

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC., DR. REDDY'S LABORATORIES, INC.,
DR. REDDY'S LABORATORIES, LTD., SUN PHARMACEUTICAL
INDUSTRIES LTD., AND SUN PHARMACEUTICAL INDUSTRIES, INC.,

Petitioner,
v.

NOVO NORDISK A/S,
Patent Owner.

Case No. IPR2023-00724¹
Patent No. 10,335,462

**MYLAN'S OPPOSITION TO PATENT OWNER'S MOTION FOR
ADDITIONAL DISCOVERY**

¹ IPR2024-00009 (Dr. Reddy's Laboratories) and IPR2024-00107 (Sun Pharmaceutical Industries) have been joined with this proceeding.

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I. INTRODUCTION

PO's motion (Paper 71) seeks additional discovery to support its meritless sanctions motion, in which PO argues that Mylan violated its *Sand Revolution*-type stipulation. Even if such a dispute were properly before the Board—and not the district court as the Board has consistently found—it is moot in view of the stipulation filed by Mylan, Zydus, and Rio on August 8, 2024, in the district court. Accordingly, because PO's additional discovery requests relate to a dispute that is not properly before the Board and is otherwise moot, the Board should deny PO's motion. Regardless, even if PO's motion is not moot, the Board should deny it because (1) PO prejudicially delayed in seeking the discovery; and (2) the relevant *Garmin* factors weigh against granting additional discovery.

II. BACKGROUND

A. PO's Request for Additional Discovery

PO alleges that the additional discovery concerns Petitioners' "respective *retention*, *direction*, and *payment* of ... three shared litigation experts" Paper 71, 3. Its motion includes three requests for production ("RFPs") or, alternatively, five interrogatories. *Id.*, 4-6. PO requests a privilege log for withheld documents. *Id.*, 4.

B. Additional Discovery Must Be in the Interests of Justice and Satisfy the *Garmin* Factors

The party seeking additional discovery "must show that ... additional discovery is in the interests of justice...." 37 C.F.R. § 42.51(b)(2); *see also* 35 U.S.C. §

316(a)(5). The *Garmin* factors guide the Board’s analysis. *See Garmin Int’l, Inc. v. Cuozzo Speed Techs. LLC*, IPR2012-00001, Paper 26, 6-7 (PTAB Mar. 5, 2013) (precedential). Among these are “(1) whether the party seeking additional discovery is ‘in possession of a threshold amount of evidence or reasoning tending to show beyond speculation that something useful will be uncovered[]’” and “(5) whether the requests are overly burdensome.” *FPUSA, LLC v. M-I LLC*, IPR2016-00213, Paper 32, 4 (PTAB Aug. 30, 2016) (quoting *Garmin*). Importantly, “[u]seful’ ... does not mean merely ‘relevant’ and/or ‘admissible.’” *Garmin*, IPR2012-00001, Paper 26, 7. Rather, “‘useful’ means **favorable in substantive value** to a contention of the party moving for discovery.” *Id.* (emphasis added).

III. PO’S REQUESTED DISCOVERY SHOULD BE DENIED

A. Compliance with *Fintiv* Stipulations Is a Matter for the District Court to Decide

The Board has repeatedly found that compliance with a *Fintiv* stipulation is a matter for the district court—and not the Board—to decide. PO’s motion should thus be denied because the discovery has no substantive value relevant to an issue properly before the Board. *See Lightspeed Com. Inc. v. Cloudfchange, LLC*, IPR2022-00779, Paper 28, 2-3 (PTAB July 25, 2023) (“We decline [PO’s] invitation for us to determine how a district court should interpret stipulations before it.”); *Google LLC v. Hafeman*, IPR2022-01188, EX3001 (PTAB Mar. 20, 2023) (“[A]ny dispute regarding the scope or alleged violation of stipulations should be addressed

in the district court proceedings”); *Samsung Elecs. Co. v. Netlist, Inc.*, IPR2022-00639, Paper 26, 2 (PTAB Jan. 18, 2023) (“Any dispute regarding the scope or alleged violation of stipulations ... should be addressed in the district court proceedings”); *Apple Inc. v. Maxell, Ltd.*, IPR2020-00204, Paper 21, 9-10 (PTAB Dec. 15, 2020) (“[T]o the extent [PO] believes Petitioner has violated the letter or spirit of its stipulation in the underlying litigation, [PO] could seek relief in the district court.”).

