

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 11,332,529 B2

Before JEFFREY N. FREDMAN, GRACE KARAFFA OBERMANN, and
SHERIDAN K. SNEDDEN, *Administrative Patent Judges*.

OBERMANN, *Administrative Patent Judge*.

JUDGMENT

Granting Request for Adverse Judgment Prior to Institution of Trial
37 C.F.R. § 42.73(b)

I. INTRODUCTION

Petitioner¹ filed a Petition (“Pet.,” Paper 2) challenging claims 1–18 of U.S. Patent No. 11,332,529 B2 (“the ’529 patent,” Ex. 1001). Patent Owner² requested a discretionary denial of the Petition (Paper 6), which Petitioner opposed (Paper 7). The Director denied Patent Owner’s request and referred the Petition to the Board. Paper 8.

Thereafter, with Board pre-authorization (Ex. 3001): (1) Patent Owner filed a Supplemental Pre-Institution Brief (“PO Supp. Br.,” Paper 9), supported by a statutory disclaimer (Ex. 2011) of all claims of the ’529 patent, in which Patent Owner argues that “trial should be denied without entry of Adverse Judgment” (PO Supp. Br. 3); (2) Petitioner filed a Response to Patent Owner’s Supplemental Brief (“Pet. Resp. Supp. Br.,” Paper 11), in which Petitioner requests adverse judgment against Patent Owner based on the statutory disclaimer; (3) Patent Owner filed a Reply to Petitioner’s responsive brief (“PO Reply Supp. Br.,” Paper 12); and (4) Petitioner filed a Sur-Reply to Patent Owner’s Reply to Petitioner’s responsive brief (Pet. Sur-Reply Supp. Br.,” Paper 13).

We instructed the parties to “identify and discuss all Board decisions, of which they are aware, in which a panel of the Board entered adverse judgment against a patent owner, prior to entry of a decision to institute, based on a disclaimer of all pending claims.” Ex. 3001. Based on the information provided, for reasons that follow, we grant Petitioner’s request for adverse judgment based on Patent Owner’s statutory disclaimer.

¹ Amgen, Inc. is the real party-in-interest for Petitioner. Pet. xiv.

² Bristol-Myers Squibb Company is the real party-in-interest for Patent Owner. Paper 3 at 1.

II. DISCUSSION

Petitioner argues that adverse judgment is appropriate because the facts here align with those in *Smith & Nephew, Inc. v Arthrex, Inc.*, IPR2016-00917, Paper 12 (PTAB Sept. 21, 2015), *aff'd* 880 F.3d 1345 (Fed. Cir. 2018), where the Board entered adverse judgment against a patent owner during the pre-institution phase of an *inter partes* review. Pet. Resp. Supp. Br. 5 and n.3; Pet. Sur-Reply Supp. Br. 1–3. Patent Owner counters that *Bestway (USA), Inc. v. Intex Marketing., Ltd.*, PGR2021-00117, Paper 16 (PTAB Mar. 14, 2022) “applies here” and supports a denial of the Petition without entry of adverse judgment. PO Reply Supp. Br. 2.

For reasons that follow, we agree with Petitioner and enter adverse judgment against Patent Owner.

A. Applicability of *Smith & Nephew*

In a decision affirmed by the Federal Circuit, the Board in *Smith & Nephew* entered adverse judgment against a patent owner during the pre-institution phase of an *inter partes* review, over the patent owner’s objection that, “[by] filing the statutory disclaimer,” it was “not requesting an adverse judgment.” *Smith & Nephew*, Paper 12 at 1. Although the Board’s decision in *Smith & Nephew* is not binding on this panel, we agree with and adopt its reasoning as fully applicable to facts of the instant case.

There is no dispute that Patent Owner currently is pursuing at least one claim through a pending continuation application (No. 18/787,822 (“the ’822 continuation application”)) that is patentably indistinct from a disclaimed claim of the ’529 patent. Pet. Resp. Supp. Br. 1–2; *see generally* PO Reply Supp. Br. (declining to dispute that fact). That circumstance strongly favors “[c]onstruing Patent Owner’s disclaimer as a request for

adverse judgment” because doing so “aligns with the policies underlying the estoppel provisions of our rules.” *Smith & Nephew*, Paper 12 at 8.

Those estoppel provisions provide that “[a] patent applicant or owner is precluded from taking action inconsistent with [an] adverse judgment, including obtaining in any patent: (i) A claim that is not patentably distinct from a finally refused or cancelled claim.” *Id.* at 3 (quoting 37 C.F.R. § 42.73(d)(3)). During the rulemaking process, the Office explained:

[Section] 42.73(d)(3) set forth in this final rule is consistent with the [America Invents Act], other statutory provisions, the common law related to estoppel, and the common law related to the recapture rule. *See, e.g., In re Deckler*, 997 F.2d 1449, 1452 (Fed. Cir. 19929; *In re Clement*, 131 F.,3d 1464, 1468 (Fed. Cir. 1997) (the recapture rule prevents a patentee from regaining through reissue the subject matter that the patentee surrendered in an effort to obtain allowance of the claim).

