

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FRESENIUS KABI USA, LLC and
FRESENIUS KABI SWISSBIOSIM GMBH,
Petitioners,

v.

AMGEN INC. and AMGEN MANUFACTURING, LIMITED,
Patent Owners.

Case IPR2019-00971
Patent 9,856,287

**PATENT OWNERS' SUR-REPLY IN SUPPORT OF ITS
PRELIMINARY RESPONSE¹**

¹ This paper was authorized by Order on August 8, 2019 (Pap. 10, 3). All emphasis is added unless noted.

Proceeding With An IPR Is Improper When A PGR Has Been Instituted.

Petitioners' Reply (Pap. 11) posits that, despite Congress's obvious concern that PGRs be *filed and addressed first* after a patent's issuance, Congress somehow enacted a legislative regime—and the PTO adopted a rule—with a gap allowing an IPR to proceed while a PGR petition is pending, so long as it was filed *after* the 9-month statutory bar and *before* the Board issued its institution decision for the PGR petition. Given the clear temporal division between PGR and IPR proceedings established by Congress and reflected in the rules (*compare* §321(c), *with* §311(c), and *compare* §42.202(a), *with* §42.102(a)), there is no reason to assume Congress or the PTO intended IPRs to run concurrently with PGRs. A scheme where the IPR petition bar briefly terminates and then restarts due to an instituted PGR makes no sense, and is not what the statute or rule provide.

Petitioners erroneously suggest Amgen misplaced its reliance on *Intex Recreation* because the Board supposedly “did not rely on the PGR as a basis for finding a previously timely petition untimely; it merely recognized that a *new* IPR could no longer be filed because the PGR had been instituted.” Not so: in discussing the “timing of *this* petition for *inter partes* review,” the Board denied institution for two reasons—because “this” IPR (which was filed at the same time as the PGR) was premature *and* because the PGR had since been instituted. *Intex Recreation Corp.*

v. Team Worldwide Corp., IPR2019-00245, Pap. 7, 10 (May 15, 2019) (citing both §311(c)(1) and §311(c)(2)).

Petitioners also assert “courts have repeatedly rejected arguments that the timeliness of a filing was altered by subsequent events,” but mistakenly rely on cases where district court litigants faced the inequity of being forever barred from appeal due to actions taken by another party or subsequent rule changes.² **First**, there is no question Petitioners here can seek an IPR after the end of the PGR proceedings. **Second**, as in those cases, Petitioners do not suggest Amgen has taken any action to render the Petition untimely or identify any subsequent rule change that, if applied, would make it untimely. **Third**, the fact that the PGR petition at issue had been filed and was being considered was public knowledge and *specifically known by Petitioners, who*, as detailed in Amgen’s POPR, *copied significant portions of it*. Pap. 8

² *Antonious v. Spalding & Evenflo Cos.*, 10 Fed. Appx. 801, 802 (Fed. Cir. May 7, 2001) (nonprecedential) (withdrawing appeal does not render responsive appeal untimely); *Nickel v. Bank of Am. Nat’l Tr. & Sav. Ass’n*, 1997 WL 419113, *3 (9th Cir. July 25, 1997) (unpublished) (timeliness of motion determined under rules in effect at filing); *Bailey v. Sharp*, 782 F.2d 1366, 1368 (7th Cir. 1986) (same).

(POPR), 24. Accordingly, contrary to Petitioners’ assertion, there is no “retroactivity” concern here—Petitioners simply need to wait until the PGR is completed, as contemplated by the statute and rule. Petitioners’ attempt to game the system and file just days before the institution decision in the PGR was due should not be rewarded.

Discretionary Denial Is Warranted Under §314. With respect to factor 1 of *General Plastic* and *Valve Corp.*, Petitioners *admit* to coordination with PGR petitioners, but assert this is “different” from a serial filing strategy. Pap. 11, 3. However, *Valve Corp.* makes clear that, “when different petitioners challenge the same patent, we consider any relationship between those petitioners when weighing the *General Plastic* factors.” *Valve Corp. v. Elec. Scripting Prods., Inc.*, IPR2019-00062, Pap. 11, 2, 9 (Apr. 2, 2019) (precedential). Petitioners’ assertions regarding the timing for its filing are entirely generic, providing no articulation for their particular timing here, and are thus insufficient. *Juniper Networks, Inc. v. Parity Networks, LLC*, IPR2018-01642, Pap. 11, 10 (Apr. 10, 2019) (*General Plastic* factor 5 weighed against institution where petitioner offered merely “generic justification” for delay).

Petitioners cite *Niantic, Inc. v. Blackbird Tech LLC*, IPR2019-00489, Pap. 8, 9 (July 11, 2019), in arguing the Board should not exercise its discretion. But *Niantic* concerned *simultaneously filed* petitions, *id.* 6, not *follow-on* petitions. And neither

the patent owner, petitioner, nor the Board there addressed the *General Plastic* factors, which that panel viewed (pre-*Valve Corp.*) as “generally geared” for follow-on petitions. *Niantic*, IPR2019-00489, Pap. 8, 8. Rather, that patent owner merely argued the prospect of facing two petitions on the same claims would be overly burdensome, and the Board disagreed. *Id.* 7-9.

Petitioners’ also cite *Moderna Therapeutics, Inc. v. Arbutus Biopharma Corp.*, IPR2019-00554, Pap. 8, 9 (July 24, 2019), as rejecting an argument that a previously filed petition on one patent warrants denial of a later-filed petition on a related patent. But there, the Board rejected patent owner’s *General Plastic* argument because the IPR represented the “first challenge to the [] patent.” *Id.*, 10. The present IPR is *not* the first challenge to this patent. Further, Amgen relies on a previously-filed PGR petition on the *same patent and* has also cited a previously-filed a petition on a *similar patent* further confirming that Petitioners here had previous knowledge of the prior art (factor 2) and did not have a sufficient explanation for the timing of their Petition (factor 5), factors which Petitioners still have not substantively explained. *See* Pap. 8 (POPR), 23-31.

Congressional intent was clearly *not* to allow an IPR to proceed while a PGR is pending, and Petitioners attempted to game the system here by filing their Petition only days before the PGR institution decision would be known. These considerations further support the Board denying institution.

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