

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SAMSUNG BIOEPIS CO., LTD.,
Petitioner,

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner

U.S. Patent No. 10,888,601
Case No.: IPR2023-00566

**PATENT OWNER'S OPPOSITION TO
SAMSUNG'S MOTION FOR JOINDER**

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I. STATEMENT OF THE PRECISE RELIEF REQUESTED

Petitioner Samsung Bioepis Co., LTD.'s ("**Samsung**") seeks joinder of this IPR2023-00566 with *Mylan Pharmaceuticals, Inc. v. Regeneron Pharmaceuticals, Inc.*, IPR2022-01226 (the "Mylan IPR"). Paper 2. Patent Owner Regeneron Pharmaceuticals, Inc. ("**Regeneron**") opposes, and respectfully requests that Board decline to grant Samsung's Motion for Joinder, unless and until Samsung commits to take a true understudy role in the joined proceedings.

II. BACKGROUND

The Mylan IPR, which challenges Regeneron's U.S. Patent No. 10,888,601 ("the '601 Patent"), was instituted on January 11, 2023. On February 10, 2023, Samsung filed a Petition against the '601 Patent that is "effectively a copy" of the Petition in the Mylan IPR, and simultaneously moved that this IPR2023-00566 be joined with the Mylan IPR. Paper 2 at 1. However, at the same time, Samsung filed an additional declaration from its own expert, Dr. Benjamin H. Bloom (Ex. 1097), and in so doing, reserved the right to file its own, different expert declaration in the event the Mylan IPR is settled.¹ While Samsung's expert Dr. Bloom purports to adopt the opinions of Mylan's experts² set forth in their opening declarations,

¹ Samsung's stated purpose for filing its own expert declaration is to "preserve its rights in the event that the Mylan IPR is settled." IPR2023-00566, Motion For Joinder, Paper No. 2 at 3.

² Dr. Albini and Dr. Gerritsen.

Samsung has refused to agree to be bound by the additional testimony of Mylan's experts (beyond their opening declarations) in this proceeding.³

The Parties met and conferred on March 3. Following that meet and confer, Regeneron proposed a joint stipulation consistent with the Board's past practice on joinder—namely, that Regeneron would not oppose joinder if Samsung would agree to (1) withdraw Dr. Bloom's declaration upon completion of the upcoming depositions of Drs. Gerritsen and Albini (which are scheduled to be completed on March 21, 2023) and (2) rely solely on, and be bound by, the representations made by Mylan and its experts and the papers filed by Mylan in IPR2022-01226. However, on the evening of March 9,⁴ Samsung alerted Regeneron that it will *not* agree to be bound by the testimony of Mylan's experts. Ex. 2001 at March 9, 2023, 5:55 PM email from M. Traupman to A. Struthers.

Samsung's narrowed stipulation is inadequate, and does not address Regeneron's concern that, in the event that lead Petitioner Mylan exits the proceeding, Samsung will attempt a "re-do" of expert testimony, inconsistent with

³ Ex. 2001 at March 9, 2023, 5:55 PM email from M. Traupman to A. Struthers.

⁴ Notably, Samsung's email refusing to be bound came the night before Regeneron's default deadline to oppose Samsung's Motion for Joinder pursuant to 37 C.F.R. § 42.25(a)(1). While Samsung has argued in follow-up email correspondence that the issue will be resolved "in the next few weeks" once it withdraws its expert declaration, Samsung's counsel is well-aware that PO's deadline for filing an opposition is today and, having failed to reach agreement, PO is left with no option other than to file a protective opposing brief. Ex. 2002 at March 10, 2023, 1:42 PM email from M. Traupman to A. Struthers.

joinder proceedings. Accordingly, absent Samsung's agreement, and to preserve its rights, Regeneron is compelled to file the present opposition.

III. ARGUMENT

Joinder is discretionary and not a matter of right. 35 U.S.C. § 315(c); 37 C.F.R. § 42.122; *Unified Patents, Inc. v. Personalweb Techs. et al.*, 2014 WL 12580241, IPR2014-00702, Paper 12 at 4 (P.T.A.B. July 24, 2014). The petitioner seeking joinder bears the burden of demonstrating it is entitled to joinder. 37 C.F.R. § 42.20(c). Moreover, the Board may impose limitations to ensure that a joinder petitioner assumes a true “understudy” role. *See, e.g., Noven Pharmaceuticals, Inc. v. Novartis AG*, IPR2014-00550, Paper 38 at 5 (PTAB Apr. 10, 2015) (adopting patent owner's proposed limitations on joinder); *see also, Facebook, Inc. v. Windy City Innovations, LLC*, 973 F.3d 1321, 1333 (Fed. Cir. 2020) (“The clear and unambiguous text of § 315(c) ... does not authorize the joinder of new issues.”).

