

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SAMSUNG BIOEPIS CO., LTD.,
Petitioner,

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner.

Case IPR2023-00566

U.S. Patent No. 10,888,601

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

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I. STATEMENT OF THE PRECISE RELIEF REQUESTED

Petitioner Samsung Bioepis Co., Ltd. (“Samsung Bioepis”) respectfully submits this Motion for Joinder, concurrently with a Petition for *inter partes* review (“IPR”) of U.S. Patent No. 10,888,601 (“the ’601 patent”) (“Petition”). Samsung Bioepis requests its Petition for *inter partes* review of the ’601 patent be instituted and joined pursuant to 35 U.S.C. § 315(c) and 37 C.F.R. §§ 42.22 and 42.122(b) with the *inter partes* review proceeding in *Mylan Pharmaceuticals, inc. v. Regeneron Pharmaceuticals, Inc.*, IPR2022-01226 (the “Mylan IPR”). The Mylan IPR was instituted on January 11, 2023.

Samsung Bioepis’s Petition is effectively a copy of the Mylan IPR. It is based on grounds identical to those that formed the basis for the pending Mylan IPR against the ’601 patent, including the same prior art combinations supported by substantially the same evidence. *See* Mylan IPR, Paper 22 (Institution of *Inter Partes* Review, 37 C.F.R. §42.108) (Jan. 11, 2023), at 2. Samsung Bioepis further stipulates herein that if joinder is granted, it will take a limited “understudy” role in the same manner previously found to support joinder so long as Mylan remains an active party. Joinder thus creates no additional burden for the Patent Trial and Appeal Board (the “Board”), Mylan, or Patent Owner. Nor will it impact the schedule of the Mylan IPR.

Accordingly, consistent with the Board’s consideration of prior joinder motions—including those in IPRs related to U.S. Patent Nos. 9,254,338 (“’338 patent”) and 9,669,069 (“’069 patent”)—Samsung Bioepis submits that joinder will promote judicial efficiency. It will also ensure that the currently pending grounds of unpatentability, which the Board found “compelling” in its Institution Decision, will most likely be seen through to the end, with Samsung Bioepis playing a backstop role.

For these and the foregoing reasons, Samsung Bioepis respectfully requests joinder be granted.

II. STATEMENT OF MATERIAL FACTS

A. Samsung Bioepis’s Motion for Joinder

Samsung Bioepis timely moves for joinder under 37 C.F.R. §§ 42.22 and 42.122(b) because Samsung Bioepis submits this motion within one month of January 11, 2023, the date on which the Mylan IPR was instituted. A party can request joinder without prior authorization under 37 C.F.R. § 42.122(b) within one month after the institution date of the proceeding to which joinder is requested.

B. Mylan’s IPR

Mylan filed its IPR Petition on July 1, 2022 challenging claims 1-9, 34-39, 41-43, and 45 the ’601 patent. The Mylan IPR was instituted on January 11, 2023.

Mylan represented that it will not oppose this Motion for Joinder.

C. Samsung Bioepis’s Petition and Proposed Role, Including Relevant Limitations

In its Petition, Samsung Bioepis asserts the same grounds of unpatentability against the same claims based on the same prior art as the Mylan IPR. *See* Mylan IPR, Paper 22. Consistent with prior practice, Samsung Bioepis has effectively copied Mylan’s IPR Petition, including the same analysis and exhibits. The only differences between Samsung Bioepis’s Petition and Mylan’s relate to the petitioner-specific information unrelated to the grounds presented in the petition, such as the introduction and mandatory notices. This is Samsung Bioepis’s first petition against the ’601 patent.

Additionally, Samsung Bioepis has resubmitted the same underlying expert opinions as Mylan. Samsung Bioepis is prepared to rely solely on the testimony of Mylan’s experts submitted in the Mylan IPR. To preserve its rights in the event that the Mylan IPR is settled or joinder is not granted, however, Samsung Bioepis further submits a short declaration of its own expert, Dr. Benjamin H. Bloom, setting out his qualifications, noting his agreement with Mylan’s experts’ analyses, and adopting them as his own. *See* Ex. 1097, Expert Declaration of Dr. Benjamin H. Bloom, in Support of Petition for *Inter Partes* Review of U.S. Patent No. 10,888,601 (“Bloom Declaration”). Neither Samsung Bioepis nor Dr. Bloom raise any new argument, analysis, or evidence.

Finally, Samsung Bioepis will take an “understudy” role. For example, so

long as Mylan remains active in the Mylan IPR, Samsung Bioepis agrees to not file additional papers or additional pages to Mylan’s papers without a showing of good cause; not present any new, additional, or supplemental arguments; and not present any arguments at oral hearings unless agreed to by Mylan or requested by the Board.

