

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FORMYCON AG,
Petitioner

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner

Case IPR2025-00233
Patent No. 11,084,865

PETITIONER'S CONDITIONAL MOTION FOR JOINDER

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I. STATEMENT OF PRECISE RELIEF REQUESTED

Under 35 U.S.C. § 315(c) and 37 C.F.R. §§ 42.22, 42.122(b), Formycon AG (“Formycon” or “Petitioner”) submits this Conditional Motion for Joinder (“Motion”) concurrently with a “copycat” petition for *inter partes* review (“Petition”) of U.S. Patent No. 11,084,865 (“the ’865 Patent”) (Ex.1001).

At present, and not including the Petition submitted concurrently with this Motion, only one IPR has been filed challenging the ’865 patent: IPR2025-00176. The petition in IPR2025-00176 was filed by Samsung Bioepis Co., Ltd. (“Samsung Bioepis”), on November 20, 2024. The Board has yet to issue a Notice of Filing Date Accorded and no decision on institution has been made in IPR2025-00176.

Formycon seeks party joinder to IPR2025-00176, if that IPR has been instituted and is still pending when the Board reaches this Motion. If IPR2025-00176 is *not* pending when the Board reaches this Motion, then this Motion is moot, and Petitioner respectfully requests that the Board consider Formycon’s Petition on its merits.

This conditional request for joinder is timely under 37 C.F.R. § 42.122(b) as it is submitted no later than one month after any institution decision in IPR2025-00176, because the Board has not yet issued any such decision. Further, and as discussed below, Petitioner would remain in an “understudy” role, following the common PTAB practice, unless and until Samsung Bioepis is no longer a party to

IPR2025-00176. While in an understudy role, Petitioner agrees to allow Samsung Bioepis to lead the joined proceedings, absent settlement, or termination for some other reason.

Joinder would not prejudice either Patent Owner or Samsung Bioepis. The Petition is a typical copycat petition that is substantively identical to the petition in IPR2025-00176 and introduces no new grounds or issues. Indeed, the Petition is a near-verbatim copy of Samsung Bioepis' petition in IPR2025-00176; the only differences are reflected in administrative portions (e.g., mandatory notices), the names and qualifications of the experts (who have otherwise submitted identical "copycat" declarations), the explanation as to why discretionary denial would be inappropriate, and other minor formatting changes and non-substantive corrections.

Samsung Bioepis has stated that it does not oppose joinder.

II. BACKGROUND AND RELATED PROCEEDINGS

The '865 patent is assigned to Regeneron Pharmaceuticals, Inc. ("Patent Owner"). Patent Owner has asserted the '865 patent against Petitioner and numerous other parties, including Samsung Bioepis, in district court. The '865 patent is the subject of the following pending civil actions:

- *Regeneron Pharmaceuticals, Inc. v. Mylan Pharmaceuticals Inc.*, Nos. 24-1965, 24-1966, 24-2002, 24-2009, 24-2019, 24-2058, 24-2082, 24-2083, 24-2147, 24-2156, 24-2351 (Fed. Cir.)

- *In re: Aflibercept Patent Litigation*, No. 1:24-md-3103 (N.D.W.Va.)
- *Regeneron Pharmaceuticals, Inc. v. Amgen, Inc.*, No. 2:24-cv-264 (C.D. Cal.)
- *Regeneron Pharmaceuticals, Inc. v. Amgen, Inc.*, No. 1:24-cv-39 (N.D.W.Va.)
- *Regeneron Pharmaceuticals, Inc. v. Formycon AG*, No. 1:23-cv-97 (N.D.W.Va.)
- *Regeneron Pharmaceuticals, Inc. v. Celltrion, Inc.*, No. 1:23-cv-89 (N.D.W.Va.)
- *Regeneron Pharmaceuticals, Inc. v. Celltrion, Inc.*, No. 1:24-cv-53 (N.D.W.Va.)
- *Regeneron Pharmaceuticals, Inc. v. Mylan Pharmaceuticals Inc.*, No. 1:22-cv-61 (N.D.W.Va.)
- *Regeneron Pharmaceuticals, Inc. v. Sandoz, Inc.*, No. 1:24-cv-85 (N.D.W.Va.)

As noted above, the '865 patent is also the subject of IPR2025-00176, initiated by Samsung Bioepis.