B. PO’s Sanctions Motion Is Moot in View of the Defendants’ August 8, 2024 Stipulation

Even if Mylan’s compliance with its stipulation were properly before the Board, PO’s purported need for the discovery is moot. On August 8, 2024, Mylan, Zydus, and Rio (the two defendants with no IPR stipulation) filed a stipulation in district court confirming they will not raise the IPR grounds at trial. EX1326. The IPR grounds will now proceed only at the PTAB for all purposes. *Id.* Thus, PO’s primary alleged harm—that the IPR grounds “will be carried forward by the co-defendants” even after a final written decision (Paper 70, 13)—cannot happen. This stipulation is similar to what the Board found would obviate termination (even if a motion to terminate were granted for failure to comply with a *Sand Revolution*-type stipulation) in *Parse Biosciences, Inc. v. 10x Genomics, Inc.*, IPR2023-00955, Paper 22, 2 (PTAB July 3, 2024); *see also id.*, Paper 21, 12:9-18:16, 23:19-24:9 (PTAB July 2, 2024). The Board in that IPR called such a stipulation a “train stopping

mechanism.” *Id.*, 24:14-24. This IPR now involves a “train stopping mechanism,” mooting any need for additional discovery.

C. PO’s Prejudicial Delay and the Relevant *Garmin* Factors Weigh Against Additional Discovery

Even if not moot, PO’s motion should be denied because (1) PO prejudicially delayed; and (2) the relevant *Garmin* factors weigh against it.

1. The Board Should Not Reward PO’s Prejudicial Delay

The rules are clear: “[a] party should seek relief promptly after the need for relief is identified,” and “[d]elay in seeking relief may justify a denial of relief sought.” 37 C.F.R. § 42.25(b). PO unduly delayed in seeking additional discovery. The litigation defendants served the expert reports at issue in March and July 2024. EX2539; EX1333. The defendants earlier served invalidity contentions with the overlapping grounds in January 2024. EX1330. But PO never complained about “overlapping grounds” or indicated that it would seek sanctions and additional discovery until it sent Mylan a draft sanctions motion on June 10, 2024 (along with discovery requests far broader than those in its motion). EX2653, 16-18. That was **five months** after the contentions and nearly **three months** after the first litigation report was served. Had PO been prompt, the issue could have been resolved long ago. PO’s delay weighs against its motion. *See, e.g., Douglas Dynamics, L.L.C. v. Meyer Prods. LLC*, IPR2015-01839, Paper 29, 8-9 (PTAB Jul. 26, 2016) (PO’s four-month delay after institution in requesting additional discovery weighed against

granting the request); *Deere & Co. v. Gramm*, IPR2015-00898, Paper 17, 3-4 (PTAB Nov. 19, 2015) (noting that granting a delayed request “may be encouraging gamesmanship”).

2. The Relevant *Garmin* Factors Weigh Against Additional Discovery

PO does not address the *Garmin* factors for each request, but instead improperly lumps its arguments together. Paper 71, 6-10. Mylan submits that PO’s failure to explain with particularity why each request is in the interests of justice and satisfies the *Garmin* factors fails to meet PO’s burden.

PO’s motion should also be denied because PO does not explain why any additional discovery would have substantive value (factor 1). PO’s RFPs and Interrogatories are also improper for the reasons discussed below.

a) PO’s RFPs and Interrogatories Do Not Seek Discovery That Has Substantive Value (Factor 1)

To support discovery, PO simply alleges that “it is known that Mylan worked with the experts to develop invalidity positions on the overlapping grounds in the litigation” and “Mylan’s participation is self-evident.” Paper 71, 7. PO further alleges that “the public record ... indicates that useful evidence is likely to be uncovered by discovery, because it shows Mylan began sharing its IPR experts with the other co-defendants on invalidity positions regarding these overlapping grounds only *after* Mylan’s institution.” *Id.*

Absent from PO's motion is any explanation for why the discovery it seeks would have substantive value beyond the facts it already knows (factor 1). PO cites no authority that the activities it complains of were improper. This is not surprising because Mylan's interpretation of its stipulation (i.e., that it could include the overlapping grounds in invalidity contentions and expert reports so long as it did not assert them by motion or at trial) was reasonable—it is consistent with the purpose of a *Sand Revolution* or *Sotera* stipulation as mitigating the concerns of “duplicative efforts between the district court and the Board” and “potentially conflicting decisions,” *Sand Revolution II, LLC v. Cont'l Intermodal Grp.—Trucking LLC*, IPR2019-01393, Paper 24, 12 (PTAB June 16, 2020); *Sotera Wireless, Inc. v. Masimo Corp.*, IPR2020-01019, Paper 12, 19 (PTAB Dec. 1, 2020), and Mylan needed to preserve the grounds in case of a change in law. There is also no contrary Board precedent. As the Board stated in *Google LLC v. Hafeman*, “[t]here's never been a [B]oard decision that actually went into the details of enforcing *Sotera* stipulations.” IPR2022-01188, Paper 31, 31:6-9 (PTAB Dec. 7, 2023).