As part of that agreement, Samsung Bioepis further agrees to consolidated filings for all substantive papers in the respective proceedings, unless a motion is made directed to Samsung Bioepis alone. Additionally, Samsung Bioepis agrees that consolidated discovery is appropriate given that it will take a subordinate role in the proceedings and have Mylan take the lead in all discovery matters. Samsung Bioepis agrees that Mylan will manage any depositions, including questioning, and Mylan will designate an attorney to conduct the cross-examination of any given witness produced by Patent Owner, within the ordinary time limits normally allotted by the rules for one party. Samsung Bioepis will not receive any separate cross-examination or redirect time from that of Mylan, unless Mylan terminates its involvement in the joined deposition or oral hearing.

III. LEGAL STANDARDS

The Leahy-Smith America Invents Act permits joinder of IPR proceedings. The statutory provision governing joinder of IPR proceedings is 35 U.S.C. § 315(c), which reads as follows:

(c) JOINDER.—If the Director institutes an inter partes review, the Director, in his or her discretion, may join as a

party to that inter partes review any person who properly files a petition under section 311 that the Director, after receiving a preliminary response under section 313 or the expiration of the time for filing such a response, determines warrants the institution of an inter partes review under section 314.

Motions for joinder should “(1) set forth the reasons why joinder is appropriate; (2) identify any new grounds of unpatentability asserted in the petition; (3) explain what impact (if any) joinder would have on the trial schedule for the existing review; and (4) address specifically how briefing and discovery may be simplified.” *Dell, Inc. v. Network-1 Security Solutions, Inc.*, IPR2013- 00385, Paper 17 (July 29, 2013), at 4.

The Board “routinely grants motions for joinder where the party seeking joinder introduces identical arguments and the same grounds raised in the existing proceeding.” *Samsung Elecs. Co., Ltd. v. Raytheon Co.*, IPR2016-00962, Paper No. 12 at 9 (PTAB Aug. 24, 2016) (quotations and citations omitted).

IV. STATEMENT OF REASONS FOR RELIEF REQUESTED

Samsung Bioepis addresses below each factor considered by the Board in evaluating a motion for joinder, showing how each weighs in favor of joinder.

A. Joinder is Appropriate

Joinder is appropriate in this case because it is the most expedient way to secure the just, speedy, and inexpensive resolution of the two related proceedings.

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See 35 U.S.C. § 316(b); 37 C.F.R. § 42.1(b). Joinder will allow the Board to resolve the unpatentability of the challenged claims without any significant impact on the Mylan IPR.

As noted above, Samsung Bioepis’s Petition is *identical* with respect to the grounds instituted in the Mylan IPR. *See Sony Mobile Communications v. Ancora Tech.*, IPR2021-00663, Paper 17 at 29-33 (PTAB June 10, 2021) (granting motion for joinder for challenge based on same grounds of unpatentability as first petition supported by essentially the same expert declaration).

Moreover, as set out above, Samsung Bioepis agrees to consolidated filings and discovery and procedural concessions previously found supportive of joinder, so that in this matter Samsung Bioepis will be bound by the schedule set forth in the Mylan IPR and its participation will only serve to streamline proceedings without any prejudice to any party. *See e.g., Samsung Elecs. Co. v. Arendi S.A.R.L.*, IPR2014-01518, Paper 10 at 6 (PTAB Mar. 18, 2015) (allowing joinder where movant takes a “limited understudy role” without a separate opportunity to actively participate).

Because this proceeding and the Mylan IPR are effectively identical and Samsung Bioepis agrees it will take an understudy role, granting joinder will thus not prejudice any party or have any significant impact on the Mylan IPR.

B. Joinder Will Not Introduce Any New Grounds of Unpatentability

Samsung Bioepis’s Petition contains the same grounds of unpatentability instituted in the Mylan IPR. Indeed, Samsung Bioepis’s Petition is the same in all substantive aspects as the instituted Mylan IPR, challenging the same claims of the ’601 patent based on the same instituted grounds of unpatentability. Samsung Bioepis’s Petition contains the same analysis and exhibits, and effectively relies on the same expert opinions—those of Drs. Thomas Albini and Mary Gerritsen submitted in connection with the Mylan IPR.

As noted above, if joinder is granted, Samsung Bioepis is prepared to rely solely on the testimony of Mylan’s experts. Exs. 1002 and 1003. Only if Mylan settles prior to a final written decision would Samsung Bioepis elect to rely on its own expert, Dr. Benjamin H. Bloom, who has reviewed and adopted the opinions set forth in the declarations of Drs. Albini and Gerritsen. The Bloom Declaration is thus substantively identical to the opinions of Drs. Albini and Gerritsen and does not alter or otherwise seek to supplement the opinions offered by Drs. Albini and Gerritsen.

