

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE PATENT TRIAL AND APPEAL  
BOARD**

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SANDOZ INC.,  
Petitioner

v.

ABBVIE BIOTECHNOLOGY LTD.,  
Patent Owner

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Case No. IPR2017-01823  
U.S. Patent No.: 8,802,100  
Issue Date: Aug. 12, 2014  
Title: Formulation of Human Antibodies  
for Treating TNF-Alpha Associated Disorders

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**PETITIONER'S REPLY TO  
PATENT OWNER'S PRELIMINARY RESPONSE  
PURSUANT TO 37 C.F.R. § 42.108(c)**

## **I. INTRODUCTION**

On July 20, 2017, Petitioner Sandoz Inc. (“Petitioner” or “Sandoz”) filed its *first and only* Petition seeking *inter partes* review (“IPR”) of U.S. Patent No. 8,802,100 (“the ’100 patent,” Ex. 1001). Sandoz has never previously sought IPR of the ’100 patent or of any other related patent.<sup>1</sup> Moreover, no third party has ever petitioned for IPR of any claim of the ’100 patent. Nevertheless, in its Preliminary Response, Patent Owner (also “AbbVie”) contends that the Board should exercise the discretion accorded to it under 35 U.S.C. §§ 314(a) and 325(d) to deny institution on Sandoz’s pending Petition, because two third parties previously sought IPR of different claims of different patents, using different combinations of prior art. Petitioner respectfully submits that the Board should decline to exercise its discretion to deny institution pursuant to 35 U.S.C. §§ 314(a) and/or 325(d).

## **II. THE BOARD SHOULD NOT DENY INSTITUTION OF THE FIRST AND ONLY PETITION CHALLENGING THE ’100 PATENT**

Patent Owner’s request relies on the fact that two third parties – Amgen Inc. (“Amgen”) and Coherus BioSciences Inc. (“Coherus”) – previously sought (and failed) to obtain IPR of three patents that are related to the ’100 patent.<sup>2</sup> In short, Patent Owner proposes that because Amgen and Coherus attempted to challenge

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<sup>1</sup> Sandoz subsequently filed petitions against unrelated Humira® indication patents.

<sup>2</sup> See *Amgen Inc. v. AbbVie Biotechnology Ltd.*, IPR2015-01514 (PTAB Jan. 14, 2016) (Paper 9) and IPR2015-01517 (PTAB Jan. 14, 2016) (Paper 9); *Coherus BioSciences Inc. v. AbbVie Biotechnology Ltd.*, IPR2016-01018 (PTAB Nov. 7, 2016) (Paper 10). Sandoz had no involvement in these petitions.

three patents in a family of more than 20 Humira<sup>®</sup> formulation patents,<sup>3</sup> all remaining members of that patent family should now be immune to IPR challenge by any party asserting the closest prior art references, including AbbVie's own prior art. AbbVie's position is inconsistent with § 325(d) and § 314(a) and would be an unwarranted and unwise extension of this Board's decisions on point.

**A. Institution Should Not Be Denied Under § 325(d)**

On its face, Section 325(d) addresses the situation where the *same patent* is challenged in multiple proceedings. 35 U.S.C. § 325(d) (“another proceeding or matter involving *the patent*...”) (emphasis added). Unsurprisingly, the Board has never denied institution pursuant to § 325(d) based solely on previous petitions filed against different (albeit related) patents.<sup>4</sup>

Claim 1 of the '100 patent is different from the claims of the previously challenged related patents, as shown by Patent Owner's Preliminary Response (“POPR”) at 24.<sup>5</sup> The other claims of the '100 patent also have different specific formulation requirements as compared to the previously challenged claims. To

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<sup>3</sup> The specification of the '100 patent (shared by the entire patent family) discloses only a single specific example of a formulation of a single antibody. Yet AbbVie's more than 20 related formulation patents purport to cover much more.

<sup>4</sup> In *Ube Maxell Co., Ltd. v. Celgard, LLC*, IPR2015-01511 (PTAB Jan. 7, 2016) (Paper 10) (cited at POPR, 30), 5 prior IPR petitions challenged the same patent. In *Unified Patents Inc. v. Berman*, IPR2016-01571 (PTAB Dec. 14, 2016) (Paper 10) (cited at POPR, 25) the same art and arguments were rejected during prosecution of the challenged patent itself.

<sup>5</sup> Petitioner Sandoz has also relied on different prior art combinations and testimony from new and different experts. *See, e.g.*, POPR, 24.

foreclose as a matter of discretion – in an unreviewable institution decision – the review of all unchallenged members of AbbVie’s family of more than 20 patents and 600 claims is inconsistent with the Board’s mandate and the purpose of IPR.

