**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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SUN PHARMACEUTICAL INDUSTRIES LTD.
AND SUN PHARMACEUTICAL INDUSTRIES, INC.,

Petitioners,

v.

NOVO NORDISK A/S,

Patent Owner.

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U.S. Patent No. 10,335,462 to Jensen
Issue Date: July 2, 2019
Title: Use of Long-Acting GLP-1 Peptides

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*Inter Partes* Review IPR2024-00107

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**PETITIONER'S MOTION FOR JOINDER**
**UNDER 35 U.S.C. § 315(c) and**
**37 C.F.R. §§ 42.22 AND 42.122(b)**

## I. A STATEMENT OF THE PRECISE RELIEF REQUESTED

Sun Pharmaceutical Industries Ltd. and Sun Pharmaceutical Industries Inc. ("Sun" or "Petitioners") submit, concurrently with this motion, a petition for *inter partes* review (the "Sun Petition") of claims 1–10 of U.S. Patent No. 10,335,462 ("the '462 patent") (Ex. 1001), assigned to Novo Nordisk A/S ("Patent Owner"). Sun respectfully requests joinder pursuant to 35 U.S.C. § 315(c) and 37 C.F.R. § 42.122(b) of the concurrently filed Petition with a pending *inter partes* review filed by Mylan Pharmaceuticals, Inc. ("Mylan"), *Mylan Pharmaceuticals Inc. v. Novo Nordisk A/S*, IPR2023-00724 (the "Mylan IPR"). Joinder is appropriate because Sun's request is timely and it will promote an efficient and consistent resolution of the validity of a single patent and will not prejudice any of the parties to the Mylan IPR. 37 C.F.R. § 42.122(b).

## II. BACKGROUND

On March 16, 2023, Mylan filed a petition for *inter partes* review challenging claims 1–10 of U.S. Patent No. 10,335,462 ("the '462 patent"), which was assigned Case No. IPR2023-00724. On October 4, 2023, the Board instituted review of claims 1–10 on five grounds: (1) Claims 1–3 of the '462 patent as anticipated by WO421; (2) Claims 1–3 of the '462 patent as anticipated by Lovshin; (3) Claims 1–10 of the '462 patent as obvious over WO421 and the '424 Publication; (4) Claims 1–10 of the '462 patent as obvious over WO537 and Lovshin; and (5) Claims 1–10 of the

’462 patent as obvious over NCT657, NCT733, and the ’424 Publication. IPR2023-00724, Paper 10.

Today, concurrent with the instant motion for joinder, Sun filed the Sun Petition, Case No. IPR2024-00107, that is substantially the same as the Mylan IPR: it involves the same patent, same claims, same grounds of unpatentability, and the same evidence (including the same prior art combinations) instituted in the Mylan IPR.

## III. ARGUMENT

### A. Legal Standard

The Board has authority to join as a party any person who properly files a petition for *inter partes* review to an instituted *inter partes* review. 35 U.S.C. § 315(c). A motion for joinder must be filed within one month of institution of any *inter partes* review for which joinder is requested. 37 C.F.R. § 42.122(b). In deciding whether to grant a motion for joinder, the Board considers several factors including: (1) the reasons why joinder is appropriate; (2) whether the party to be joined has presented any new grounds of unpatentability; (3) what impact, if any, joinder would have on the trial schedule for the existing review; and (4) how briefing and discovery may be simplified. *See, e.g.*, *Hyundai Motor Co. v. Am. Vehicular Sciences LLC*, IPR2014-01543, Paper 11 at 3 (Oct. 24, 2014); *Macronix*

*Int'l Co. v. Spansion*, IPR2014-00898, Paper 15 at 4 (Aug. 13, 2014) (quoting *Kyocera Corp. v. Softview LLC*, IPR2013-00004, Paper 15 at 4 (April 24, 2013)).

### B. The Relevant Factors Weigh in Favor of Joinder

Each of the four factors considered by the Board weighs in favor of joinder.

#### 1. Joinder Is Appropriate

Joinder with the Mylan IPR is appropriate because the Sun Petition is limited to the same grounds instituted in Mylan's IPR2023-00724 petition. It also relies on the same prior art analysis and expert analysis submitted by Mylan. Indeed, the Petition raises grounds identical to those raised in the IPR2023-00724 petition and does not include any new grounds not raised in that petition. As such, the Sun Petition does "not present issues that might complicate or delay" Mylan's IPR. *See Enzymotec Ltd. v. Neptune Techs & Bioresources, Inc.*, IPR2014-00556, Paper 19 (PTAB July 9, 2014).

