

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

TEVA PHARMACEUTICALS USA, INC. AND WATSON
LABORATORIES, INC,
Petitioners,

v.

MERCK SHARP & DOHME CORP.,
Patent Owner.

Case No. IPR2020-01045
U.S. Patent No. 7,326,708

PATENT OWNER'S PRELIMINARY RESPONSE

The Petition at issue is a “Me-Too” petition brought by Teva Pharmaceuticals USA, Inc. and Watson Laboratories, Inc. (collectively, “Petitioners” or “Teva”) after the Board instituted trial on the petition of Mylan Pharmaceuticals Inc. (“Mylan”) in IPR2020-00040 (“Mylan Proceeding”). Paper 3, at 1 n.1. Teva filed a motion for joinder within one month of institution of the Mylan Proceeding, seeking joinder. Paper 4. Merck has filed an opposition to the joinder motion, Paper 9, and has participated in two calls with the Board to address various conditions pertinent to joinder.

Pursuant to 37 C.F.R. § 42.107(b), Patent Owner Merck Sharp & Dohme Corp. (“Merck”) hereby files a preliminary response in the above captioned case.

I. If Joinder Is Ordered, Merck Reserves All Rights To Present Evidence and Argument In Response to the Teva Petition in Its Patent Owner Response and Other Papers.

In the Mylan Proceeding, Merck filed a Preliminary Patent Owner Response opposing institution. IPR2020-00040, Paper 10. In that filing, Merck argued that the Board should exercise its discretion pursuant to §§ 325(d) and 314(a) to deny institution, and also argued that Mylan’s grounds were deficient because they did not address the stoichiometry required by all challenged claims. *Id.* The Board granted Mylan’s petition and instituted review in IPR2020-00040 notwithstanding Merck’s Preliminary Patent Owner Response.

For efficiency and to conserve judicial resources, Merck will not restate, in this Preliminary Patent Owner Response, the arguments it made in the Preliminary Patent Owner Response in the Mylan Proceeding, which the Board has rejected, preliminarily or otherwise. IPR2020-00040, Paper 21 at 64. However, Merck does not waive any such evidence or arguments and reserves all rights in the above captioned or any consolidated proceeding. Patent Owner specifically reserves all rights to submit a Patent Owner Response and/or a Motion to Amend pursuant to 37 C.F.R. §§ 42.120 and 42.121. Patent Owner reserves the right to address grounds presented in the Petition should the Board institute *inter partes* review, to dispute in the Patent Owner's Response any fact alleged to be material by Petitioners, and to provide material facts in support of Patent Owner's position. Patent Owner reserves the right to raise any and all arguments against those grounds and in favor of patentability during the trial.

II. If Joinder Is Not Ordered, the Teva Petition Is Time Barred.

If joinder is not ordered in the instant proceeding, Merck opposes institution because Petitioners are time barred from petitioning for *inter partes* review of U.S. Patent No. 7,326,708. Merck filed patent infringement complaints concerning U.S. Patent No. 7,326,708 on February 13, 2019, EX2039 (Teva complaint); EX2042 (Watson Complaint), and the Teva petition was not filed until June 10, 2020. Paper 3 (filed 6/10/2020). Hence, both Petitioners were served with a complaint

alleging infringement of U.S. Patent No. 7,326,708 more than one year prior to the filing of the instant petition. Absent joinder, the Petition is thus time barred. *See* 35 U.S.C. § 315(b).

Date: August 14, 2020

Respectfully submitted,

/Stanley E. Fisher/

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), the undersigned hereby certifies that a true and correct copy of the foregoing was served on August 14, 2020, by delivering a copy via electronic mail on the following attorneys of record:

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