**B. Institution Should Not Be Denied Under § 314(a)**

As with § 325(d), the Board has never denied institution of a petition pursuant to § 314(a) based solely on previous petitions filed against different patents. As noted above, Sandoz has never filed an IPR petition on a related patent. The cases cited by Patent Owner, *NetApp* and *Samsung*<sup>6</sup>, are plainly distinguishable as, there, the same patent that was the subject of the later-filed petition had been challenged in multiple previous IPR petitions. The ’100 patent, however, has never before been the subject of an IPR challenge. This is in sharp contrast to *NetApp* where six other parties, including two of NetApp’s litigation co-defendants, had filed earlier IPRs against *the same patent* that NetApp belatedly challenged only after failing to procure a litigation stay based on the prior IPRs. Similarly, in *Samsung*, two other parties had previously challenged *the same patent* challenged by Samsung. Moreover, Samsung itself had previously filed **14** IPR challenges against related patents, and “had the opportunity to develop and present its arguments in the fourteen [IPRs],” all of which were litigated to final

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<sup>6</sup> Respectively, *NetApp Inc. v. Realtime Data LLC*, IPR2017-01195 (PTAB Oct. 12, 2017) (Paper 9); *Samsung Elecs. Co., Ltd. v. Elm 3DS Innovations, LLC*, IPR2017-01305 (PTAB Oct. 17, 2017) (Paper 11).

written decision. *Samsung*, 4, 16.

Accordingly, the Board should decline AbbVie's invitation to extend § 314(a) and the fully distinguishable decisions of *NetApp* and *Samsung* to the present facts where *no party* has previously challenged the '100 patent and where Sandoz has never challenged any related patent. To deny institution pursuant to § 314(a) here would immunize from IPR review any patent from a family where even a single member had faced prior IPR challenge, by any party. And even if the factors set forth in *General Plastic*<sup>7</sup> were applied in this case, they do not weigh in favor of denying institution pursuant to § 314(a).

*General Plastic* Factor 1 "weighs in favor of considering [Petitioner's] petition on the merits because [Petitioner] has not previously filed a petition challenging the [challenged] patent." *NetApp* at 10. Additionally, here *no party* has previously challenged the '100 patent in an IPR Petition. Factor 1 therefore

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<sup>7</sup> *General Plastic Indus. Co., Ltd v. Canon Kabushiki Kaisha*, IPR2016-01357, at 9-10 (PTAB Sept. 6, 2017) (Paper 19) (precedential) (listing as factors (1) whether same petitioner previously filed a petition directed to the same claims of the same patent; (2) whether at the time of filing the first petition petitioner knew or should have known of the prior art asserted in the second petition; (3) whether at the time of filing the second petition petitioner had the patent owner's preliminary response to the first petition or the Board's institution decision on the first petition (4) length of time elapsed between when petitioner learned of the prior art asserted in the second petition and the filing of the second petition; (5) whether petitioner provides adequate explanation for the time elapsed between the filings of multiple petitions directed to the same claims of the same patent; (6) the finite resources of the Board; and (7) the requirement for a final determination within 1 year of institution).

weighs heavily in favor of considering Sandoz's Petition on the merits.

Factor 2 is "directed to situations in which the same petitioner files two separate petitions at different times" and therefore does not apply here. *Id.*; *see also Samsung*, 20.

Factor 3 weighs in favor of considering the petition on its merits. The '100 patent has not previously been challenged in an IPR petition by any party, and its claims are different than the claims of the related patents that were challenged in the (unsuccessful) petitions by Amgen and Coherus.

Factors 4 through 7 are not applicable here. *Samsung*, 22-23. The pending Petition is Sandoz's first and only IPR challenge of the '100 patent, and no third party has previously filed a petition challenging the '100 patent. Moreover, with respect to Factor 5, Sandoz has an "important and reasonable explanation" for not having filed its IPR petition previously. *Id.*, 22. In contrast to petitioners in *NetApp* and *Samsung*, Sandoz filed its petition *before* being accused of infringing the challenged patent – and before even filing its aBLA – in an effort to narrow the issues for any future litigation concerning Sandoz's biosimilar.

### **III. CONCLUSION**

For all of the above reasons, Petitioner respectfully requests that the Board decline to exercise its discretion under 35 U.S.C. §§ 314(a) and/or 325(d), and instead consider Sandoz's Petition on the merits.

Dated: Dec. 15, 2017

Respectfully Submitted,  
**ARNOLD & PORTER KAYE SCHOLER LLP**

*s/ Deborah E. Fishman*

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that the foregoing document  
 PETITIONER’S REPLY TO PATENT OWNER’S PRELIMINARY  
 RESPONSE PURSUANT TO 37 C.F.R. § 42.108(c) is being served on  
 December 15, 2017 via electronic mail upon the following counsel of record for  
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