

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX INC.,
Petitioners

v.

NOVO NORDISK A/S,
Patent Owner

Case IPR2024-00631
Patent 10,335,462

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

PROTECTIVE ORDER INFORMATION

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Patent Owner Novo Nordisk A/S (“PO”) submits this Opposition to Petitioner’s four-month-late Motion for Joinder (“Motion”/Pap.5) and its alternative request to “consolidate” its late proceeding with IPR2023-00724 (the “Mylan IPR”)—an IPR in which a POR has already been filed, and in which a Reply and Sur-Reply would be filed, and oral argument presented, long before any institution decision would even be due in this case.

I. Petitioner Does Not Establish Good Cause For Its Untimely Joinder Motion

No special circumstances exist that would justify waiver of the one-month time period for requesting joinder. *See* 37 C.F.R. §42.5(b). Petitioner filed its copycat petition and motion for joinder on March 1, 2024, almost four months after the deadline to move to join IPR2023-00724, and about a month and a half after the Patent Owner Response was filed in IPR2023-00724. 37 C.F.R. §41.122.¹

¹ Petitioner’s motion for joinder was, itself, also unauthorized as it was not filed within the Rule 41.122(b) deadline, and Petitioner has not sought (nor shown the required basis for) permission to file its motion out of time.

As movant, Petitioner has the burden to show entitlement to the requested relief, and has not shown “special” or “extraordinary circumstance[s]” to justify waiver of the joinder deadline. *Google Inc. v. Personalweb Techs., LLC*, IPR2014-00978, Pap.11, 4-5 (Oct. 30, 2014) (“Simply because the parties in IPR2014-00062 stipulated to new dates for DUE DATES 1 and 2—a common practice in proceedings before us—does not constitute an extraordinary circumstance that would persuade us to waive the one-month time limit for Google to file its Motion for Joinder” even where the request occurred before the POR); *Shaw Indus. Grp., Inc. v. Automated Creel Sys., Inc.*, IPR2013-00584, Pap.20, 4-5 (Dec. 31, 2013) (“We are not persuaded that special circumstances exist that would justify waiver of the one-month time period for requesting joinder... ***Petitioner does not contend that it was unable to file its Petition in the instant proceeding within one month of July 25, 2013. Rather, it simply preferred to wait and see*** if the Board granted its request for rehearing.”)²; 37 C.F.R. §42.20(c) (“The moving party has the burden of proof to establish that it is entitled to the requested relief”). Here, Petitioner provides no showing of any “special” or “extraordinary circumstance.”

² Unless stated, all statutory and regulatory citations are to 35 U.S.C. or 37 C.F.R., as context indicates, all internal citations omitted, and all emphases/annotations are added.

Indeed, Petitioner's brief does not even acknowledge this standard. Petitioner's preference to wait to file an IPR, despite knowing of the patent and the IPR it seeks to join (confirmed in the March 11, 2024 call with the Board), is the opposite of a special or extraordinary circumstance.³

Petitioner's own admissions about the circumstances of its filing shows that it merely made a business decision to wait to file (waiting for "heightened

³ Apotex asserts, without explaining, that the fact that the Board has not issued a joinder decision in the *Dr. Reddy's Laboratories, Inc. ("DRL")* or *Sun Pharmaceutical Ltd. ("Sun")* IPRs means the joinder deadline here should be waived. Pap.5, 1-2. But these assertions are irrelevant to whether the untimely and opposed Apotex joinder motion should be granted, particularly where the timely DRL and Sun joinder motions were not opposed. *Dr. Reddy's Labs., Inc. v. Novo Nordisk A/S*, IPR2024-00009, Pap.12, 1 (Nov. 20, 2023); *Sun Pharm. Ltd. v. Novo Nordisk A/S*, IPR2024-00009, Pap.8, 1 (Nov. 28, 2023). Further, Apotex is differently situated than DRL and Sun, who have submitted ANDAs and are parties to parallel litigation, and for whom motivations relating to, *e.g.*, settlement, may be different. *Dr. Reddy's Labs., Inc. v. Novo Nordisk A/S*, IPR2024-00009, EX2010, 2 (Jan. 26, 2024); *Sun Pharm. Ltd. v. Novo Nordisk A/S*, IPR2024-00009, EX2010, 2 (Feb. 29, 2024).

