

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMNEAL PHARMACEUTICALS LLC, PAR PHARMACEUTICAL, INC., and
WOCKHARDT BIO AG,

Petitioners,

v.

JAZZ PHARMACEUTICALS, INC.

Patent Owner

Case IPR2015-00547¹

Patent 7,765,107

**PATENT OWNER'S OPPOSITION TO PETITIONERS'
MOTION PURSUANT TO 37 C.F.R. § 42.5(c)(3)**

¹ Case IPR2015-01820 has been joined with this proceeding.

Patent Owner (“Jazz”) submits this opposition to Petitioners’ motion to excuse their late filing of objections under 37 C.F.R. § 42.5(c)(3) (“Mtn.”).

I. RESPONSE TO PETITIONERS’ “STATEMENT OF FACTS”

On May 19, 2015, 37 CFR § 42.64(b)(1) was amended “to require filing of objections, which also requires service under 37 CFR 42.6(e)(2).” 80 Fed. Reg. 28563. Thus, for objections to be proper, they must be both filed and served. *See id.* The amendment was published in the Federal Register. *See id.* On November 13, 2015, Petitioners served, but did not properly file, objections to evidence Jazz submitted with its Response. *See Ex. 1060 at 3.* Jazz denies that Petitioners “inadvertently” did not file their objections as they assert. *See Mtn. 1.* If they truly did not know of the rule, their failure to comply with it could not be inadvertent.

Jazz also denies Petitioners’ assertion that because Jazz served supplemental evidence, “Jazz had actual notice of Petitioners’ objections here.” *See Mtn. 1.* Instead, by rule: “Once a trial has been instituted, **any objection must be filed** within five days of service of evidence to which the objection is directed.” 37 C.F.R. § 42.64(b)(1) (emphasis added). Also, by rule: “The party relying on evidence to which an objection is **timely served** may respond to the objection by serving supplemental evidence within ten business days of **service** of the objection.” 37 C.F.R. § 42.64(b)(2) (emphasis added). In other words, serving certain supplemental evidence in response to “timely served” objections under

§42.64(b)(2) is not a concession or acknowledgment of timely “filed” objections under §42.64(b)(1). And in fact, Jazz expressly “reserve[d] the right to argue that Petitioners have waived their objections.” Ex. 1059 at 1.

Four months later, Petitioners e-mailed Jazz, asking “whether Jazz will object to Petitioners seeking leave to file these evidence objections before the Board. . . .” Ex. 1060 at 5. Jazz denies that it refused Petitioners’ request “on the sole grounds that the request was untimely,” as Petitioners assert. *See* Mtn. 2. Jazz also raised, and continues to assert, issues of prejudice. *See* Ex. 1060 at 1-2.

II. ARGUMENT

Petitioners bear the burden of proving that they are entitled to relief. *See* 37 C.F.R. § 42.20 (c). The Board stated that “Petitioners’ motion [to excuse their late objections] must make a showing of good cause to support their request and explain why ‘consideration on the merits would be in the interests of justice.’” Ex. 1060 at 1. Petitioners fail to meet their burden on both points.

A. Petitioners cannot show good cause

First, Petitioners admit that they failed to comply with §42.64(b)(1). Mtn. 2. The only excuse Petitioners offer is that their attorneys were ignorant of the law—i.e., the version of §42.64(b)(1) that requires filing objections. *Id.* at 2-3. But that version of §42.64(b)(1) was enacted *and published in the Federal Register* on May 19, 2015—*six months before* Petitioners failed to file the objections.

Even if Petitioners' counsel's lack of knowledge of what was published in the Federal Register was reasonable, it does not excuse Petitioners' counsel's ignorance of the law. Indeed, the PTAB has refused to grant motions under §42.5(c)(3) when the requirement missed was published in the Federal Register and the movant "misunderstood the law." *Reflectix Inc. v. Promethean Insulation Tech.*, IPR2015-00039, 2015 WL 1927414, at *7 (Apr. 24, 2015). That is the case here, and the Board should similarly refuse Petitioners' motion.²

Second, Petitioners argue that the Board "has allowed parties who timely served their evidence objections *under the prior rule* to file them with a motion to exclude after promulgation of the new rule." Mtn. 3 (emphasis added). To be clear, in the IPR cited, the rule changed *after* the party served its objections in March 2015. *TRW Auto v. Magna Elecs.*, IPR2014-01348, Paper 25 at 3 (Jan. 15,

² Petitioners' motion is ironic given their position that the references in this IPR qualify as prior art because a POSA, interested in "drug distribution, safety and abuse," would "[n]aturally" look to the Federal Register. *See* Paper 50 at 8. Here, not one of Petitioners' counsel—registered patent attorneys who litigate IPRs—was aware of the rule governing IPRs that was published in the Federal Register.

2016). Here, the rule changed *six months before* Petitioners failed to comply.

Any implication by Petitioners that this case supports their position is misleading.

Third, Petitioners allege that “[g]ood cause exists to extend a deadline where delay is due to an attorney error and the extension causes no prejudice.” Mtn. 3. Again, the caselaw cited does not support Petitioners’ position. In *Bronner*, the delay was only seventeen days, not four months, and was caused by a calendaring error, not ignorance of the rule. *Bronner v. Unum Life Ins.*, No. 03-5742, 2008 WL 4951031, at *1-2 (N.D. Cal. Nov. 18, 2008). Further, the opposing party “d[id] not explain how they would suffer actual prejudice from an extension.” *Id.* at *2.³

But here, prejudice is irrelevant under the rule. *Nintendo of Am. v. Motion Games LLC*, IPR2014-00164, Paper 51 at 26-27 (May 15, 2015) (finding untimely objections waived and refusing to allow an exception based on argument of no prejudice). Regardless, Jazz explained how it would be prejudiced. For example, Petitioners seek to rely on their improper objections to exclude a third-party’s deposition as hearsay. *See* Paper 56 at 8-9. While Jazz disagrees with Petitioners’

³ *Lopez v. Burris Logistics* has nearly the same facts. No. 31-1039, 2013 WL 5962100, at *2-3 (D. Conn. Nov. 6, 2013) (extending deadline where the three-day delay was caused by a calendaring error and the other side admitted no prejudice).

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