III. STATEMENT OF REASONS FOR THE RELIEF REQUESTED

The Board has discretion to join a party that properly files an *inter partes* review petition to an existing proceeding addressing the same patent. *See* 35

U.S.C. § 315(c); 37 C.F.R. § 42.122(b); *see also Dell Inc. v. Network-1 Sec. Sols., Inc.*, IPR2013-00385, Paper 17 at 4–6 (July 29, 2013); *Sony Corp. v. Yissum Res. & Dev. Co. of the Hebrew Univ. of Jerusalem*, IPR2013-00326, Paper 15 at 3–4 (PTAB Sep. 24, 2013); *Microsoft Corp. v. Proxyconn, Inc.*, IPR2013-00109, Paper 15 at 3–4 (PTAB Feb. 25, 2013). “The Board will determine whether to grant joinder on a case-by-case basis, taking into account the particular facts of each case, substantive and procedural issues, and other considerations.” *Dell* at 3. The movants bear the burden of proof in establishing entitlement to the requested relief. 37 C.F.R. §§ 42.20(c), 42.122(b). A motion for joinder should:

[A] set forth the reasons why joinder is appropriate; [B] identify any new grounds of unpatentability asserted in the petition; [C] explain what impact (if any) joinder would have on the trial schedule for the existing review; and [D] address specifically how briefing and discovery may be simplified.

Dell at 4.

A. The Statutory Requirements Are Satisfied, and Joinder Would Properly Balance the Parties’ Interests

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 12 at 9 (PTAB Aug. 24, 2016) (cleaned up). Here, joinder with IPR2025-00176 is appropriate because there are no substantive differences between the Petition and

the petition in IPR2025-00176. The two petitions have identical unpatentability arguments, grounds and supporting evidence, and challenge the same claims.

When, as here, the petitions are identical, joinder should be granted as a matter of right. *See* 157 CONG. REC. S1376 (daily ed. Mar. 8, 2011) (statement of Sen. Kyl) (“The Office anticipates that joinder will be allowed as of right—if an *inter partes* review is instituted on the basis of a petition, for example, a party that files an identical petition will be joined to that proceeding, and thus allowed to file its own briefs and make its own arguments.”).

Petitioner may be prejudiced if it is not permitted to join IPR2025-00176. Patent Owner has asserted the '865 patent against Petitioner in pending litigation. *See supra* Related Proceedings. Petitioner should be permitted to join IPR2025-00176 to participate in a proceeding affecting a patent asserted against it, and thereby allowed to continue the proceeding should Samsung Bioepis settle under 37 C.F.R. § 42.74 before the Board issues a final written decision. *See Lowes Cos. Inc. v. Nichia Corp.*, IPR2017-02011, Paper 13 at 19 (Mar. 12, 2018) (“[d]enial of the Petition in part would prejudice the Petitioner in this proceeding should the Vizio Petitions be resolved by settlement”).

In addition, permitting Petitioner to join IPR2025-00176 helps ensure that the patentability of the challenged claims will ultimately be decided by the Board,

efficiently protecting the public and providing the patent owner with predictable and reliable expectations regarding its patent rights.

This factor favors joinder.¹

B. Joinder Will Not Add Any New Grounds of Unpatentability or Issues

Formycon's Petition is based on the same grounds and combinations of prior art as Samsung Bioepis' petition in IPR2025-00176. For simplicity and efficiency, Petitioner has copied the substance of the petition in IPR2025-00176 and relies on the same or substantially the same supporting evidence.² Petitioner does not seek

¹ The factors outlined by *General Plastic Industries Co. v. Canon Kabushiki Kaisha*, IPR2016-01357, Paper 19 (Sept. 6, 2017), are not particularly relevant here "where a different petitioner files a 'me-too' or 'copycat' petition in conjunction with a timely motion to join." See, e.g., *Celltrion, Inc. v. Genentech, Inc.*, IPR2018-01019, Paper 11 at 9-11 (Oct. 30, 2018); *Pfizer, Inc. v. Genentech, Inc.*, IPR2017-02063, Paper 25 at 7-8 (Feb. 21, 2018).

² Petitioner submits "copycat" declarations from Drs. Forrest, Zhou, and Lefkowitz, on whom Petitioner will rely only in the event that trial in IPR2025-00176 is not instituted or Samsung Bioepis is terminated from that proceeding. The declarations submitted by Petitioner differ from those Samsung Bioepis filed

to introduce grounds or claims not currently presented in IPR2025-00176 and seeks only to join the proceeding as instituted. Patent Owner should not require any discovery beyond that which it may need in IPR2025-00176—nor should the Board permit any. Formycon’s Petition introduces no new substantive issues relative to IPR2025-00176 and does not seek to broaden the scope of IPR2025-00176.