PO also fails to identify authority suggesting that litigation expert and cost sharing is impermissible. To the contrary, coordinating theories and sharing experts are “common activities.” *See, e.g., Intel Corp. v. Alacritech, Inc.*, IPR2017-01393, Paper 8, 18 (PTAB Nov. 30, 2017). Indeed, PO anticipated shared experts among

the defendants.² On this issue, it is notable that PO already attempted to argue that expert sharing is improper in opposing institution of Sun’s joinder IPR. In response, the Board rejected PO’s arguments, stating that Director “guidance does not condition or otherwise qualify the effect of a *Sotera* stipulation on our exercise of discretion to deny the Petition based on any remaining defendants in the parallel litigation that are not subject to the stipulation or any alleged ‘behind the scenes’ participation by Petitioner such as paying for experts, participating in expert reports or deposition preparation ‘in connection with any of the stipulated grounds.’” *Sun Pharm. Indus. Ltd. v. Novo Nordisk A/S*, IPR2024-00107, Paper 16, 10 (PTAB May 28, 2024).

² In seeking to have the Judicial Panel on Multidistrict Litigation transfer Mylan from West Virginia to Delaware, PO argued that it “anticipated overlapping expert witnesses for the generics, who often share experts.” EX1327 (MDL3038, Paper 21). PO further noted that “Mylan did not rule out sharing experts with other defendants, as often occurs in multi-filer Hatch-Waxman litigations. If Mylan does share experts, it is another reason transfer and consolidation will convenience the parties and witnesses and further the efficient conduct of the actions.” *Id.*, 9, n.4. Thus, sharing experts is convenient for all parties, not improper.

b) The Relevant *Garmin* Factors Weigh Against Granting PO's Request for Production of Documents

PO's RFPs should be denied for additional reasons. They seek irrelevant and overly burdensome discovery that, in some cases, impinges on privileged communications and work product facially protected by Fed. R. Civ. P. 26(b)(4)(B), (C). RFP No. 1 seeks documents regarding the date and terms of retention of the experts by each defendant and any instructions regarding scope of retention as it relates to the overlapping grounds. Further, RFP No. 2 seeks documents regarding the "timing and frequency" of communications between defendants and the experts "relating to or reflecting any direction, instruction, or consultation of such expert(s) regarding the overlapping grounds." Finally, RFP No. 3 seeks documents regarding which defendants paid the experts for work on the overlapping grounds, instructions regarding payment, engagement/payment agreements, and invoices/payment requests/payment confirmations.

As discussed, PO does not explain why cost sharing is improper (it is not) or why these documents would provide substantive value beyond what PO already knows (factor 1). Moreover, to the extent the RFPs seek documents containing instructions to, directions to, or consultation with the experts, this invades privilege, and the documents are overly burdensome to provide or log (factor 5). *See, e.g., Tennant Co. v. Oxygenator Water Techs., Inc.*, IPR2021-00625, Paper 30, 2, 10

(PTAB Oct. 18, 2021) (finding that factor 5 weighed against discovery requests seeking production of “instructions, suggestions, or advice provided to” an expert).

c) The Relevant *Garmin* Factors Weigh Against Granting PO’s Request for Interrogatory Responses

PO’s interrogatories are an alternative to the RFPs. Paper 71, 5. If any discovery is ordered (it should not be), Mylan submits that interrogatories are a more appropriate vehicle for discovery. However, like the RFPs, PO’s interrogatories seek irrelevant information, are overly burdensome, and impinge on privileged communications and work product.

Interrogatory No. 1 asks for the dates that Mylan retained the experts. This has no substantive value beyond what PO already knows (factor 1).

Interrogatory No. 2 asks for the identity of defendants that had any role in directing or reviewing work on overlapping grounds in the expert reports, and Interrogatory No. 3 asks whether Mylan ever specified that it will not interact with an expert concerning overlapping grounds. PO provides no explanation for why this information would add substantive value beyond the facts it already knows (factor 1). Moreover, any communications solely among the defendants or with their experts are privileged, and to provide responsive information through a privilege log is overly burdensome given the lack of substantive value (factor 5). *See, e.g., Tennant*, IPR2021-00625, Paper 30, 10.

Interrogatory No. 4 asks how much each defendant has paid/been invoiced for overlapping grounds, and Interrogatory No. 5 asks if Mylan ever specified that it will not/was not compensating the experts for portions of expert reports addressing overlapping grounds. Once again, PO cites no authority that expert cost sharing is improper. Further, PO provides no basis for asserting that details regarding payments/invoices would have substantive value beyond the simple fact that defendants are sharing costs (factor 1). Moreover, Interrogatory No. 5 invades privilege to the extent it calls for what Mylan “specified” to other defendants.

IV. CONCLUSION

For the foregoing reasons, there is no reason to order additional discovery and potentially disrupt the Board’s prompt resolution of the IPR within the one-year statutory deadline set by 35 U.S.C. § 316(a)(11).

Dated: August 16, 2024

Respectfully submitted,

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I certify that I caused to be served a true and correct copy of the foregoing: **MYLAN'S OPPOSITION TO PATENT OWNER'S MOTION FOR ADDITIONAL DISCOVERY** by email to the electronic service addresses for Patent Owner and Petitioners in IPR2024-0009 and IPR2024-00107:

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