UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PFIZER, INC.,
Petitioner,

v.

GENENTECH, INC.,
Patent Owner.

Inter Partes Review No. IPR2017-01923
Patent No. 7,976,838 B2
Issued: July 12, 2011
Filed: March 20, 2008

Title: THERAPY OF AUTOIMMUNE DISEASE IN A PATIENT WITH AN INADEQUATE RESPONSE TO A TNFα-INHIBITOR

PETITIONER'S AUTHORIZED REPLY TO PATENT OWNER'S PRELIMINARY RESPONSE

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Patent Trial and Appeal Board
United States Patent and Trademark Office
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Pursuant to the Board's authorization in Paper 11, Pfizer files this Reply to Patent Owner's Preliminary Response. On August 29, 2017, Petitioner Pfizer, Inc. filed its *first and only* Petition seeking *inter partes* review of the '838 patent. Patent Owner invoked the Board's decisions in *General Plastic* and *Samsung*[1]—both decided *after* Pfizer filed its Petition—to argue that the Board should exercise its discretion to deny Pfizer's Petition as an improper "follow-on" petition under §314(a). POPR, 22. Pfizer's challenge to the '838 patent is unique and honors the Board's finite resources. The Petition should be granted.

Legal Standard. *General Plastic* established a "non-exhaustive" list of seven factors to guide the exercise of discretion under §314(a) to deny "multiple petitions by the *same* petitioner against the *same* claims of a patent." IPR2016-01357, Pap. 19 at 17–18 (emphasis added). By its very terms, the Board's binding authority does not apply to Pfizer's *first and only* Petition challenging the '838 patent. Patent Owner hopes to expand *General Plastic* to challenges filed by a different petitioner, citing *Samsung*. But as discussed below, *Samsung* is distinguishable. Regardless, each *General Plastic* factor supports reaching the merits of the Petition. *Id.* at 16.

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[1] *Gen. Plastic Indus. Co. v. Canon Kabushiki Kaisha*, IPR2016-01357, Paper 19 (Sept. 6, 2017) (precedential); *Samsung Elecs. Co. v. Elm 3DS Innovations, LLC*, IPR2017-01305, Paper 11 (Oct. 17, 2017) (informative).

Factor 1 examines "whether the *same* petitioner previously filed a petition directed to the *same* claims of the *same* patent." *Id.* (emphasis added). Because this is the first time that Pfizer has filed a petition challenging *any* claim of the '838 patent, this factor strongly favors reaching the merits of the Petition.

In arguing otherwise, Patent Owner relies on *Samsung*, where the panel found that "a high degree of similarity" between a petition and the petitioner's previous challenges to other patents may also weigh in favor of denial. POPR, 26. In *Samsung*, however, there were *14 final written decisions* in which the petitioner had previously presented issues with such a "high degree of similarity" that all 14 cases were consolidated. IPR2017-01305, Pap. 11 at 18–19. By contrast, here, the Board has not issued a final written decision for any of Pfizer's prior petitions relating to rituximab, and none has a "high degree of similarity" to the Petition here. Only one of Pfizer's petitions involved rituximab and rheumatoid arthritis ("RA")—IPR2017-01115, a joinder petition. And that petition had different primary prior art, a different priority date, and different dosing/population claim limitations. Pfizer's other petitions concern different diseases and present distinct factual inquiries.

Also, the procedural posture here is unique, because the Board instituted the first-filed petition on the '838 patent (later withdrawn) but then, unexpectedly, declined to institute a later petition that included the previously-instituted ground. *Compare* IPR2015-00417, Pap. 11 *with* IPR2016-01667, Pap. 15. And on the merits,

Pfizer's Petition, unlike the prior petitions, focuses on the pathology of RA and rituximab's distinct mechanism of action, rebutting Patent Owner's assertions during prosecution that these RA patients were "hard to treat." *E.g.*, EX2007, 413. The Petition cites prior art that the Board and Examiner have not considered and relies on experts who have not testified about the '838 patent. *Cf.* IPR2017-01305, Pap. 11, at 19. Thus, Factor 1 favors reaching an institution decision on the merits.

