

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SANDOZ INC.
Petitioner,

v.

GENENTECH, INC.
Patent Owner

Patent No. 7,976,838 B2

Issued: July 12, 2011

Filed: March 20, 2008

Inventors: Mark C. Benyunes and Randall M. Stevens

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

Inter Partes Review No. 2017-02036

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

Sandoz files this reply pursuant to the Board's authorization. *See* Paper 11 at 2, 4. On August 31, 2017, Sandoz simultaneously filed two petitions for IPR against the '838 patent. In response, Genentech invites the Board to broadly and unfairly expand the application of *General Plastic* and *Samsung*¹ to deny petitions from parties that have *never* before challenged the patent at issue (or any patent in its family) in an IPR. The instant Petitions are the only time Sandoz has challenged any patent in the '838 patent family, and the arguments and evidence Sandoz presents are substantially different than those raised during prosecution and any of the prior petitions challenging the '838 patent. Sandoz's Petition should be granted.

General Plastic provided a non-exhaustive list of factors that the Board may consider when faced with multiple follow-on petitions by the *same* petitioner against the same patent. IPR2016-01357, Paper 19, at 17–18. Despite Genentech's arguments otherwise, *Samsung* did not expand *General Plastic* to include a Petitioner like Sandoz that was not involved in *any* prior related proceedings and who is filing its first challenge to the patent at issue. In any event, the *General Plastic* factors favor hearing the merits of Sandoz's petition.

Factor 1: Sandoz has not “previously filed a petition directed to the same

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

patent.” IPR2016-01357, Paper 19, at 16. Therefore, this factor weighs heavily against an exercise of discretion. Genentech argues that “Petitioner has effectively taken advantage of 10” challenges, but that count includes: the instant Petitions; Pfizer’s petition, filed two days before the instant Petitions; and petitions challenging the ’161 patent.² *See* POPR at 21–23. Other than the instant Petitions, Sandoz was not involved in any of the petitions Genentech counts. By contrast, in *Samsung* the “Petition present[ed] many issues and arguments . . . that [were] also present in *fourteen* other *inter partes* reviews for which *Samsung is a petitioner*.” IPR2017-01305, Paper 11, at 18 (emphases added).

Conceding that Sandoz was not involved in any earlier petition, Genentech argues that there is a “high degree of similarity” between the instant Petition and three previously filed petitions.³ POPR at 22–23. This statement is conclusory and unsupported by the record. For example, Sandoz emphasizes through argument and

² Sandoz was not involved in the ’161 patent challenges, despite Genentech’s unsupported insinuations (*see* POPR at 21–23), and in any case, the distinct differences between the ’161 and ’838 patents (*e.g.*, different claims, specification, and priority date) are such that those petitions would not have informed, and did not inform, Sandoz’s challenge here.

³ Genentech repeatedly references “four” petitions which includes Pfizer’s petition (IPR2017-01923) filed two days before the instant Petitions. *See, e.g.*, POPR at 22.

evidence not previously before the Examiner or addressed in prior petitions that rituximab, an anti-CD20 antibody, has a different mechanism of action than any prior RA therapy and for this reason, among others, TNFIRs are not “harder to treat.” *See* Paper 1 at 7–8, 12–13, 18, 43–44, 50, 52–53, 59. Sandoz supported its arguments with expert testimony, the historical context of rituximab therapy at the time of the purported invention, and specific teachings in the cited references as seen from the perspective of an ordinary skilled artisan. *See, e.g., id.* at 22–23. Genentech’s POPR addressed this important issue with only attorney argument, insufficient to rebut Sandoz’s affirmative evidence. *See* POPR at 38–39; *Perfect Web Technologies, Inc. v. InfoUSA, Inc.*, 587 F.3d 1324, 1332 (Fed. Cir. 2009) (“this position is merely attorney argument lacking evidentiary support”).⁴

Finally, Genentech’s argument repeatedly invokes Celltrion’s denied petition against the ’838 patent while ignoring the fact that Boehringer’s IPR2015-00415 *was instituted*. POPR at 22–23. First, Sandoz’s Petition includes arguments and evidence not addressed in any prior petition. Second, the Board’s institution in Boehringer’s IPR demonstrates that it is certainly possible to establish a reasonable

⁴ Genentech also notes that Sandoz has hired some of the same attorneys as Boehringer in its successful petition. POPR at 22–23; *see also* IPR2015-00417. But Genentech cites no authority holding that hiring an attorney with subject-matter experience is cause for the Board to exercise its discretion, let alone relevant at all.

likelihood that at least one claim of the '838 patent is unpatentable. The Board should decline Genentech's invitation to grant preclusive effect to Celltrion's failed attempt and reach the merits of Sandoz's Petition.

Factor 2: Sandoz has not previously challenged the '838 patent. Therefore, this factor weighs against an exercise of discretion. *See* IPR2017-01305, Paper 11, at 19–20 (assigning minimal weight to Samsung's *fourteen* earlier petitions).

Factor 3: Genentech argues that Sandoz has used earlier proceedings brought by third-parties to strengthen its position and preempt Genentech's arguments here. POPR at 24–25; *see also* IPR2016-01357, Paper 19, at 16. But most of what Genentech cites was presented in detail during prosecution, *see* Ex. 1042 at 427–31, and Sandoz's response has not been presented in any prior proceeding, including prosecution. Accordingly, this factor weighs against an exercise of discretion. The remainder of Genentech's comments relate to secondary considerations that Sandoz bore no burden to address. *Sega of Am., Inc. v. Uniloc USA, Inc.*, IPR2014-01453, Paper 11, at 20 (P.T.A.B. Mar. 10, 2015) (Patent Owner must first present a *prima facie* case for secondary considerations).

Factor 4: Genentech does not analyze this factor. POPR at 25; *see also* IPR2017-01305, Paper 11, at 22. Because this is Sandoz's first petition against the '838 patent, this factor weighs against an exercise of discretion.

Factor 5: Sandoz did not “delay” in filing its petitions. *See* IPR2016-01357,

Paper 19 at 16. Genentech cites no authority for the argument that Sandoz must explain the timing of its decision to challenge the '838 patent when it has never challenged it before. *See* IPR2017-01305, Paper 11, at 22–23 (noting delay based on fourteen earlier related petitions). When Sandoz determined it had an interest in challenging the '838 patent it assembled and filed the instant Petition. There was no delay; therefore, this factor weighs against an exercise of discretion.

Factor 6: As discussed above, Sandoz's petition presents substantial arguments and evidence that have not been presented to the Examiner or the Board and therefore respects the Board's finite resources. Therefore, this factor weighs against an exercise of discretion.

Factor 7: Genentech admits that this factor does not weigh against institution. POPR at 26; IPR2017-01305, Paper 11, at 23.

Conclusion: Genentech invites the Board to grant preclusive effect to Celltrion's denied petition. But Sandoz was not involved in the referenced earlier proceedings and has not been heard on any of the issues raised in its Petition. *Cf. In re Trans Texas Holdings Corp.*, 498 F.3d 1290, 1297 (Fed. Cir. 2007) (noting that the Federal Circuit has "never applied issue preclusion *against* a non-party to the first action"). For the reasons stated above, the Board should not deny Sandoz's petition under § 314(a); the Board should reach the merits of Sandoz's Petition and institute proceedings.

Dated: February 2, 2018

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CERTIFICATE OF SERVICE

I hereby certify that true and correct copies of the foregoing PETITIONER'S AUTHORIZED REPLY TO PATENT OWNER'S PRELIMINARY RESPONSE was served on February 2, 2018 via electronic mail to the following attorneys of record for Patent Owner:

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