



UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ADELLO BIOLOGICS LLC,
APOTEX INC. and APOTEX CORP.,
Petitioners,

v.

AMGEN INC. and AMGEN MANUFACTURING LIMITED
Patent Owner.

Case PGR2019-00001
Patent No. 9,856,287 B2

Before ZHENYU YANG, CHRISTOPHER G. PAULRAJ, and
J. JOHN LEE, *Administrative Patent Judges*.

YANG, *Administrative Patent Judge*.

ORDER

PETITIONERS' MOTION TO AMEND MANDATORY NOTICES
and
PATENT OWNER'S REQUEST FOR DISCOVERY

35 U.S.C. § 322(a)(2) and 37 C.F.R. §§ 42.5, 42.8, 42.71

With our authorization, Adello Biologics, LLC, Apotex Inc., and Apotex Corp. (collectively “Petitioners”) filed a Motion to Amend Mandatory Notices. Paper 9 (“Mot.”). In the Motion, Petitioners seek to amend their mandatory notices to add Amneal Pharmaceuticals LLC (“Amneal LLC”) as a real party in interest (“RPI”) without altering the petition filing date. *Id.* at 1. Patent Owner opposes Petitioner’s request. Paper 19 (“Opp.”). Patent Owner also “requests authorization to move for discovery into the pertinent facts.” *Id.* at 7. After considering the parties’ arguments and evidence, we grant Petitioners’ Motion and deny Patent Owner’s request.

On October 1, 2018, Petitioners filed a Petition (Paper 3, “Pet.”), requesting a post-grant review (“PGR”) of claims 1–30 of U.S. Patent No. 9,856,287 (“the ’287 patent”). In addition to Petitioners, the Petition also identified Amneal Pharmaceuticals, Inc. (“Amneal Inc.”), Apotex Pharmaceuticals Holdings Inc., Apotex Holdings, Inc., ApoPharma USA, Inc., and Intas Pharmaceuticals Limited as real parties in interest. Pet. 2.

On January 2, 2019, Patent Owner contacted Petitioners’ counsel, stating that Amneal LLC also should have been named as an RPI. Ex. 2023. According to Petitioners, they “promptly investigated the issue, and agreed that Amneal LLC should have been listed as a[n] RPI.” Mot. 1. Petitioners assert that “there was no intentional concealment or bad faith” in the “inadvertent omission” of Amneal LLC as an RPI. *Id.* at 4.

Noting that the RPI issue is not jurisdictional, Petitioners request that we exercise our discretion under 37 C.F.R. §§ 42.5(a), (b), and (c)(3) to allow them to amend the mandatory notices to add Amneal LLC as an RPI, while maintaining the current filing date. *Id.* at 1–6. According to

Petitioners, doing so would ensure the proper application of the statutory estoppel provisions, and would not prejudice Patent Owner. *Id.* at 3–6.

Patent Owner responds that we should deny Petitioners’ Motion. Opp. 2. Patent Owner contends that 35 U.S.C. § 322(a)(2) requires Petitioners to identify all RPIs “*when they file their petition.*” *Id.* at 1. According to Patent Owner, Petitioners “were well aware of the central role played by the missing RPI” at the time the Petition was filed. *Id.* Patent Owner argues that the surrounding circumstances “raise[] serious questions” about Petitioners’ “gamesmanship or bad faith” in omitting Amneal LLC as an RPI. *Id.* at 5–6.

We find Petitioner’s arguments more persuasive. Although we agree with Patent Owner that it is important for the petition to identify all RPIs, if a petition fails to do so, “the Director can, and does, allow the petitioner to add a real party in interest.” *Wi-Fi One, LLC v. Broadcom Corp.*, 878 F.3d 1364, 1374 n.9 (Fed. Cir. 2018). Indeed, “the PTO has established procedures to rectify noncompliance” of § 322(a)(2). *Id.*¹

Patent Owner contends that because Petitioners did not identify all RPIs, they are “indisputably time-barred from bringing a PGR.”² Opp. 1–2 (citing 35 U.S.C. § 322(a)(2); 37 C.F.R. § 42.206(b)), 7. But neither the

¹ In *Wi-Fi One*, the Federal Circuit recognized that a mistake in identifying RPI is correctable in an *inter partes* review. We see no reason, nor have the parties identified a reason, why the same is not also true for a post-grant review.

² “A petition for a post-grant review may only be filed not later than the date that is 9 months after the date of the grant of the patent.” 35 U.S.C. § 321(c). The ’287 patent issued on January 2, 2018 (Ex. 1001). Thus, a petition for a PGR of the ’287 patent must be filed no later than October 2, 2018.

statute nor the rule governing RPI disclosures is designed to award a patent owner such a windfall. Instead, requiring a petition to identify all RPIs serves “to assist members of the Board in identifying potential conflicts, and to assure proper application of the statutory estoppel provisions.” Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,759 (Aug. 14, 2012).