confidence”), which is the opposite of a “special” or “extraordinary circumstance.” *Google*, IPR2014-00978, Pap.11, 4-5; *Shaw Indus. Grp.*, IPR2013-00584, Pap.20, 4-5. Here, just as in *Shaw*, “Petitioner does not contend that it was unable to file its Petition in the instant proceeding within one month [of institution of the petition it seeks to join]. Rather, it simply *preferred to wait* and see if the Board granted its request for rehearing.” *Shaw Indus. Grp.*, IPR2013-00584, Pap.20, 4-5. Petitioner has not provided a sufficient excuse for any delay, let alone a ***four-month*** one. See *TrickleStar LLC v. Embertec Pty Ltd.*, IPR2017-00839, Pap.11, 32-33 (June 10, 2017) (denying joinder motion filed ***five days*** after deadline).

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Petitioner’s own admissions show that it could have timely filed an IPR with a motion for joinder. Petitioner’s preference to wait to file long after the

deadline does not and cannot constitute special circumstances. *Shaw Indus. Grp.*,

IPR2013-00584, Pap.20, 4-5. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

⁴ Petitioner provides no documentary evidence supporting the unsubstantiated assertions of its employee. EX1507.

[REDACTED]

[REDACTED]

At each step of the way, Petitioner made the business decision not to prepare the IPR, and to continue to delay filing its Petition. Petitioner's business decision is similar to the rejected excuse offered by the petitioner, Roche, in *Roche Molecular Systems Inc. v. Illumina, Inc.*, IPR2015-01091, Pap.18 (Oct. 30, 2015). There, Roche waited to file its motion for joinder "nearly four months after trial was instituted" despite being aware of the proceeding to which it sought joinder, and despite the acquisition being completed just four days after trial was instituted. *Id.* at 9-10. There, like here, "Petitioner has not provided a reason as to why it waited [months] to file the instant Petition," let alone "special circumstances that would justify waiving the one-month time limit for the filing of the Motion for Joinder." *Id.* at 11, 9. The Board in *Roche* denied joinder noting "Petitioner could have also filed its own petition at any time, as there is no standing requirement to file a petition for *inter partes* review." *Id.* at 11. The same is true here. [REDACTED]

[REDACTED]

[REDACTED]: Petitioner *chose* to file past the joinder deadline.

Petitioner cites no case waiving the deadline for joinder under similar circumstances. Indeed, the only cases Petitioner cites in arguing the Board should

waive the requirements are *GlobalFoundries U.S. Inc. v. Godo Kaisha IP Bridge 1*, IPR2017-00925, Pap.13, 8 (June 9, 2017) and *Sony Corp. of Am. v. Network-1 Security Sols.*, IPR2013-00495, Pap.13, 9 (Sept. 16, 2013). Yet those two cases are easily distinguished. In both of those cases, the copycat petitioner or its parent attempted to join the original proceeding ***within the one-month period***.

GlobalFoundries, IPR2017-00925, Pap.13, 7-8 (“here Petitioner’s parent company filed its petitions... within one month of institution in the -1246 Case, then Petitioner re-filed shortly thereafter to include both entities as real parties-in-interest.”); *Sony Corp.*, IPR2013-00495, Pap.13, 7-9 (“Petitioners attempted previously within the one-month time period to be joined”). The later-filed petitions, for which joinder was ultimately granted, were submitted only because the timely petitions were denied or to add a real party-in-interest.

GlobalFoundries, IPR2017-00925, Pap.13, 7-8; *Sony Corp.*, IPR2013-00495, Pap.13, 7-9. Here, Petitioner never attempted to file any IPR or motion for joinder within a month of institution of the Mylan IPR. Instead, it made the business decision to wait.⁵

⁵ In the event Apotex’s motion for joinder is granted, Apotex consented to the stipulations agreed to by DRL and Sun so long as the fourth and fifth stipulations are revised as follows: (1) “In the event Apotex’s Petition is instituted, only

