

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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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

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Case IPR2023-00724  
Patent 10,335,462

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**REPLY TO JOINED PETITIONERS DRL AND SUN IN SUPPORT OF  
PATENT OWNER'S MOTION FOR SANCTIONS  
PURSUANT TO 37 C.F.R. §§ 42.11 and 42.12<sup>1</sup>**

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

In their separate Opposition (Pap.82, “Opp.”), “silent understudy” joiners DRL and Sun both try to portray themselves as several things they are not, *e.g.*:

- independent petitioners who “have every right...to have the instituted grounds...adjudicated by the Board” (Opp.1);
- unwitting bystanders who “have not engaged in any misconduct” (Opp.1); and even
- “exemplary” actors (Opp.3).

But in fact, DRL and Sun both did not timely file their own IPR petitions—instead, they signed on to receive the result achieved by Mylan (so long as Mylan didn’t settle), and both were **well aware of, joined, and benefitted from Mylan’s violation** of Mylan’s stipulation in the district court.

Both DRL and Sun **would have been time-barred** had they tried to bring their respective Petitions without Mylan. *See, e.g., Novo Nordisk Inc. v. Sun Pharm. Indus. Ltd.*, No. 1:22-cv-00296, D.I. 6, 8 (D. Del. Mar. 4 & 16, 2022); *Novo Nordisk Inc. v. Dr. Reddy’s Lab’ys Ltd.*, No. 1:22-cv-00298, D.I. 6-7 (D. Del. Mar. 10, 2022); 35 U.S.C. §315(b). Thus, **their only path** “to have the instituted grounds...adjudicated by the Board” was **through joining Mylan’s instituted petition**, which relied on the stipulation Mylan has violated to avoid discretionary denial and achieve institution. Recognizing this, each of them explicitly agreed to join this proceeding

only as passengers, so long as Mylan remains a party. DRL confirmed it “will assume a ‘silent understudy’ role and **will not take an active role in the *inter partes* review proceeding unless the Mylan Petitioner ceases to participate in the instituted IPR**” (IPR2024-00009, Pap. 3, 2, 6-7), and Sun similarly committed to silent understudy status, “only assuming an active role in the event of termination of Mylan as a party.” IPR2024-00107, Pap. 2, 7-8.

Moreover, both of these silent understudies—DRL and Sun—***knew of, participated in, and benefitted from*** Mylan’s violation of Mylan’s stipulation here.

Both ***knew of Mylan’s Sand Revolution stipulation***: each copied it into their respective Petition. IPR2024-00009, Pap.2, 65 (DRL); IPR2024-00107, Pap.3, 64-65 (Sun). Both of them subsequently ***agreed with Mylan to share Mylan’s IPR experts and their opinions on the instituted IPR grounds for purposes of the district court litigation***, and did so ***only after Mylan’s IPR was instituted***. Br.2, 4-5. And again, *despite* knowing of Mylan’s stipulation, both of them were a full part of the March 19 expert reports at issue here—each of them ***joined Mylan in signing onto the substance of those three reports***, and each of them let Mylan’s counsel serve those reports on Sun’s and DRL’s behalf. Br.3-5. Further, both have continued to benefit from the fact that defendants Rio and Zydus have been fully educated and

prepared by Mylan to continue litigating the grounds Mylan stipulated to stop pursuing in court—and that DRL and Sun are prevented from pursuing in court by their own *Sotera* stipulations. Br.10-11, 13.

Nor can there be any doubt here that DRL and Sun were **well aware that those reports were a violation of Mylan’s stipulation**: PO filed a paper in each of their IPRs *before they were instituted and joined as “silent understudy” petitioners*, saying precisely that. For DRL, PO stated the following within about two weeks of Mylan’s service of the March 19 expert reports in litigation:

Mylan and the remaining litigation defendants. The full scope of that undisclosed relationship and resulting prejudice is only now becoming clearer: Petitioner used

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three IPR experts different from Mylan’s, suggesting it had no choice (e.g., Pap.3, 2, 5 (“in the event that Mylan does not agree to allow DRL to retain [them]”)), but *Petitioner actually shares those same experts (and their declarations and presumably their cost) in litigation with both Mylan (in violation of the stipulation Mylan promised in its Petition, but never provided in litigation) and other parties who have not agreed to any estoppel. See EX2024, 10; EX2025, 9; EX2026, 6. Cf.*

IPR2024-00009, Pap. 18 (Apr. 3, 2024), 1-2. And for Sun:

email). Sun’s groundwork is already laid: initially representing it retained different experts (Pap.2, 4, 6), Sun now shares those same experts in litigation to argue IPR

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grounds with Mylan (*violating Mylan’s own Sand Revolution stipulation* (IPR2023-00724, Pap.1, 66)), Dr. Reddy’s, and parties who have not agreed to *any* estoppel.

IPR2024-00107, Pap. 14 (May 20, 2024), 1-2.

As “silent understudies” who voluntarily chose and agreed to tie their substantive outcomes in this IPR to Mylan’s, DRL and Sun will now be bound by Mylan’s substantive result as it may be impacted by PO’s motion for sanctions. And while this should not be troubling—DRL and Sun each knew of, participated in, and have benefited from Mylan’s sanctionable conduct here, and both proceeded to join *despite explicit notice of Mylan’s violation*—this is ***not a §42.12 sanction against Sun or DRL*** (*cf.* Opp.2-3), but rather ***the agreed-to consequence of their requested joinder***. Thus, PO need not show harm caused by “threshold...misconduct” ***of Sun or DRL*** (Opp.3-4)—and, instead, PO addresses arguments about harm in response to Mylan’s separate opposition (Pap.80).<sup>2</sup>

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<sup>2</sup> And even if, *arguendo*, it were pertinent here, PO has certainly “established harm caused by ***any petitioner***” (Opp. 3 (emphasis original)): Mylan’s violation of Mylan’s stipulation (which Sun and DRL knew of, joined in, and benefitted from) has harmed the Office, the System, and PO. *E.g.*, Br.11-13. And despite Mylan’s attempt to tweak the optics during briefing of this Motion, PO ***continues*** to face harm imposed by Mylan’s violation, which improperly prepared and educated co-

Having made the voluntary choices they did to have their invalidity arguments decided by the Board (rather than the district court), having entered this proceeding only through Mylan's IPR, and having joined in and benefitted from the conduct for which *Mylan* should now be sanctioned, Sun and DRL are in no position to try to run from Mylan as "unrelated" (or, for that matter, to suggest they "invested considerable resources" in merely copying Mylan's petition materials) in a way that would entitle either of them to decouple from Mylan while Mylan remains a party to this IPR. *Cf.* Opp.5. And of course PO has not asked, and does not request, the termination of Mylan as a party. *Cf.* Opp.5. To the contrary, PO has explicitly stated that Mylan should remain "free to pursue in the IPR any non-overlapping grounds" (Br.14)—and Sun, DRL, and Mylan will share the common outcome that Sun and DRL explicitly agreed to achieve institution and joinder.

Respectfully submitted: /J. Steven Baughman/

August 23, 2024

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defendants Rio and Zydus to continue litigating Mylan's arguments on the overlapping grounds in Mylan's absence. See EX1326, 5 n.9 (Rio and Zydus reserving "their right to pursue...the IPR Grounds, should the PTAB terminate...").

**CERTIFICATE OF PAGE COUNT**

The undersigned certifies that the foregoing REPLY TO JOINED PETITIONERS DRL AND SUN 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 TO JOINED PETITIONERS DRL AND SUN 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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