Here, Petitioners explain, and Patent Owner does not dispute, that Amneal LLC, the missing RPI, is a wholly owned subsidiary of Amneal Inc. Mot. 4. Because the Petition properly identified Amneal Inc. as an RPI, the Board was able to check for conflicts.

Requiring a petition to identify all RPIs also protects a patent owner from “harassment via successive petitions by the same or related parties,” and prevents parties from having a “second bite at the apple.” Trial Practice Guide, 77 Fed. Reg. at 48,759. Allowing Petitioners to—before an institution decision is made—add Amneal LLC as an RPI serves exactly this “core function.”

Patent Owner emphasizes that “Amneal LLC’s role and connections to the ’287 [patent], the accused biosimilar product and infringement litigation leading to this PGR, and the other named Petitioners and RPIs, was being *actively discussed* with named Petitioner Adello *precisely when this PGR Petition was being finalized.*” Opp. 4. Even so, we decline to infer, as Patent Owner would have us do, that the omission of Amneal LLC suggests “gamesmanship or bad faith.” *See id.* at 5–6.

After all, by filing the Motion, Petitioners and their counsel certify “[a]ll statements made therein of [Petitioners’] own knowledge are true, all statements made therein on information and belief are believed to be true.” 37 C.F.R. § 11.18(b)(1). Indeed, Petitioners affirm their understanding of

duty of candor and good faith to the Office during the course of a proceeding. Mot. 4 (citing 37 C.F.R. § 42.11(a)). And “[w]ith that understanding, Petitioner Adello expressly represents that there was no intentional concealment or bad faith in the accidental omission of Amneal LLC as a[n] RPI.” *Id.* at 4–5. Given the severe penalties imposed on one who knowingly and willfully falsifies or conceals a material fact (*see* 37 C.F.R. § 11.18(b)(1)), we are satisfied with Adello’s express representation that it did not act in bad faith, or engage in gamesmanship.

We observe that although counsel for Patent Owner in this proceeding overlap with those in the parallel infringement action in district court (*compare* Paper 5, *with* Ex. 2002, 37), Petitioners are represented by different counsel in the two venues (*compare* Paper 2, *with* Ex. 2018). We also note that on January 23, 2019, Petitioners voluntarily added Kashiv BioSciences, LLC as an RPI. Paper 7. To be sure, neither fact exonerates Petitioners from omitting Amneal LLC as an RPI in the Petition. Nonetheless, they suggest the omission may have been a human error, and Petitioners, instead of attempting to circumvent estoppel rules, are attempting to be diligent in updating the mandatory notices.

In sum, Petitioners’ delay in identifying all RPIs does not result in any undue prejudice against Patent Owner. Allowing Petitioners to update the mandatory notices while maintaining the original filing date promotes the core functions of RPI disclosures and secures a “just, speedy, and inexpensive resolution” of this proceeding. *See* 37 C.F.R. § 42.1. Thus, we exercise our discretion under 37 C.F.R. § 42.5(b) to allow Petitioners to add Amneal LLC as an RPI while maintaining the original filing date.

In an email communication with the Board, and during the January 18 conference, Patent Owner requested “leave to file a motion for discovery regarding Petitioners’ asserted position” that “the missing real party-in-interest was inadvertently omitted.” Ex. 2025. In its Opposition, Patent Owner states that “to the extent the Board determines further evidence is needed to deny this motion, Amgen again requests authorization to move for discovery into the pertinent facts.” Opp. 7. Given that Amneal LLC is now disclosed as an RPI and is subject to the relevant statutory restrictions, such discovery appears to have little, if any, substantive relevance, and Patent Owner does not provide a persuasive explanation to the contrary. Thus, we deny Patent Owner’s request for authorization.

Accordingly, it is

ORDERED that Petitioners’ Motion to Amend Mandatory Notices to add Amneal LLC as a real party in interest is *granted*;

FURTHER ORDERED that the filing date of the Petition shall remain unchanged; and

FURTHER ORDERED that Patent Owner’s request for authorization to file a motion for discovery of facts surrounding the omission of Amneal LLC as a real party in interest is *denied*.

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PETITIONER:

Teresa Rea
trea@crowell.com

Deborah Yellin
dyellin@crowell.com

Shannon Lentz
slentz@crowell.com

PATENT OWNER:

J. Steven Baughman
sbaughman@paulweiss.com
GRP-AmgenPGR@paulweiss.com

Megan Raymond
mraymond@paulweiss.com

Catherine Nyarady
cnyarady@paulweiss.com

Jenifer Wu
jwu@paulweiss.com