Apotex will be joined to *Mylan Pharmaceuticals, Inc. v. Novo Nordisk, A/S*, IPR2023-00724. Apotex's Petition and related papers will not be joined or added as part of institution"; (2) "In the event (1) Apotex's Petition is instituted, (2) Apotex is joined to the Mylan IPR, and (3) Mylan is terminated before Novo has had the opportunity to depose an expert for which Mylan filed a corresponding expert declaration (and within the time period for taking the corresponding deposition), the parties will meet and confer as to (1) depositions, (2) whether any substitute expert(s) will be needed and/or deposed on the already-filed expert declaration(s) or whether the expert declaration(s) themselves will be expunged and replaced by the declaration(s) filed with one (and only one) of the copycat petitions, and (3) what sort of adjustment to the schedule, if any, is needed. Having met and conferred, the parties will then request a call with the Board regarding these issues"; (3) "Unless Mylan is terminated, Apotex will serve in the silent understudy role. In the event that either or both (1) Sun's Petition is instituted and Sun is joined to the Mylan IPR and (2) DRL is instituted and DRL is joined to the Mylan IPR, only one of the joined Petitioners should take the lead role, and the other(s) should assume the understudy role"; (4) "In the event that Apotex's Petition is instituted and Apotex is joined to the Mylan IPR, Apotex shall not be permitted to raise any new grounds not instituted by the Board in the Mylan

II. Petitioner's Request For Consolidation of IPRs On Different Timelines Is Nonsensical

Petitioner, without authorization, used its joinder motion to alternatively request consolidation of this IPR with the Mylan IPR, asserting it is appropriate for the same reasons as joinder. Pap.5, 11. First, this is an improper attempt to end-run the joinder deadline without justification. Second, because of Petitioner's extensive delay in filing its IPR, the schedules in this IPR and the Mylan IPR would be entirely incompatible. Indeed, in the *Mylan* IPR, the POR was already filed on January 17, 2024, the Reply is due on May 1, 2024, and the Sur-Reply is due on June 12, 2024. *Mylan Pharms. Inc. v. Novo Nordisk A/S*, IPR2023-00724, Pap.14, 1 (Nov. 9, 2023). But even the *institution decision* in *this* IPR is not due until September 12, 2024.

IPR, or introduce any argument not already introduced by Mylan"; (5) "With regard to the taking of testimony, in the event that Apotex's Petition is instituted and Apotex is joined to the Mylan IPR, Apotex will abide by 37 C.F.R. §42.53 and any agreement between the Patent Owner and Mylan." *Dr. Reddy's Labs.*, IPR2024-00009, Pap.12, 1-3; *Sun Pharm. Ltd.*, IPR2024-00009, Pap.8, 1-3.

Petitioner's citation to *Sony Elecs. Inc. v. Jawbone Innovations, LLC*, IPR2023-01110, Pap.12 (Feb. 9, 2024) is also distinguishable.⁶ Pap.5, 11. The joined petitions there were instituted *within two days of one another* and consolidated with each other only about a month after institution. *Sony Elecs.*, IPR2023-01119, Pap.14, 2. Further, the Petitioners in the two IPRs that were ultimately consolidated had both filed timely joinder motions to join an earlier IPR, which was terminated before joinder. *LG Elecs. Inc. v. Jawbone Innovations, LLC*, IPR2023-01110, Pap.3, 3 (June 23, 2023) (filed motion for joinder on June 23, 2023 where the proceeding petitioner sought to join was instituted May 24, 2023); *Sony Elecs. Inc. v. Jawbone Innovations, LLC*, IPR2023-01119, Pap.3, 3 (June 23, 2023) (same). And in *ZTE (USA) Inc. v. Evolved Wireless LLC*, IPR2016-01277, Pap.8 (Dec. 21, 2016), the petitions were instituted on the same day as each other, and consolidated at the same time. *See Apple Inc. v. Evolved Wireless, LLC*, IPR2016-01209, Paps. 7 & 8 (Dec. 21, 2016).

⁶ PO assumes Petitioner intended to cite *Sony Elecs. Inc. v. Jawbone Innovations, LLC*, IPR2023-01119, Pap.14 (Feb. 9, 2024) or *LG Elecs. Inc. v. Jawbone Innovations, LLC*, IPR2023-01110, Pap.12 (Feb. 9, 2024), which are the same document.

Petitioner's request for consolidation should be denied for all the reasons joinder should be denied, and because consolidation is not appropriate (or feasible) for two IPRs instituted at such vastly different points in time.

Respectfully submitted,

Dated: April 1, 2024

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PAGE COUNT CERTIFICATE

The undersigned certifies that the foregoing PATENT OWNER'S
OPPOSITION TO PETITIONER'S MOTION FOR JOINDER complies with the
15-page limitation in 37 C.F.R. §42.24(a)(1)(v).

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CERTIFICATE OF SERVICE

It is certified that a copy of the following document has been served in its entirety on the patent owner as provided in 37 CFR §42.205:

The copy has been served on April 1, 2024 by causing the aforementioned document to be electronically mailed to the following attorneys of record for Petitioner listed below:

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