Id. at 8 (quoting Rules of Practice for Trials Before the Patent Trial and Appeal Board and Judicial Review of Patent Trial and Appeal Board Decisions, 77 Fed. Reg. 48,612, 48,649 (Aug. 14, 2012).)

In other words, the *Smith & Nephew* decision makes plain that entry of adverse judgment (as opposed to a denial without adverse judgment) is appropriate in situations where a patentee seeks to regain, through continued prosecution, subject matter that is patentably indistinct from previously surrendered subject matter. *Id.*

That is precisely the situation at hand. Claim 43, pending in the ’822 continuation application, is of the same or broader scope than disclaimed claim 1 of the ’529 patent, as shown in Petitioner’s claim chart:

'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”).

Pet. Resp. Supp. Br. 2.

Patent Owner does not contest that fact. *See generally* PO Reply Supp. Br. (nowhere disputing that fact). “Just two weeks prior to” Patent Owner’s disclaimer of claim 1 of the ’529 patent, Patent Owner reaffirmed its intention to pursue patentably indistinct claim 43. Pet. Resp. Supp. Br. 2.

“Having presented a challenge to the patentability of claims” 1–18 of the ’529 patent, “Petitioner is entitled to finality and repose on those claims. Finality and repose would not be achieved if this proceeding were terminated in a manner that left Patent Owner free to seek claims that are not patentably distinct through its continuation applications.” *Smith & Nephew*, Paper 12 at 8.

B. Inapplicability of *Bestway*

Patent Owner counterargues that, under the *Bestway* decision, even where prosecution is ongoing, adverse judgment is less preferable than a

denial without adverse judgment; because the latter, according to Patent Owner, “encourages patent owners to disclaim prior to institution rather than litigate every instituted AIA trial through Final Written Decision.” PO Reply Supp. Br. 2 (citing *Bestway*, Paper 16 at 6–7).

The facts of this case materially differ from those in *Bestway*. Most notably, nothing in the *Bestway* decision indicates that the patent owner there was pursuing the same or broader subject matter, through continuing prosecution, as compared to the subject matter that was surrendered through a statutory disclaimer. *See Bestway*, Paper 16 at 6–7. Entering adverse judgment under the unique and particular facts at hand will not force patent owners *en masse* “to defend every challenged claim in future” *inter partes* proceedings. Pet. Sur-Reply Supp. Br. 2. “The facts here are a far cry from an everyday case,” because Patent Owner “does not dispute that newly added claim 43 in its pending continuation is broader than disclaimed claim 1.” *Id.* at 2–3.

Other circumstances distinguish the facts of this case from those at issue in *Bestway*. “The patentee in *Bestway* had not ‘threatened to assert any claim of the [disclaimed] patent,’” whereas Patent Owner here has indicated its intention to assert the ’529 patent “against Petitioner as part of the ‘Patent Dance.’” *Id.* at 2. Further, and tellingly, Patent Owner “has not provided a covenant not to sue on indistinct claims, which would easily moot this debate.” *Id.* at 3 n.3.

Patent Owner asserts as justification for the timing of its statutory disclaimer an alleged lack of commercial interest in some (but not all) of the claims of the ’529 patent. PO Reply Supp. Br. 2–3. That justification rings hollow where, as Petitioner points out, Patent Owner has disclaimed

challenged claim 1 of the '529 patent to avoid review in this proceeding while at the same time pursuing in the '822 continuation application patentably indistinct claim 43. *See* Pet Sur-Reply Supp. Br. 3.

Against that backdrop, we agree with Petitioner that Patent Owner employs a “wack-a-mole’ strategy” that “has no parallel in *Bestway*.” *Id.* at 2. Indeed, should claim 43 mature to issue in its current form, Patent Owner (unlike the patentee in *Bestway*) could characterize any subsequent petition for review of that claim as a repeat challenge against the same subject matter.

C. Summary

The *Smith & Nephew* panel entered adverse judgment against a patent owner during the pre-institution phase of an *inter partes* review, noting “the pendency of continuations,” but without discussing “the specifics of the pending claims.” Pet. Resp. Supp. Br. 5 n.3. “The case for adverse judgment is thus even stronger here” because Patent Owner undisputedly is attempting to secure through a pending continuation application subject matter that is patentably indistinct from a disclaimed challenged claim. Pet. Resp. Supp. Br. 5 n.3; *see id.* at 2 (comparison claim chart); *see generally* PO Reply Supp. Br. (nowhere disputing these circumstances).

As a result, “[c]onstruing Patent Owner’s disclaimer as a request for adverse judgment” is “the more equitable result in the circumstances of this case.” *Smith & Nephew*, Paper 12 at 8. Patent Owner unfairly seeks “to avoid Petitioner’s challenge through a statutory disclaimer” only to “pursue patentably indistinct claims in” the '822 continuation application. *Id.* at 9. We reject Patent Owner’s attempt to exit “one door of the agency, only to

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walk back in another door to resurrect the same claims in an *ex parte* proceeding.” Pet. Resp. Supp. Br. 3.

For the above reasons, we enter adverse judgment against Patent Owner based on the statutory disclaimer. Ex. 2011.

III. ORDER

It is

ORDERED that adverse judgment is entered against Patent Owner under 37 C.F.R. § 42.73(b); and

FURTHER ORDERED that this proceeding is terminated.

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