C. Joinder Will Not Impact the Mylan IPR’s Trial Schedule

35 U.S.C. § 316(a)(11) and 37 C.F.R. § 42.100(c) provide that IPR proceedings should be completed and the Board’s final decision issued within one year of institution of the review, with flexibility to extend the one-year period by up

to six months for good cause, or in the case of joinder. *See* 35 U.S.C. § 316(a)(11); 37 C.F.R. § 42.100(c).

Joinder will not impact the Board’s ability to complete its review in a timely manner and would have no impact on the Mylan IPR schedule. Samsung Bioepis’s Petition does not present any new issues, arguments, or evidence for the Board or Patent Owner to address, and Samsung has further committed to consolidated filings with Mylan.

Moreover, the difference between the filing date of Samsung Bioepis’s Petition and the Mylan IPR is of no consequence should the proceedings be joined. The trial schedule for the Mylan IPR would not need to be delayed to effect joinder based on Patent Owners’ preliminary response and Samsung Bioepis’s Petition. Indeed, because Samsung Bioepis asserts identical grounds of unpatentability as those instituted in the Mylan IPR, Patent Owner does not need to submit a preliminary response at all. Further, the Board does not need to extend any other deadlines following joinder for the same reason.

Accordingly, joinder does not impact any aspect of the trial schedule for the Mylan IPR. Rather, a joint proceeding would allow the Board and parties to focus on the merits in one consolidated proceeding without unnecessary duplication of effort.

D. Joinder Will Simplify the Proceedings

Because Samsung Bioepis relies on grounds of unpatentability that are identical to Mylan’s, the case is amenable to consolidated filings and discovery, which will simplify the briefing and discovery process.

In short, as long as the Mylan IPR remains pending and Mylan remains active following joinder, no additional briefing or discovery would be needed. Samsung Bioepis will adopt an “understudy” or “second chair” role and would only assume the primary role if Mylan ceases to participate in the IPR. *See, e.g., Novartis AG, IPR2015-00268, Paper 17, at 5.*¹

E. The *General Plastic* Factors Are Not Relevant Here

This is Samsung Bioepis’s first petition against the claims of the ’601 patent. Samsung Bioepis has not coordinated with Mylan or any other party regarding its Petition, and has never discussed its Petition with any other party other than to seek Mylan’s position on whether it opposes this Motion for Joinder. Accordingly, the

¹ In the event that Mylan ceases to participate and Samsung Bioepis is required to rely on Dr. Bloom, there would be no impact on the Board’s ability to complete its review in a timely manner. Moreover, there would only be a modest impact on Patent Owner, given that Samsung Bioepis’s contingent expert’s opinions are virtually identical to those already introduced and relied upon by Mylan’s experts.

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factors in *General Plastic Indus. Co. v. Canon Kabushiki Kaisha*, IPR2016-01357, Paper 19 at 17–18 (PTAB Sept. 6, 2017) (Paper 19), which relate to serial filings by the same party or by parties coordinating their filings, are not relevant here and do not weigh in favor of denying institution. See *Sony Mobile Communications v. Ancora Tech.*, IPR2021-00663, Paper 17 at 11-15 (PTAB June 10, 2021) (finding factors weigh “strongly” in favor of institution of petition where joinder was sought and the joining party had not previously filed a challenge to the claims of the patent); *Netflix, Inc. v. Broadcom Corp.*, IPR2020-01423, Paper 7 at 5-6 (PTAB Mar. 11, 2021) (finding prior petition filed by an unrelated petitioner irrelevant to institution).

V. CONCLUSION

For the foregoing reasons, Samsung Bioepis respectfully requests that its Petition be instituted and the proceeding be joined with *Mylan Pharmaceuticals Inc. v. Regeneron Pharmaceuticals, Inc.*, IPR2022-01226. Although no additional fee is believed to be required for this Motion, the Commissioner is hereby authorized to charge any additional fees which may be required for this Motion to Deposit Acct. No. 505708.

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DATED: February 10, 2023

Respectfully submitted,

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CERTIFICATE OF SERVICE

In accordance with 37 C.F.R. §§ 42.6(e) and 42.105, I hereby certify that true and correct copies of the foregoing PETITIONER’S MOTION FOR JOINDER PURSUANT TO 35 U.S.C. § 315(c) AND 37 C.F.R. §§ 42.22 AND 42.122(b) were served on February 10, 2023 via FedEx Priority Overnight on Patent Owner at the correspondence address of record for U.S. Patent No. 10,888,601 as evidenced in Patent Center:

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