

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

TEVA PHARMACEUTICALS USA, INC.,
Petitioner,

v.

INDIVIOR UK LIMITED,
Patent Owner.

Case IPR2016-00280
Patent 8,475,832 B2

Before TONI R. SCHEINER, JACQUELINE WRIGHT BONILLA, and
ZHENYU YANG, *Administrative Patent Judges*.

BONILLA, *Administrative Patent Judge*.

ORDER
Conduct of the Proceeding
37 C.F.R. § 42.5

On May 16, 2016, we conducted a conference call between respective counsel for the parties and the panel judges. A court reporter also was present on the call.¹ Petitioner requested the conference to address its request to file a motion to compel discovery of information that Petitioner contended is in Patent Owner's possession and is inconsistent with a position advanced by Patent Owner in its Preliminary Response (Paper 16, "Prelim. Resp."). The information purportedly relates to two documents, i.e., "Suboxone® Label" (Ex. 1008) and "Suboxone® Tablet Summary Basis of Approval" or "SBOA" (Ex. 1009), relied upon in challenges raised in the Petition (Paper 1 at 20, 35, 37, 45). Petitioner also requested the conference to address its request to file a reply to the Preliminary Response under § 42.108(c). *See* 37 C.F.R. § 42.108(c) (revised April 1, 2016, stating that a petitioner may seek leave to file a reply to the preliminary response, but "must make a showing of good cause").

In the Petition as filed, Petitioner contends that "Patent Owner stipulated in a co-pending litigation that the Suboxone® 2002 Label and SBOA are prior art to the '832 patent," citing footnote 12. Pet. 18–19. Footnote 12 in the Petition reads in full:

¹² *Reckitt Benckiser Pharmaceuticals, Inc. v. Watson Laboratories, Inc.*, No. 13-cv-0167-RGA P.I. 347, Ex. 1, at ¶¶ 123–24. The Suboxone® Label and SBOA qualify as 102(b) prior art as both were publicly available printed publications at least as early as 2002.

Id. at 18–19 n.12.

¹ Petitioner has filed a copy of the transcript of the call as Exhibit 1034. This Order summarizes statements made during the conference call. A more detailed record may be found in the transcript.

In its Preliminary Response, Patent Owner asserts, *inter alia*, that Petitioner fails to show that either the Suboxone® Label or SBOA constitutes a “printed publication” and qualifies as prior art under 35 U.S.C. § 102. Prelim. Resp. 17–24. For example, Patent Owner points out that the above-quoted contentions and footnote 12 in the Petition constitute Petitioner’s entire argument that Exhibits 1008 and 1009 qualify as prior art. *Id.* at 20.

During the conference call, Petitioner requested leave to file: (1) the “pretrial stipulation” mentioned in the Petition (Pet. 18); (2) “further evidence” from a trial in the district court litigation that took place on December 17–19, 2016, after Petitioner filed its Petition on December 3, 2016; and (3) a reply “so that [Petitioner] could pull everything together” for the panel. Ex. 1034, 5:12–12:6, 23:9–24:3. In relation to the “further evidence” from the district court trial, Petitioner asserted that Patent Owner admitted there that, for example, the Food and Drug Administration published SBOA in 2002, before the priority date for the ’832 patent. *Id.* at 7:11–8:9. Petitioner also requested leave to “serve limited requests for admission[s]” from Patent Owner “so that [Petitioner] could submit them as evidence here.” *Id.* at 11:17–12:6.

Patent Owner responded in the call that its Preliminary Response challenged only the sufficiency of evidence cited by Petitioner in its Petition, required to meet Petitioner’s burden to provide a threshold showing that Exhibits 1008 and 1009 qualify as a printed publication. Ex. 1034, 13:10–14:3. Patent Owner argued that its challenge to the sufficiency of the evidence “does not impose an obligation on our part to provide evidence to supplement the petitioner’s case.” *Id.* at 15:4–9. Patent Owner argued,

citing similar arguments in its Preliminary Response, that the pretrial stipulation took place in a district court case that did not involve Petitioner, and the stipulation “is not binding on the patent owner in other proceedings.” *Id.* at 16:8–19, 21:13–17 (citing Prelim. Resp. 23–24). Patent Owner further argued that Petitioner had an opportunity to present the pretrial stipulation, and make it an exhibit of record, when filing the Petition, but they “chose to do what they did.” *Id.* at 17:7–12, 19:19–20:8.

Upon considering both parties’ positions, Petitioner does not persuade us that sufficient good cause exists to grant its request to file a reply to the Preliminary Response or to file new evidence regarding the public accessibility of Exhibits 1008 and 1009. First, as Patent Owner notes, in relation to the pretrial stipulation, Petitioner could have, but did not, file that document when it filed its Petition. Petitioner has not established good cause as to why we should allow Petitioner to file that document as an exhibit now.

In addition, neither party disputes that a statutory bar to institution under 35 U.S.C. § 315(b) exists in relation to a petition filed by Petitioner as of December 4, 2015. Although it may be that good cause could exist in certain situations where new evidence comes to light after the filing of a petition, we are not persuaded that sufficient good cause exists in this case. Here, Petitioner essentially asks to significantly bolster its Petition with new substantive argument and evidence, well after a statutory bar date, in relation to an issue where it has the burden to make a threshold showing. *See Apple Inc. v. DSS Tech. Mgmt., Inc.*, Case IPR2015-00369, slip op. at 5 (PTAB Aug. 12, 2015) (Paper 14) (noting that Petitioner has the burden to establish

a threshold showing that a reference is “printed publication” prior art under 35 U.S.C. §§ 102 and 311(b)).

To the extent a reply and newly filed evidence by Petitioner would be necessary to show a reasonable likelihood that it would prevail with respect to at least one challenged claim, we are not persuaded to allow Petitioner to “fix” its Petition in this fashion. Petitioner had the opportunity to file additional evidence along with its Petition, if it so wished. For example, rather than rely on “stipulations” or “admissions” by Patent Owner in another proceeding, Petitioner could have obtained, provided, and cited in its Petition evidence relevant to whether Exhibits 1008 and 1009 actually were publicly accessible, how one could have obtained a copy of those documents, and/or whether documents were reasonably accessible through generally available means, in the relevant time frame.

In relation to Petitioner’s request to serve requests for “admissions” from Patent Owner, i.e., purported routine discovery under 37 C.F.R. § 42.51(b)(1)(iii), we agree with Patent Owner that its own arguments in the Preliminary Response that Petitioner fails to provide a threshold showing in the Petition (Prelim. Resp. 17–24) do not impose an obligation on Patent Owner to answer requests for “admissions” that support Petitioner’s position. *See Hughes Network Sys., LLC v. Cal. Inst. of Tech.*, Case IPR2015-00059, slip op. at 7 (PTAB Dec. 30, 2015) (Paper 34) (“Arguments pointing to a deficiency in petitioner’s case do not impose an obligation on the part of [Patent Owner] to provide evidence supplementing that provided by [Petitioner].”).

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