UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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DR. REDDY'S LABORATORIES S.A. AND
DR. REDDY'S LABORATORIES, INC.
Petitioners,

v.

INDIVIOR UK LIMITED,
Patent Owner.

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IPR2019-00328
Patent 9,687,454

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PATENT OWNER'S SUR-REPLY TO PETITIONER'S REPLY

Petitioner's Reply (Paper 19) attempts to re-raise the same arguments made in its Petition. As already addressed in Indivior UK Limited's ("Indivior") Patent Owner Preliminary Response (Paper 12, "POPR"), and as discussed here, the factors established under *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, 2018 WL 2671360 (PTAB Dec. 15, 2017) (informative) strongly favor denial of institution under 35 U.S.C. 325(d).

I. Section 325(d) Factors Favor Denial of Institution

Petitioner relies on *Navistar, Inc. v. Fatigue Fracture Tech., LLC*, IPR2018-00853, Paper 13 (PTAB Sept. 12, 2018), and *St. Jude Medical, LLC v. Snyders Heart Valve LLC*, IPR2018-00105, Paper 15 (PTAB May 3, 2018), in alleging that the consideration of Fuisz and EMEA during examination is immaterial so long as "the Examiner's rejections never cited most of DRL's references individually, much less in the particular combination set forth in the asserted ground." (Reply, Paper 19, at 5.) These cases do not support Petitioner's claim.

In *Navistar*, the Board declined to exercise its discretion to deny institution under § 325(d) because the examiner had not relied on the Cavallo and Becker references in a rejection and, to the contrary, had explicitly listed the references as "prior art made of record and not relied upon." *Navistar*, IPR2018-00853, Paper 13 at 16–18. In fact, the examiner did not present *any* rejections under 35 U.S.C. §§ 102

or 103 during examination. *Id.* at 17. In explaining how these circumstances related to the *Becton, Dickinson* factors, the Board significantly noted:

> [T]o the extent "the prior art involved during examination" and "the prior art evaluated during examination" set out in [*Becton*] considerations (a) and (b) refer mainly to prior art applied by the Examiner in a rejection during examination, because the Examiner did not make any prior art rejections during prosecution of the '915 patent, these factors do not persuade us to exercise our discretion under § 325(d) in this case.

Id. at 17–18.

Moreover, unlike the combination of references in *Navistar*, Petitioner's proposed combination of prior art is cumulative of the prior art evaluated by the examiner. As addressed in Indivior's POPR, the examiner thoroughly analyzed the Euro-Celtique and Suboxone® Tablet references and ultimately withdrew her 35 U.S.C. § 103 non-final rejection after the applicants amended their proposed claims to require an "acidic buffer." The remaining references, Fuisz, Suboxone® PDR, EMEA, and the IIG Database, do not disclose any material information that is not already disclosed by the other references. Suboxone® PDR, EMEA, and the IIG Database all relate to the Suboxone® sublingual tablet, and do not disclose more information about the tablet than the many Suboxone® Tablet references relied upon and discussed by the examiner. Furthermore, Fuisz was explicitly cited and discussed in Euro-Celtique, which was thoroughly examined. (Ex. 1007, 14.)

Petitioner fails to identify any section of Fuisz providing alleged "non-cumulative information" that is not already described in Euro-Celtique. (Paper 1 at 59.)

There are likewise clear and significant differences between the references at issue in *St. Jude Medical* and the prior art references here. In *St. Jude Medical*, the Leonhardt prior art reference was not before the examiner, and the petitioner was not relying on Leonhardt in a manner cumulative of the prior art evaluated by the examiner. Here, in stark contrast, the few remaining references are clearly cumulative of the prior art evaluated and applied by the examiner, as discussed above and in Indivior's POPR (Paper 12, at 1–21).

Separately, Petitioner attempts to argue that Indivior raises "factual disputes" as to whether the Das Declaration warrants reconsideration of the prior art. (Reply, Paper 19, at 5–6.) To the contrary, Indivior's arguments highlight that the Das Declaration "does not present any substantively new information that was not already before the examiner." (POPR, Paper 12, at 28.) As explained in detail in Indivior's POPR, Dr. Das relies on references or arguments that were already before the examiner in opining that a POSA would have known that the citric acid disclosed in Euro-Celtique could serve as an "acidic buffer" in a buprenorphine and naloxone sublingual film formulation. (*Id.* at 22–23.) Indeed, Dr. Das's arguments regarding the effects of pH on the absorption of buprenorphine were rejected in a separate IPR proceeding regarding the '832 Patent. *See Teva Pharm. USA, Inc. v. Indivior UK*

Ltd., IPR2016-00280, Paper No. 23, 13–15 (PTAB June 10, 2016). The Board's decision and reasoning rejecting Dr. Das's statement on pH and buprenorphine absorption were disclosed to the examiner during prosecution of the '454 Patent. (Ex. 1002, 604.)

Petitioner also attempts to argue that *Becton, Dickinson* mandates considering the applicant's characterizations of the prior art in a separate IPR proceeding, *after* the patent has issued, and in the context of a different patent. (Reply, Paper 19, at 5.) This is not a *Becton, Dickinson* factor. Indeed, the factor that Petitioner relies on clearly states, "the extent of the overlap between the arguments made ***during examination*** and the manner in which Petitioner relies on the prior art or Patent Owner distinguishes the prior art." *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper No. 8, 17–18, 2018 WL 2671360 (PTAB Dec. 15, 2017) (informative) (emphasis added).

Furthermore, Petitioner erroneously argues that Indivior's "easy dismissal of its reversal in positions on the prior art is legal error." As Indivior explained in its POPR, Petitioner attempts to mischaracterize Indivior's arguments made about a different patent with different claims that are directed to different subject matter. Indivior has already explained why its statements concerning U.S. Patent No. 9,370,512 in IPR2018-00795 were directed to whether the prior art discloses the "instant release" capability of a film—not whether the references disclose or suggest

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