

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FORMYCON AG,
Petitioner,

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner.

IPR2025-00233
Patent 11,084,865 B2

PATENT OWNER'S RESPONSE TO MOTION FOR JOINDER

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Petitioner Formycon AG (“Formycon”) conditionally seeks joinder with Samsung Bioepis Co., Ltd. (“SB”) in IPR2025-00176. Paper 1 (“Mot.”). Both this IPR and the SB IPR were accorded filing dates on December 17, 2024. IPR2025-00176, Paper 5; IPR2025-00233, Paper 4.

Formycon purports to take an understudy role and agrees to certain conditions that would define that role. Mot. 8-9. These conditions, however, would allow Formycon to play a much larger role than that of the silent observer. Unless Formycon is confined to a true understudy role as set forth below, joinder is inefficient and prejudicial to Patent Owner (“Regeneron”). The Board should therefore either impose the joinder conditions enumerated below or deny joinder.

I. LEGAL STANDARD

The decision to grant joinder is discretionary. 35 U.S.C. § 315(c); 37 C.F.R. § 42.122. Even in the context of nearly identical, copycat petitions, joinder is not a “matter of right.” *Unified Patents, Inc. v. PersonalWeb Techs. LLC*, IPR2014-00702, Paper 12 at 4 (P.T.A.B. July 24, 2014). A joinder petitioner bears the burden of establishing entitlement to joinder. 37 C.F.R. § 42.20(c).

The Board “determine[s] whether to grant joinder on a case-by-case basis, taking into account the particular facts of each case.” *Harmonix Music Sys., Inc. v. Princeton Digital Image Corp.*, IPR2015-00271, Paper 15 at 3 (P.T.A.B. June 2, 2015). The Board specifically considers any prejudice to the patent owner, *id.* at 7,

and any briefing and discovery inefficiencies, complications, or delays that could arise from joinder, *Chegg Inc. v. Netsoc, LLC*, IPR2019-01165, Paper 19 at 6 (P.T.A.B. Jan. 13, 2020).

II. ARGUMENT

Regeneron would agree to joinder only if Formycon is confined to a true “silent understudy” role. Without such confinement, this IPR proceeding will be inefficient and will prejudice Regeneron. Although Formycon has agreed to several limitations on its participation, *see* Mot. 8-9, Formycon’s conditions allow it to maintain a much more active role than is typically allowed of silent understudies. Thus, Regeneron would agree to joinder only subject to the conditions set forth below.

First, Formycon offers to rely on its copycat declarations from Drs. Forrest, Zhou, and Lefkowitz “only in the event that trial in IPR2025-00176 is not instituted or [SB] is terminated from that proceeding.” Mot. 6 n.2. Formycon’s offer inappropriately enables Formycon to rely on its own set of experts—none of whom is advanced as an expert in the SB IPR—if SB is terminated after the deposition of SB’s experts. Such a reservation of rights is unacceptable. In such a scenario, Regeneron would have to depose Formycon’s newly resurrected experts after Regeneron already has deposed SB’s experts and laid bare its questioning. That would be fundamentally unfair and greatly prejudice Regeneron. It also would

complicate trial by potentially requiring an additional round of multiple expert depositions whenever SB is terminated. *ZTE Corp. v. Adaptix, Inc.*, IPR2015-01184, Paper 10 at 5 (P.T.A.B. July 24, 2015) (“We agree with Patent Owner that the new issues raised by reliance on the different declarant in the instant Petition would adversely impact the IPR ’1525 trial.”). If joined, Formycon should be required to commit not to rely upon its copycat declarations from Drs. Forrest, Zhou, and Lefkowitz after the deposition of SB’s experts, and to be bound by the SB’s experts’ deposition testimony to the same extent as SB, consistent with the Board’s joinder decisions in analogous scenarios. *See Am. Honda Motor Co. v. Neo Wireless, LLC*, IPR2023-00791, Paper 11 at 13 (P.T.A.B. Oct. 10, 2023) (ordering joinder where petitioner agreed to “not rely on expert testimony beyond that submitted by the Volkswagen IPR Petitioner unless the Volkswagen IPR Petitioner is terminated from the case *prior to any necessary depositions*” (emphasis added)); *Mercedes-Benz USA, LLC v. Neo Wireless, LLC*, IPR2023-00079, Paper 11 at 11 (P.T.A.B. May 5, 2023) (same).