This factor favors joinder.

C. Joinder Would Not Impact the Trial Schedule in IPR2025-00176

Joinder will not impact a trial schedule in IPR2025-00176 because Formycon’s Petition presents no new issues or grounds of unpatentability. *See Sony Corp. v. Memory Integrity, LLC*, IPR2015-01353, Paper 11 at 6 (PTAB Oct. 15, 2015) (granting a motion where “joinder should not necessitate any additional briefing or discovery from Patent Owner beyond that already required in [the original IPR]”). Patent Owner will not be required to provide any additional analysis or arguments beyond what it will already provide in responding to the petition in IPR2025-00176.

(from Drs. Yaman, Butler, and Chaum, respectively), in that they have been updated to list the qualifications and personal experience of Drs. Forrest, Zhou, and Lefkowitz.

Petitioner's experts submitted substantively identical declarations to Samsung Bioepis' experts (except for their respective qualifications and experience). Petitioner's experts need not be deposed in the proposed joined proceeding unless Samsung Bioepis is terminated from IPR2025-00176 prior to any necessary depositions.

This factor favors joinder.

D. Procedures to Simplify Briefing and Discovery

Petitioner expressly agrees to take an "understudy" role, which would simplify briefing and discovery. Specifically, Petitioner expressly agrees, upon joining IPR2025-00176, that the following conditions, as previously approved by the Board in similar circumstances, shall apply so long as Samsung Bioepis remains an active party in IPR2025-00176:

- a) all filings by Formycon in IPR2025-00176 shall be consolidated with the filings of Samsung Bioepis, unless a filing concerns issues solely involving Formycon;
- b) 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 Samsung Bioepis;
- c) Formycon shall be bound by any agreement between Patent Owner and Samsung Bioepis concerning discovery and/or depositions; and

- d) Formycon at deposition shall not receive any direct, cross-examination or redirect time beyond that permitted under either 37 C.F.R. § 42.53 or any agreement between Patent Owner and Samsung Bioepis.

See Noven Pharmaceuticals, Inc. v. Novartis AG, IPR2014-00550, Paper 38 at 5 (PTAB Apr. 10, 2015). Unless and until Samsung Bioepis ceases to participate, Petitioner will not assume an active role in IPR2025-00176.

Thus, by Petitioner accepting an “understudy” role, the parties can comply with the trial schedule assigned to IPR2025-00176 without duplicative efforts. These steps minimize the possibility of any complication or delay from joinder. *See Sony*, IPR2015-01353, Paper 11 at 6-7 (granting a motion for joinder where petitioner agreed to an “understudy” role because “joinder would increase efficiency by eliminating duplicative filings and discovery, and would reduce costs and burdens on the parties as well as the Board”). Petitioner is further willing to agree to any other reasonable conditions the Board deems necessary.

IV. CONCLUSION

For the foregoing reasons, Formycon respectfully requests that the Board institute review in this proceeding and grant this motion for joinder with IPR2025-00176, if and when a trial instituted in that proceeding. If a trial in IPR2025-00176 is *not* instituted, however, this Motion is moot, and Petitioner respectfully requests that the Board consider Formycon’s Petition on its own merits.

Respectfully submitted,

Dated: November 29, 2024

/Louis E. Fogel/

Louis E. Fogel (Reg. No. 54,731)

Fish & Richardson P.C.

60 South Sixth Street, Suite 3200

Minneapolis, MN 55402

T: 202-783-5070

F: 877-769-7945

(Control No. IPR2025-00233)

Attorneys for Petitioner

CERTIFICATE OF SERVICE

Pursuant to 37 CFR § 42.6(e), the undersigned certifies that on November 29, 2024, a complete and entire copy of this Motion for Joinder was provided via email to the Patent Owner by serving the correspondence email addresses of record as follows:

A&P - REGENERON (PROSECUTION)
601 MASSACHUSETTS AVE., NW
WASHINGTON, DC
UNITED STATES

/Anastasia Renard/
Anastasia Renard
Fish & Richardson P.C.
60 South Sixth Street, Suite 3200
Minneapolis, MN 55402
renard@fr.com