Samsung's refusal to be bound by the testimony of Mylan's experts is prejudicial and inconsistent with this Board's precedent and practice. The agreement that Regeneron requested from Samsung is taken directly from the Board's case law addressing this precise circumstance, where an aspiring joinder party submitted a “placeholder” declaration from its own expert. *See Z-Shade Co., Ltd. v. Caravan Canopy Int'l, Inc.*, No. IPR2020-01026, 2021 WL 1978970, at *3 (P.T.A.B. May 17, 2021) (granting joinder where joinder petitioner “agree[ed] to rely entirely on, and

be bound by, the expert declaration(s) and deposition(s) in the [primary] IPR, and ... waive its own expert declaration” if the primary petitioner “[did] not terminate its IPR before its expert is deposed.”); *Samsung Elecs. Co., Ltd. v. Yu*, No. IPR2020-00492, 2020 WL 4680058, at *3 (P.T.A.B. Aug. 12, 2020) (“Samsung agrees to be bound by the expert deposition and declarations of Apple’s expert, and Samsung will waive its own expert own expert declaration, unless Apple ceases to be an active participant in its IPR prior to its expert’s deposition). Indeed, the Board has recognized that this is one of the conditions “regularly cited in...cases where joinder of a me-too petitioner is granted.” *Sun Pharm. Indus. Ltd. v. Merck Sharp and Dohme Corp.*, No. IPR2020-01060, 2020 WL 5223131 at *3 (P.T.A.B. Sept. 1, 2020) (“Petitioner persuades us that it has agreed to play the role of a true and silent ‘understudy’ to Mylan in the joined proceeding—agreeing to conditions like those regularly cited in other Board cases where joinder of a me-too petition was granted. [Joinder Petitioner’s] Mot. 1, 5-7 (agreeing, for example, **to rely on and be bound by the testimony of Mylan’s expert**)”) (emphasis added). Conversely, in refusing to agree, Samsung has pointed only to cases where the joinder party “relie[d] on the same expert declaration” as the main petitioner from the start.⁵ These cases are

⁵ See Ex. 2001 at March 9, 2023, 5:55 PM email from M. Traupman to A. Struthers. citing *Ecobee Techs. Ulc v. Ecofactor, Inc.*, No. IPR2022-00473, 2023 WL 372383, at *3 (P.T.A.B. Jan. 24, 2023); *Dell Inc. v. Neodron Ltd.*, No. IPR2020-00731, 2020 WL 4390670, at *3 (P.T.A.B. July 31, 2020); *Ericsson Inc. v. Uniloc 2017 LLC*, No. IPR2020-00376, 2020 WL 2613358, at *7 (P.T.A.B. May 22, 2020).

inapposite, as they do not implicate the issues raised by Samsung's decision to submit a declaration from its own, independent expert here.⁶

Samsung's refusal to be bound by the representations of Mylan's experts in this proceeding expands the "understudy" role Samsung is presumed to occupy as a joinder party. Specifically, Samsung's refusal to be bound leaves open the possibility that Samsung may later submit new testimony from its own expert, thus changing the scope of the proceeding. In that case, Regeneron would, at a minimum, need to seek a modification of the schedule to allow sufficient time for additional discovery and response, which could add significant procedural complications and delay to the proceedings. *See, e.g., Mylan Pharmaceuticals, Inc., v. Janssen Oncology, Inc.*, IPR2016-01332, Paper 21 at 10-11 (P.T.A.B. Jan. 10, 2017) (denying joinder where movant had filed its own expert declarations, and did "not offer a practical way to accommodate the additional discovery without inconveniencing all involved or delaying the due dates in the [main] IPR.>").

IV. CONCLUSION

In sum, because of the uncertainty caused by Samsung's submission of a separate expert submission coupled with its refusal to be bound by the

⁶ Indeed, in separate proceedings challenging the '601 patent another party, Celltrion, Inc. ("Celltrion"), has also filed a copycat petition and moved to be joined with the Mylan IPR, but because Celltrion has committed to take an understudy role and has not submitted any additional expert testimony, Regeneron has not opposed Celltrion's Motion for Joinder.

representations of Mylan's experts in this proceeding, Regeneron cannot consent to joinder absent appropriate safeguards being put in place. Regeneron therefore respectfully requests that the Board decline to grant joinder unless Samsung is held to the following conditions:

- That upon completion of the upcoming depositions of Mylan's experts Dr. Gerritsen and Dr. Albini in IPR2022-01226, which depositions are scheduled to be completed on March 21, 2023, Samsung will withdraw the Declaration and curriculum vitae of Dr. Benjamin Harris Bloom, M.D. (IPR2023-00566, Exs. 1097, 1098);
- That, upon joinder of IPR2023-00566 with IPR2022-01226, Samsung will take an "understudy" role in the joined proceedings, as stated in Samsung's Motion for Joinder (IPR2023-00566, Paper 2); and
- That Samsung will be bound in the joined proceedings by every paper filed by Mylan and every representation made by Mylan and its experts in IPR2022-01226, except for papers and representations regarding settlement between Mylan and Regeneron.

Dated: March 10, 2023

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned certifies that a copy of the foregoing **PATENT OWNER'S OPPOSITION TO SAMSUNG'S MOTION FOR JOINDER** was served on March 10, 2023, to the following Counsel for Petitioner via e-mail at:

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