Factor 2 turns on whether the petitioner "knew of the prior art asserted in the second petition or should have known of it" when it filed its first petition. IPR2016-01357, Pap. 19, at 16. Again, this *is* Pfizer's first petition challenging the '838 patent. Accordingly, this factor favors an institution decision on the merits.[2]

Factor 3 examines whether, "at the time of filing the second petition," Petitioner had received the preliminary response, institution decision, patent owner response, patent owner's expert testimony, and/or the final written decision in the previous proceeding. IPR2017-01305, Pap. 11, at 20–21. Patent Owner contends that Pfizer used the "prior POPRs to try to preempt Genentech's arguments and strengthen [Pfizer]'s position." POPR, 27. But any reliance on the prior POPRs is cumulative of the '838 patent's original prosecution. *See* EX2007, 406–14, 533–55.

[2] Patent Owner concedes that "this factor [as well as factors 4 and 7] may have less probative value." POPR, 26 (quoting *Samsung*, Pap. 11 at 20).

The only "new" arguments that Pfizer cited from the previous POPRs concerned secondary considerations and Patent Owner's attempt to antedate Edwards 2002 (EX1003). Yet, Pfizer had no burden to address secondary considerations in its Petition (Pet., 59–60), and it received no benefit from Patent Owner's previous attempt to antedate Edwards 2002, because *all* of the relevant arguments *and* supporting documents were entirely redacted (EX1038, 31–40). In any event, Pfizer properly raised these additional arguments out of an abundance of caution to avoid any argument by Patent Owner that they had been waived. Indeed, elsewhere Patent Owner faulted Pfizer for *not* "addressing [its] prior responses." POPR, 31. Factor 3 thus weighs in favor of deciding the Petition on its merits.

Factor 4 examines "the length of time that elapsed between the time the petitioner learned of the prior art asserted in the second petition and the filing of the second petition." IPR2016-01357, Pap. 19, at 16. This *is* Pfizer's first petition challenging the '838 patent. Thus, this factor favors a decision on the merits.

Factor 5 evaluates whether the petitioner "provides adequate explanation for the time elapsed between the filings of multiple petitions." *Id.* Here, Patent Owner faults Pfizer for "provid[ing] *no explanation* for its failure to file its Petition sooner" after waiting "more than five months" to file IPR2017-01115 (a joinder petition) challenging the related '161 patent. POPR, 29. But the explanation is simple: Pfizer intended to file a motion for joinder with Celltrion's IPR2016-01667, which

included the same ground (among other grounds) that the Board had previously instituted in Boehringer's IPR2015-00417. Given the Board's previous institution decision, Pfizer expected the Board to institute review of Celltrion's petition as well. When the Board instead denied Celltrion's petition, Pfizer began preparing an independent challenge to the '838 patent, which required five months to review the prior art and draft a new petition with arguments that neither Boehringer nor Celltrion had raised. If IPR2016-01667 had been instituted, Pfizer would have filed a joinder petition as it did in the related '161 patent proceedings. *See* IPR2016-01614; IPR2017-01115. Factor 5 thus favors a decision on the merits.

Factor 6 turns on whether denial is needed to conserve "the finite resources of the Board." IPR2016-01357, Pap. 19, at 16. It is not. Again, Pfizer intended to conserve the Board's resources by seeking joinder in IPR2016-01667, which Pfizer expected would be instituted. When it was not, Pfizer filed a single new petition challenging the '838 patent. This factor thus favors a decision on the merits.

Factor 7 examines the need "to issue a final determination not later than 1 year" after institution. *Id.* Nothing about Pfizer's first and only Petition impacts the Board's ability to do so. This factor, too, favors reaching the Petition's merits.

Conclusion. For these reasons, the Board should decline to exercise its discretion to deny the Petition under §314(a); and, for the reasons set forth in the Petition, institute trial and cancel the claims of the '838 patent.

Dated: January 26, 2018

Respectfully submitted,

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6(e) and 42.105(a), I certify that, on January 26, 2018, I caused true and correct copies of the foregoing PETITIONER'S AUTHORIZED REPLY TO PATENT OWNER'S PRELIMINARY RESPONSE to be served by electronic mail on the following attorneys:

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