials in “*similar circumstances*.” See Patent Owner’s Supplemental Pre-Institution Brief (Paper 9) at 3. But the circumstances here are unlike any previous case.¹

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 set of claims that are indistinct (indeed *broad*) than those purportedly disclaimed in the ’529 Patent. There can be no meaningful disclaimer where PO is *already* attempting to resurrect its claims elsewhere in the Office. 37 C.F.R. § 1.321(a). Adverse judgment exists to prevent such “whack-a-mole” patent strategies from adversely impacting the public and undermining work of the agency in assessing improvidently granted patents. 37 C.F.R. 42.73(b)(1). Adverse judgment is necessary to *estop* this damaging behavior before it spreads to other filings. 37 C.F.R. § 42.73(d)(3)(i).

Accordingly, Petitioner requests that the Board enter adverse judgment.

¹ PO simply concluded the authority relied upon reflected “similar circumstances.”

II. Patent Owner’s Shell Game

Just two weeks prior to PO’s disclaimer of the ’529 Patent, PO replaced all of its pending claims in the child ’822 Application with a new claim set. Those new claims are not only patentably indistinct from the disclaimed ’529 claims, but *broaden*. Compare, *e.g.*, disclaimed claim 1 and pending claim 43:

’529 Patent Claim 1 (Disclaimed)	’822 Application Claim 43 (New)
A method of treating a subject afflicted with a tumor derived from a colorectal cancer, comprising administering to the subject:	A method of treating a subject afflicted with a tumor derived from a colorectal cancer, comprising administering to the subject:
(i) an anti-PD-1 antibody, and	(i) an anti-PD-1 antibody, and
(ii) an anti-CTLA-4 antibody;	(ii) an anti-CTLA-4 antibody;
wherein the tumor is a colon cancer or a rectal cancer; and	
wherein the tumor exhibits a high degree of microsatellite instability (MSI-H).	wherein the tumor exhibits a high degree of microsatellite instability (“MSI-H”).

As shown, every element of new claim 43 is identically found in disclaimed claim 1, but new claim 43 *broadens* disclaimed claim 1 by omitting the limitation that “the tumor is a colon cancer or a rectal cancer” and instead covering any tumor “derived from a colorectal cancer.” *See* EX1001, 10:49-51 (distal tumor can be “derived from” original tumor following metastasis); EX1002, 2554-2555.

Petitioner’s other pending claims are likewise patentably indistinct, and—as

with claim 43—often broader than those PO has disclaimed. For example, new claims 35-42 omit any requirement for anti-CTLA-4 antibodies and instead merely require administering 240 mg of an anti-PD-1 antibody every two weeks or 480 mg every four weeks.² They are broader than disclaimed claim 16, which requires administering 240 mg of an anti-PD-1 antibody every two weeks *after* previously administering anti-PD-1 and anti-CTLA-4 antibodies together. New independent claim 35 instead merely requires *any* sort of “prior cancer treatments.”

It is no coincidence that PO’s new continuation claims are broader than the disclaimed claims and were filed just two weeks prior to PO’s disclaimer. PO is attempting to short-circuit PTAB scrutiny of the ’529 Patent by exiting one door of the agency, only to walk back in another door to resurrect the same claims in an *ex parte* proceeding. The agency has the power to stop this gamesmanship through adverse judgment and it should do so—especially where PO is also actively extending its patent exclusivity with such follow-on filings. *See* IPR2025-00601, (Paper 8) at 1; IPR2025-00602 (Paper 8) at 1.

III. Adverse Judgment is Necessary to Protect the Public

37 C.F.R. 42.73(b) states that a party “may request judgment against itself at any time during a proceeding” (“adverse judgment”). Subsection (1) explains that

² Space constraints preclude addressing each new claim individually.

“[a]ctions construed to be a request for adverse judgment include: (1) Disclaimer of the involved... patent.” PO’s disclaimer of every claim in the ’529 Patent satisfies subsection (1), and adverse judgment is necessary here to protect the public from PO’s demonstrated gamesmanship.

The Board is permitted to enter adverse judgment in an IPR proceeding where claims are disclaimed prior to institution. *Arthrex, Inc. v. Smith & Nephew, Inc.*, 880 F.3d 1345, 1349-1350 (Fed. Cir. 2018). While Rule 42.73(b) states that “[a] party may request judgment against itself,” this is not a decision solely left to the PO. *Arthrex*, 880 F.3d at 1349 (“If... adverse judgment depended on whether the patent owner requested an adverse judgment, a patent owner could always avoid an adverse judgment by simply stating that it is not requesting one, even with respect to the specific instances articulated in 37 C.F.R. § 42.73(b). This would render the rule a nullity.”). PO’s desire to avoid adverse judgment is immaterial. The balanced approach is to enter adverse judgment where warranted. Here, PO’s gamesmanship, demonstrated above, necessitates adverse judgment to protect the public from PO clawing back subject matter it has affirmatively surrendered.

Moreover, the Board’s discretion to enter adverse judgment here must be fact specific. *See Bestway (USA), Inc. v. Intex Marketing, Ltd.*, PGR2024-00036, Paper 9 at 6-8 (PTAB Oct. 28, 2024) (declining to be bound by decisions on adverse judgment that “do not align with the facts”). Neither Rule 1.321(a) nor *General*

Electric Co. v. United Techs. Corp., IPR2017-00491, Paper 9 (PTAB July 6, 2017) (precedential), dictate the ***manner of denying*** an IPR on a disclaimed patent, nor do they even mention adverse judgment. And in no other case cited thus far, including *Bestway* and *Western Digital Techs. Inc. v. Godo Kaisha IP Bridge I* (see Paper 9 at 3), was adverse judgment sought to stop a patentee from actively undermining the agency to resurrect claims to extend its patent, as PO does here. Cf. *Smith & Nephew, Inc. v. Arthrex, Inc.*, IPR2016-00917, Paper 12 at 8-9 (PTAB Sept. 21, 2016) (entering adverse judgment: “[I]t would be unfair if Patent Owner were able to avoid Petitioner’s challenge through a statutory disclaimer and then pursue patentably indistinct claims in its continuation applications.”).³

IV. Conclusion

The Board should enter adverse judgment so that Patent Owner is estopped from resurrecting indistinct claims to those purportedly disclaimed.

Dated: August 25, 2025

Respectfully submitted,

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³ There were no active continuations in *Western Digital*, and the claims of the pending continuation in *Bestway* were not discussed. *Smith & Nephew* noted the pendency of continuations, although it did not discuss the specifics of the pending claims. The case for adverse judgment is thus even stronger here.

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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