UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SANDOZ INC.,
Petitioner

v.

ABBVIE BIOTECHNOLOGY LTD.,
Patent Owner

Case No. IPR2018-00002
U.S. Patent No.: 9,512,216
Issue Date: Dec. 6, 2016
Title: Use of TNFα Inhibitor

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

I. INTRODUCTION

In its Preliminary Response, Patent Owner contends that the Board should deny institution of Petitioner's instant petition under 35 U.S.C. §314(a) and §325(d) because, it says, this petition is substantially the same as Petitioner's earlier-filed petition on the '216 patent ("the First Petition"). Petitioner respectfully submits that the Board should decline to exercise its discretion to deny institution on the pending Petition pursuant to 35 U.S.C. §314(a) and/or §325(d) because (1) the instant petition is not redundant of the First Petition — to the contrary, it provides a new prior art reference backed by the evidentiary support that Patent Owner argued was lacking in the First Petition and grounds not previously considered; (2) the First Petition was denied without a merits review[1]; and (3) Petitioner obtained no tactical advantage by presenting this second petition, having filed it before Patent Owner's Preliminary Response (Paper 10, "POPR") to the First Petition.

II. BACKGROUND

Sandoz filed its First Petition for IPR of the '216 patent (IPR2017-01824) on July 20, 2017. On October 2, 2017 Sandoz filed the pending Petition (IPR2018-

[1] Petitioner has requested rehearing of the Decision Denying Institution of *Inter Partes* Review on the First Petition. (Paper 15 in IPR2017-01824) If the rehearing request and institution were granted in IPR2017-01824, Petitioner would move to consolidate with the instant petition.

00002) ("the Pending Petition"). The Pending Petition relies, *inter alia*, on the 2003 Humira Label – a prior art reference that was not asserted in the First Petition, and that Petitioner supported with evidence not previously before the Board, namely: (1) a screenshot capture from the WayBack Machine internet archive showing that the 2003 Humira Label was published on the FDA's website as of March 31, 2003 (Ex. 1072) and (2) an affidavit from Christopher Butler, Office Manager at the Internet Archive, affirming that the 2003 Humira Label was publicly accessible on and archived from www.fda.gov on March 31, 2003 (Ex. 1076). On November 13, 2017, more than a month after Sandoz filed the Pending Petition, AbbVie filed its Preliminary Response to the First Petition. The Board denied institution on the First Petition on February 9, 2018, based solely on its finding that Petitioner failed to demonstrate a reasonable likelihood that one asserted reference – the 2002 Humira Package Insert – is a "printed publication" for purposes of 35 U.S.C. §102(b) and §311(b). The Board did not address the merits of the grounds for unpatentability based on the 2002 Humira Package Insert, nor did it address the 2003 Humira Label or its supporting evidence, which are first asserted in the Pending Petition.

III. THE BOARD SHOULD NOT DENY INSTITUTION OF THE PENDING PETITION UNDER §314(a) AND §325(d)

The Board should not deny institution of the Pending Petition under 35 U.S.C. §314(a) and §325(d).

First, the Pending Petition does not rely on the same or substantially the same art and arguments as the First Petition. The 2003 Humira Label and the evidence supporting its public accessibility before the priority date of the '216 patent were not asserted in the first Petition. Patent Owner ignores Petitioner's evidence on the 2003 Humira Label in its Preliminary Response and asks the Board to do the same (POPR at 56). But this is exactly the sort of evidence that Patent Owner criticized the First Petition as lacking (Paper 7 in IPR2017-01824 at 43, arguing that, in the First Petition "Petitioner provides no evidence of the source of [the 2002 Humira Package Insert], how one could have obtained a copy, or whether it was reasonably accessible to the interested public."). Patent Owner cannot now credibly assert that these differences between the First Petition and the Pending Petition are insignificant.

Second, the Board's decision on the First Petition did not reach the merits of Petitioner's invalidity arguments. The Board decided the First Petition solely on the basis of public accessibility of the 2002 Humira Label and did not consider the merits of the grounds for unpatentability, nor did it consider the 2003 Humira label, which was not before it in the First Petition. The Board has previously been presented with virtually identical circumstances, and has declined to deny institution under §314(a) and §325(d). *See, e.g., Coalition for Affordable Drugs (ADROCA) LLC v. Acorda Therapeutics, Inc.*, IPR2015-01853, Paper 13 at 12-13,

2016 WL 2848882 at *6 (P.T.A.B. Mar. 11, 2016) (Paper 13) (declining to deny institution under §314(a) or §325(d) where institution was denied on the first-filed petition based solely on the printed publication status of two previously asserted references); *see also Panduit Corp. v. CCS Tech., Inc.*, IPR2017-01375, Paper 8 at 8-10, 2017 WL 5201685 at *3-4 (P.T.A.B. Nov. 8, 2017).

The cases cited by Patent Owner do not hold otherwise, and are factually distinguishable from the present circumstances. In *Unified Patents*, the Board denied institution on one asserted ground because it found that the patent examiner had previously considered and rejected – ***on the merits*** – substantially the same art and arguments presented by petitioner. *Unified Patents Inc. v. Berman*, IPR2016-01571, Paper 10 at 12, 2016 WL 10033540 at *5 (P.T.A.B. Dec. 14, 2016). In *Toyota*, Petitioner filed its second petition after having the opportunity to read Patent Owner's Preliminary Response to its first petition on the same patent – a circumstance that the Board reasonably found to be "unjust." *Toyota Motor Corp. v. Cellport Sys., Inc.*, IPR2015-01423, Paper 7 at 8 (P.T.A.B. Oct. 28, 2015). Indeed, Patent Owner has pointed to no case where a second petition was denied as redundant over a first petition where, as here, there was no merits review of the first petition, and Petitioner gained no tactical advantage (*e.g.*, a Preliminary Response or Board decision to use as a road map) before filing the second petition. Petitioner is not aware of any such case.

Additionally, the factors set forth in *General Plastic*, on balance, weigh against denying institution on the Pending Petition pursuant to §314(a). *Gen. Plastic Indus. Co., Ltd. v. Canon Kabushiki Kaisha*, IPR2016-01357, Paper 19 at 9-10, 2017 WL 3917706 at *4 (P.T.A.B. Sept. 6, 2017) (precedential). Petitioner gained no tactical advantage as the Pending Petition was filed only 2.5 months after the First Petition, before Petitioner received the Preliminary Response on the First Petition. The two petitions were filed close enough in time that, had IPR been instituted on the First Petition, the cases easily could have been consolidated. Thus, it is not "a situation in which Petitioner is" using the POPR or "using [Board] decisions as a roadmap." *Panduit*, Paper 8 at 10, 2017 WL at *4.

Moreover, the First Petition was not considered on the merits, but was instead denied – in its entirety – solely on the basis of the Board's finding with respect to the printed publication status of the 2002 Humira Package Insert. Reviewing the Pending Petition on the merits, therefore, will not be a duplication of effort or a waste of the Board's finite resources.

IV. 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 Pending Petition on the merits.

Dated: Mar. 12, 2018

Respectfully Submitted,
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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 March 12, 2018 via electronic mail upon the following counsel of record for Patent Owner AbbVie Biotechnology Ltd.:

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Dated: Mar. 12, 2018 **ARNOLD & PORTER KAYE SCHOLER LLP**

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