Second, although Formycon has stated that “[u]nless and until [SB] ceases to participate, [it] will not assume an active role in IPR2025-00176,” Mot. 9, it has not offered to limit its participation in the SB IPR in ways that the Board has found necessary in other proceedings. However, Formycon also has stated that it is “willing to agree to any other reasonable conditions the Board deems necessary.”

Id. To ensure that joinder does not introduce inefficiencies, complicate briefing and discovery, and prejudice Regeneron, the following additional conditions should be imposed so long as SB remains an active party in IPR2025-00176:

1. SB will be subject to the word-count limits for a single party when filing papers on behalf of itself and Formycon. *Aurobindo Pharma U.S.A. Inc. v. AstraZeneca AB*, IPR2016-01117, Paper 12 at 11 (P.T.A.B. Oct. 21, 2016).
2. Formycon must obtain prior Board authorization to file any paper or to take any action on its own in the SB IPR, with the exception of *pro hac vice* motions, updated mandatory notices, and similar administrative filings that do not constitute argument or evidence relating to the merits. *Ericsson Inc., v. Uniloc 2017 LLC*, IPR2020-00376, Paper 16 at 10 (P.T.A.B. May 22, 2020).
3. Formycon will not serve discovery requests in connection with the SB IPR. *Aurobindo*, IPR2016-01117, Paper 12 at 6.
4. Counsel for Formycon will not participate in a speaking role in any telephonic conference before the Board in the SB IPR. *Teva Pharm. USA, Inc. v. Eli Lilly & Co.*, IPR2016-01340, Paper 8 at 3 (P.T.A.B. Aug. 22, 2016), Paper 9 at 11 (P.T.A.B. Oct. 6, 2016).
5. Counsel for Formycon will not participate in oral argument in the SB IPR. *Dr. Reddy's Labs., Inc. v. Horizon Pharma USA, Inc.*, IPR2018-01341, Paper 21 at 7 (P.T.A.B. Apr. 19, 2019).

6. Counsel for Formycon shall not participate in any speaking role in any deposition in the SB IPR, including by participating in the questioning of any witness or the defense of any witness. *LG Elecs., Inc. v. Fundamental Innovation Sys. Int'l LLC*, IPR2018-00461, Paper 10 at 5-6 (P.T.A.B. May 29, 2018).
7. As Formycon already agreed, “Formycon shall not be permitted to raise any new grounds not instituted by the Board in IPR2025-00176, or introduce any argument or discovery not introduced by [SB].” Mot. 8.
8. As Formycon already agreed, “Formycon shall be bound by any agreement between Patent Owner and [SB] concerning discovery and/or depositions.” *Id.*

By imposing these conditions and thereby confining Formycon to a true silent understudy role, the Board can ensure that joinder does not create inefficiencies and complications and does not prejudice Regeneron. In prior matters, the Board has required similar covenants as a condition of joinder, precisely because these conditions ensure the efficient and orderly resolution of the proceedings. *See, e.g., Dr. Reddy's*, IPR2018-01341, Paper 21 at 7. These conditions are thus the type of “reasonable conditions” that Formycon has already stated its willingness to agree to. Mot. 9.

In the absence of the aforementioned safeguards, Regeneron opposes joinder. The enumerated safeguards, including the requirement that Formycon commit not to rely upon its own experts after the deposition of SB's experts, are necessary to prevent prejudice to Regeneron and to "ensure the just, speedy, and inexpensive resolution of [this] proceeding." *Central Security Grp. – Nationwide, Inc., v. Ubiquitous Connectivity, LP*, IPR2019-01610, Paper 12 at 6 (P.T.A.B. Feb. 26, 2020).

Regeneron would agree to joinder subject to the conditions set forth above. Without the requested safeguards, the Board should deny joinder.

Date: December 30, 2024

Respectfully submitted,

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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 Response was served on December 30, 2024, by delivering copies via electronic mail on the following counsel of record for the Petitioner:

IPR57795-0001IP1@fr.com

Date: December 30, 2024

Respectfully submitted,

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