In order to further simplify the proceeding, Sun will rely on the same declarants as Mylan, Dr. John Bantle, Dr. William J. Jusko, and Dr. Paul Dalby (collectively, the "Mylan Declarants"), should Mylan permit it. If Mylan allows Sun to use the Mylan Declarants, then Sun will withdraw the declarations of Dr. Melissa Weinberg, Dr. Craig Dyar, and Dr. Alekha K. Dash (the "Sun Declarants") and rely solely on the declarations and testimonies of the Mylan Declarants. Given Sun's reliance on Mylan's IPR Petition and Declarants, the primary difference between

Sun's and Mylan's Petitions are the sections on Real Party-In-Interest, Related Matters, and Counsel, which have been appropriately updated.

The Board has previously acknowledged that such concessions on the part of a party seeking to join are sufficient to minimize the impact on the original proceeding. *Sawai USA, Inc. v. Biogen MA, Inc.*, IPR2019-00789, Motion for Joinder, Paper 2, at 4-5 (Mar. 5, 2019); *Teva Pharm. USA, Inc. v. Eli Lilly & Co.*, IPR2016-01343, Mot. for Joinder, Paper 3, at 8 (July 1, 2016) (offering same procedure); *Argentum Pharms. LLC v. Janssen Oncology, Inc.*, IPR2016-01317, Mot. for Joinder, Paper 3, at 6-7 (June 29, 2016) (same); *Argentum Pharms. LLC, v. Cosmo Techs., Ltd.*, IPR2016-01317, Mot. for Joinder, Paper 3, at 4-5 (Oct. 20, 2017) (same). Further, the declarations of the Sun Declarants submitted in support of the present Petition present substantively identical testimony to that of the Mylan Declarants, thus streamlining the issues for trial even if Mylan does not permit Sun to rely directly on the Mylan Declarants.

Even if, despite its best efforts with Mylan, Sun were required to proceed with its own Declarants, there would be no impact on the Board's ability to complete its review in a timely manner, in light of the substantially identical testimony between the Sun Declarants and the Mylan Declarants. In such a situation, there would be at most a modest impact on the Patent Owner given that little additional preparation would be needed for the deposition of the Sun Declarants beyond that required for

the depositions of the Mylan Declarants. Still further, in the event that Mylan does not agree to allow Sun to rely on the Mylan Declarants, Sun would agree to withdraw the Sun Declarants if the Mylan Declarants have already been deposed based on their declarations in the Mylan IPR and the deposition transcripts have been made of record. In that case, Sun would rely on the declarations and testimony of the Mylan Declarants. *Teva*, IPR2016-01343, Mot. for Joinder, Paper 3, at 9, n.2 (offering the same concessions).

In view of the above, joinder will promote the just, speedy, and inexpensive resolution of patentability issues, including the determination of validity of the challenged claims of the ’462 patent. For example, a final written decision on the validity of the ’462 patent has the potential to minimize issues and potentially resolve any litigation altogether with respect to the ’462 patent.

**2. No New Grounds Are Presented**

The Sun Petition does not present any new ground of unpatentability. As above, the Petition presents for review only grounds from the petition in the Mylan IPR that have been instituted. The present Petition is based on the same prior art analysis submitted by Mylan, and the Sun Declarants’ testimony in support of these grounds is substantively identical to that of the Mylan Declarants in the Mylan IPR, which further weighs in favor of joinder. *See, e.g.*, *Hyundai*, IPR2014-01543, Paper 11 at 2–4; *Sony Corp. of Am. v. Network-1 Sec. Solutions, Inc.*, IPR2013-00495,

Paper 13 at 5–9 (Sep. 16, 2013); *Dell Inc. v. Network-1 Solutions, Inc.*, IPR2013-00385, Paper 17 at 6–10 (Jul. 29, 2013); *Motorola Mobility LLC v. Softview LLC*, IPR2013-00256, Paper 10 at 4–10 (June 20, 2013).

Because the Sun Petition raises no new grounds of unpatentability than those already presented in the Mylan IPR, joinder will have no substantial effect on the parties or have a negative impact on the schedule of the Mylan IPR, much less prevent the Board from issuing a final written decision in a timely manner. *See LG v. Memory Integrity, LLC.*, IPR2015-01353, Paper 11 at 6 (Oct. 5, 2015) (granting IPR and motion for joinder where "joinder should not necessitate any additional briefing or discovery from Patent Owner"). Sun will adhere to all applicable deadlines set in the Scheduling Order for the Mylan IPR.

Moreover, as discussed below, Sun is willing to limit its participation in the proceeding as a "silent understudy" to Mylan, only assuming an active role in the event of termination of Mylan as a party. Sun does not anticipate that any extension of the trial schedule will be required as a result of joinder.

