

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC., DR. REDDY'S LABORATO-
RIES, INC., DR. REDDY'S LABORATORIES, LTD, SUN PHARMA-
CEUTICAL INDUSTRIES LTD., AND SUN PHARMACEUTICAL IN-
DUSTRIES, INC.

Petitioner

v.

NOVO NORDISK A/S,
Patent Owner

Case IPR2023-00724
Patent 10,335,462

**REPLY IN SUPPORT OF PATENT OWNER'S MOTION FOR
SANCTIONS PURSUANT TO 37 C.F.R. §§ 42.11 and 42.12¹**

¹ Abbreviations and cites are from Pap.70 ("Br."), and emphasis/annotations added.

Under the 3-part *PQA/OpenSky* test: **1. Mylan’s violation of its stipulation is sanctionable.** Its Opposition (Pap.80) reiterates Mylan’s still-unsupported arguments that (1) Mylan can now **limit** its promise to prohibit only pursuit “**by motion or at trial,**” permitting other duplicative litigation like expert discovery (Opp.3, 10), and (2) to “preserve” its rights, Mylan had to **break** its promise in case the law later changes (Opp.2-3, 10). Both excuses are facially baseless: (1) The Board’s *Fintiv* policies—requiring a stipulating party **cease** duplicative litigation **at institution**—clearly target **all** harassing, duplicative efforts from that party.² Br.11-12. And (2), if Mylan sought “mere **preservation**” (Opp.1)—an argument Mylan **never made until July** (Br.6; EX2655, 2)—it wouldn’t have **joined, quarterbacked,** and apparently **funded** Rio, Zydus, and the other litigants on the overlapping grounds. Mylan’s overt attempts to **rewrite** its promise raise no “novel [interpretive] questions” (Opp.1)—they just confirm its violations. And it’s unsurprising Mylan found **no supporting precedent:**³ Mylan’s involvement, “**on its face,** appears to be in **direct conflict with**

² *Sun* (IPR2024-00107, Pap.16, 9-10) decided simply that the *Fintiv* guidance required no additional affirmative statement of details beyond *Sotera*’s to avoid denial.

³ *Samsung* (Opp.11) contradicts Mylan’s position by **rejecting** patentee’s contention that a “change in the law” caveat creates an “out”: “we are not persuaded that this

the stipulation Mylan included in its Petition.” Pap.69, 5. Mylan never explains how its violations evade the §42.12(a) list of sanctionable acts. Br.9. And its repeated protests that sanctioning broken promises **to the Board** should be solely within the ambit of **district courts** (Opp.1, 9-10) are nonsensical (the Board certainly has the power to police parties and matters before it) and late (the Board ruled on July 26 that it would hear this Motion). Mylan’s cases don’t help it. Two—*Google v. Hafe-man*, IPR2022-01188, EX3001, 1, 3 (Mar. 20, 2023),⁴ and *Apple Inc. v. Maxell, Ltd.*, IPR2020-00204, Pap.21, 1-2 (Dec. 15, 2020)—request rehearing of institution, not §42.12 sanctions. The other two involved fact disputes about whether litigated combinations fell within the stipulations. *See, e.g., Samsung Elecs. Co. v. Netlist, Inc.*, IPR2022-00639, EX3003 (dispute over “reasonably could have been raised” scope); *Lightspeed Commerce Inc. v. Cloudfchange, LLC*, IPR2022-00779, EX2031, 14:2-14 (conceding “we...expect...a ruling from the Court about the scope of the stipulation”), Pap.28, 2-3 (July 25, 2023) (noting court would decide issue). Here, it is uncontested that Mylan duplicated three **identical** grounds. *See also* Br.9 n.8.

‘out,’ in reality, would...**allow[] Petitioner to continue its prior-art based invalidity arguments in district court.**” IPR2021-00980, Pap. 11, 17-18.

⁴ Mylan’s Paper 31 snippet is from a hearing question—and before Board decisions this week conditionally terminating IPRs for stipulation violations. *See infra* at 5.