### 3. Discovery and Briefing Will Be Simplified

As a "silent understudy," Sun agrees that, if joined, the following conditions will apply so long as Mylan remains an active party, as previously approved by the Board in other joinder circumstances:

(a) All filings by Sun in the joined proceeding will be consolidated with the filings of Mylan, unless a filing solely concerns issues that do not involve Mylan;

(b) Sun shall not be permitted to raise any new grounds not instituted by the Board in the Mylan IPR or introduce any argument not already introduced by Mylan; and

(c) With regard to taking of testimony, Sun will abide by 37 C.F.R. § 42.53 or any agreement between the Patent Owner and Mylan. *See DRL Pharms. Inc. v. Novartis AG*, IPR2015-00268, Paper 17 at 5–6 (PTAB Apr. 10, 2015) (finding the same proposed limitations "are consistent with the 'understudy' role that Petitioner agrees to assume, as well as Petitioner's assertion that its presence would not require introducing any additional arguments, briefing, or discovery."). Sun is also willing to abide by any additional conditions that the Board deems appropriate.

**4. No Prejudice to Patent Owner**

Joinder of Petitioner to the Mylan IPR will not create any additional burden on the Patent Owner. The Patent Owner need not expend any additional resources above and beyond those required in the current Mylan IPR. Moreover, joinder

eliminates the need for the Patent Owner to participate in multiple, staggered *inter partes* review proceedings instituted upon identical grounds of unpatentability.[1]

## IV. CONCLUSION

For the foregoing reasons, Sun respectfully requests that its Petition for *Inter Partes* Review of claims 1–10 of the ’462 patent be granted on the same grounds and for the same reasons discussed in the Institution Decision of IPR2023-00724, and that this proceeding be joined therewith.

Respectfully submitted,

Dated: November 2, 2023

/s/ Brian Sodikoff
Brian Sodikoff

[1] The argument that joinder may theoretically frustrate settlement between Mylan and Patent Owner is not a basis to deny joinder because that same possibility exists in every joinder situation. *Global Foundries U.S. Inc. v . Godo Kaisha IP Bridge 1*, IPR2017-00925 and IPR2017-00926, Paper 13 at 10 (June 9, 2017).

**CERTIFICATE OF SERVICE**

Pursuant to 37 C.F.R. §§ 42.6(e) and 42.105, I certify that I caused to be served a true and correct copy of the foregoing: PETITIONER'S MOTION FOR JOINDER, by Federal Express (or equivalent) Next Business Day Delivery on this day on the Patent Owner's correspondence address of record for the subject patent as follows:

Novo Nordisk Inc.
Intellectual Property Department
800 Scudders Mill Road
Plainsboro, NJ 08536

Courtesy copies of the Petition for *Inter Partes* Review of U.S. Patent No. 10,335,462 and any accompanying exhibits and materials have been sent by Federal Express (or equivalent) Next Business Day Delivery on this day to Patent Owner's counsel of record as follows:

J. Steven Baughman
Groombridge, Wu, Baughman & Stone LLP
801 17th Street, NW, Suite 1050
Washington, DC 20006

with courtesy copies sent via electronic means to:

- J. Steven Baughman at steve.baughman@groombridgewu.com;
- Megan Raymond at megan.raymond@groombridgewu.com; and
- Novo-Semaglutide-IPR@groombridgewu.com.

A courtesy copy of the foregoing has been sent by Federal Express (or equivalent) Next Business Day Delivery on this day to Mylan Pharmaceuticals, Inc.'s counsel of record as follows:

Brandon M. White
Perkins Coie LLP
700 13th Street, NW, Suite 800
Washington, DC 20005

with courtesy copies by electronic means to:

- Brandon M. White: White-ptab@perkinscoie.com
- Emily J. Greb: Greb-ptab@perkinscoie.com
- Courtney Prochnow, PhD: Prochnow-ptab@perkinscoie.com
- Christopher D. Jones: Jones-ptab@perkinscoie.com
- Jonathan I. Tietz, PhD: Tietz-ptab@perkinscoie.com
- Matthew A. Lembo: Lembo-ptab@perkinscoie.com

A courtesy copy of has been sent by Federal Express (or equivalent) Next Business Day Delivery on this day to Doctor Reddy's Laboratories, Inc.'s counsel of record as follows:

Jovial Wong
Winston & Strawn LLP
1901 L Street NW
Washington, DC 20036

with courtesy copies by electronic means to:

- Jovial Wong: jwong@winston.com
- Scott Border: sborder@winston.com
- Sharon Lin McIntosh: slin@winston.com

Dated: November 2, 2023

/s/ Brian Sodikoff
Brian Sodikoff