2. Mylan’s late efforts to tweak the record (while obscuring the timeline) don’t remove its harm to the Office, System, and PO. Mylan buries its brief mention of “harm to the **PTO**” in one closing paragraph (Opp.14), and simply ignores the bulk of PO’s detailed arguments. Br.11-12, 14. Nor did Mylan eliminate harm to **PO** by (1) apparently promising in litigation, the ***night of PO’s Opening Brief***, to discontinue at least some discovery efforts (EX1329), and (2) filing a stipulation ***even later*** (August 8) cooked up with Rio and Zydus—after the corresponding March and responsive July expert reports were already fully baked. EX1326. Mylan says nothing about the costs, burdens, and distractions it imposed on PO in responding to Mylan’s misconduct and seeking compliance—only a fraction will be compensated by §42.12(b)(6) IPR attorney fees. Mylan also ignores PO has already been forced to analyze, respond to, and prepare to depose Mylan-sponsored experts on topics Mylan promised to stop pursuing. And, as to Rio’s and Zydus’s supposed promise, its ***footnote 9*** still ***permits them to keep litigating those 3 identical grounds “should the PTAB terminate or otherwise conclude the pending IPRs without reaching a final written decision on the merits...”*** (EX1326, 5 n.9)—requiring PO to keep defending them. While PO views the relief it seeks as “on the merits,” Mylan tells the Board ***all of it “would...effectively result in termination of those grounds”*** (Opp.15)—confirming this loophole is meant to render the stipulation ***meaningless***.

The Opposition’s other meritless arguments include that: Mylan should be

free to pursue overlapping grounds because it's already permitted to do "**most** of" the things its experts have done (5-6); because a *Sand Revolution* stipulation is narrower than a *Sotera* stipulation, it can be ignored (5); because "**DRL, Sun, Rio and Zyklus were** all free to assert the IPR grounds," including public reports, **Mylan** (which **isn't**) should still be allowed to join and lead them in doing so (4); because Mylan chose to share experts (which PO never argued was itself a violation) Mylan can **use** them to break its promise by directing and paying them to do **things Mylan can't** (5); Mylan's cheating is excused because it spared PO the burden of **more** experts (4); and, because Mylan hopes to explain away its roadmapping changes in the *March* litigation reports (it can't⁵), breaking its promise not to participate doesn't

⁵ All 3 experts made changes responding to PO's IPR arguments. While Mylan casts the examples as "trivial" (Opp.12), it **never explains why (other than roadmapping from PO's IPR criticisms) the changes were made**. Further, the undisputedly new paragraph at EX2551, ¶342 and different placement of REOS arguments (*e.g.*, "**As a result**") within EX1005, ¶¶ 252-53, 255 and EX2551, ¶¶340-42, **changes their meaning**; Mylan concedes EX1005, ¶350 includes a new "sentence," which makes an **additional argument with data**; and Mylan concedes EX1005, ¶349 makes an added assertion about "still provid[ing] some degree of efficacy"—all responsive to PO's IPR criticisms. And Mylan never even mentions the July **responsive** reports.

matter (12-14). Finally, Mylan argues PO's IPR counsel—who had to discover the violation in litigation, then draft a §42.11(d)(2) proposed motion—failed to save Mylan from itself soon enough. This, too, is meritless: as Mylan's continuing July violations confirm, Mylan paid no heed to PO's draft or negotiations. The Board just rejected the same argument, conditionally terminating IPRs for stipulation violations: "Petitioner's argument turns the situation upside down" and "[i]n any event, ...no delay by Patent Owner could excuse Petitioner from honoring its representation to the Board." *Parse Biosciences, Inc. v. 10x Genomics, Inc.*, IPR2023-00955, Pap.28, 4 (Aug. 21, 2024); IPR2023-00958, Pap.30, 4 (Aug. 21, 2024).⁶

And while the Board will determine what sanctions are appropriate, **3. PO's requested sanctions are proportional to the harm.** Br.13-15. Contrary to Mylan's complaints (Opp.15), *they yield (in Mylan's reading) what Mylan's unprecedented breach was working towards*: as Mylan argues it (Opp.15), EX1326 n.9 means Rio and Zydus, prepared and educated by Mylan, can litigate the IPR grounds in court with Mylan's experts, while Mylan pursues its non-overlapping IPR grounds here.

Respectfully submitted: /J. Steven Baughman/

August 23, 2024

⁶ While informative in this respect, the *Parse* IPRs didn't involve a sanctions request: the Board *sua sponte* suggested termination when approached about confirming the stipulations in litigation (which had no non-estopped co-defendants), and petitioner had sought court relief from its stipulations. See *id.* EX3001; cf. Opp.3-4.

CERTIFICATE OF PAGE COUNT

The undersigned certifies that the foregoing REPLY IN SUPPORT OF PATENT OWNER'S MOTION FOR SANCTIONS PURSUANT TO 37 C.F.R.

§ 42.12 complies with the Board's July 26, 2024 Order (Pap.69) limiting this reply to 5 pages.

Dated: August 23, 2024

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of REPLY IN SUPPORT OF PATENT OWNER’S MOTION FOR SANCTIONS PURSUANT TO 37 C.F.R. § 42.12 has been served in its entirety on August 23, 2024, by causing the aforementioned documents to be electronically mailed to the following attorneys of record for the Petitioner listed below.

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