

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.,
Petitioners,

v.

NOVO NORDISK A/S,
Patent Owner.

U.S. Patent No. 10,335,462 to Jensen
Issue Date: July 2, 2019
Title: Use of Long-Acting GLP-1 Peptides

Inter Partes Review IPR2023-00724

**PETITIONER DRL'S AND SUN'S OPPOSITION TO PATENT OWNER'S
MOTION FOR SANCTIONS PURSUANT TO 37 C.F.R. §§ 42.11 AND 42.12**

DRL and Sun timely filed petitions that were instituted on the merits over Novo's *Fintiv* arguments. As DRL and Sun have not engaged in any misconduct, they therefore have every right—as does the strong public interest—to have the instituted grounds (“IGs”) adjudicated by the Board. Novo's requested sanctions, which include adverse judgment, preclusion of instituted grounds and the exclusion of evidence, would significantly impact DRL and Sun despite the absence of any credible argument that either have engaged in sanctionable conduct. The prejudice is particularly severe here because the *Sotera* stipulations submitted by DRL and Sun would effectively leave them without the ability to challenge the validity of the '462 Patent on the IGs (or any other §§102 or 103 grounds) in any forum. Accordingly, Novo's Motion seeking extraordinary and unprecedented sanctions must be denied because it has failed to prove any misconduct (because none exists) by DRL or Sun.

I. Factual Background

In October 2022, the IGs were first asserted in the parallel district court proceeding by Mylan, DRL, Sun and non-petitioners Zydus and Rio (“All Defendants”). IPR2024-00107, EX2001. DRL and Sun thereafter timely filed their petitions, which included the IGs and expert declarations that mirrored those in Mylan's petition. IPR2024-00009, Pap. Nos. 2, 3; IPR2024-00107; Pap. Nos. 2, 3.

In January 2024, All Defendants served final invalidity contentions (including the IGs), and in March 2024, served corresponding expert reports. *E.g.*, EX2551.

DRL and Sun also filed *Sotera* stipulations in the district court which were effective upon institution. EX2541, EX2542. In opposing DRL and Sun’s petitions, Novo extensively argued the *Fintiv* factors warranted discretionary denial, but the Board found that the stipulations were dispositive even though other district court defendants (Rio and Zydus) were still free to pursue those IGs.¹ *E.g.*, *id.* at 10 (refusing “to condition or otherwise qualify the effect of” those stipulations “based on any remaining defendants in the parallel litigation that are not subject to the stipulation”). The Board further granted DRL’s and Sun’s motions for joinder, based upon their respective agreement to assume a “silent understudy” role “unless Mylan ceases to participate in the instituted IPR.” *E.g.*, *id.* at 13.

II. Argument

A. DRL and Sun Did Not Engage In Misconduct

DRL and Sun have duly instituted petitions and have complied with their obligations to this Board and the district court at all times. For Novo to obtain sanctions adversely impacting DRL or Sun, Novo would have to demonstrate that DRL or Sun—not Mylan—engaged in sanctionable misconduct. 37 C.F.R. §

¹ Mylan, Rio and Zydus have since stipulated that they will not pursue the IGs. EX1326.

42.12(a); *accord Patent Quality Assurance, LLC v. VLSI Tech. LLC*, IPR2021-01229, Pap.102, 36-37 (Dec. 22, 2022) (prec.) (“PQA”); *OpenSky Indus., LLC v. VLSI Tech. LLC*, IPR2021-01064, Pap.102, 26 (Oct. 4, 2022) (prec.) (“OpenSky”). But here the only “conduct” mentioned by Novo—appropriately relegated to a footnote—is the March 2024 submission of expert reports in the district court litigation. Paper 70, n. 5. But DRL and Sun were free to engage in such “conduct” because their IPRs had not yet instituted. And critically, after their IPRs were instituted, DRL and Sun’s actions are identified by Novo as exemplary, as Novo concedes DRL and Sun abided by their stipulations. Paper 70 at 6. Thus, DRL and Sun cannot be sanctioned because they have simply not engaged in any misconduct.

B. DRL and Sun Caused No Harm

Novo would also have to show that DRL or Sun—not Mylan—“caused” any harm. *PQA* at 36–37; *OpenSky* at 26; *accord Goodyear Tire & Rubber Co. v. Haeger*, 137 S. Ct. 1178, 1186, n.5 (noting “Rule-based and statutory sanction regimes similarly require courts to find such a causal connection before [imposing sanctions].”) Because Novo has not established as a threshold any misconduct by either DRL or Sun, Novo cannot meet the Board’s “causation” requirement. *Id.*

In any event, while not necessary to deny Novo’s sanctions, it is notable that Novo has not established harm caused by *any petitioner*. The IGs are not “Mylan’s invalidity theories” as Novo contends, but were raised by all Defendants in the

district court in October 2022, before the IPR proceedings began. IPR2024-00107, EX2001. And Novo would continue to face the IGs from Rio and Zydus even after the institution of the IPR petitions. *E.g.*, IPR2024-00107, Pap. No. 16 at 10. As to the expert opinions supporting the IGs, Novo’s suggestion that it was “harm’d” by facing a single set of three experts when the alternative was facing multiple sets of experts (DRL and Sun submitted independent expert analysis from that of Mylan’s, *id.* at 11) lacks credibility. And even that purported harm no longer exists because the IGs are not being pursued in the district court. EX1326. With no harm, sanctions are unsupportable.

C. The Draconian Sanctions Sought Are Prejudicial to DRL and Sun

The sanctions Novo seeks against petitioners that have not engaged in any misconduct—adverse judgment, preclusion of instituted grounds, and exclusion of certain of their evidence—are unprecedented. Paper 70 at 13-15. Adverse judgment is harsh in any circumstances, but here DRL and Sun offered *Sotera* stipulations that became effective while Novo knew of Mylan’s alleged conduct but had not given notice to any party of the sanctions it was seeking. Dismissal of this IPR, thus, could preclude DRL and Sun from advancing effectively *any* §§102 or 103 invalidity grounds in *any* forum. Novo cannot demonstrate such sanctions are “proportionate.” Novo has also not identified any statute or Board precedent that suggests properly joined petitioners—like DRL and Sun here—must bear the consequences of any

sanctions imposed on a lead petitioner. In fact, no such authority exists. *Accord Google v. Hafeman*, IPR2022-01188, Paper 31 at 29-31 (noting “there’s never been a board decision that terminated a case because of a *Sotera* stipulation”).

DRL’s and Sun’s consignment to a “silent understudy” role does not bind them to the conduct of Mylan, as Novo suggests. *E.g.*, Paper 70 at n. 5. Indeed, Novo cites no precedent for this novel theory, and its interpretation would have the absurd result of stripping DRL and Sun of the rights afforded them by the Board based on the conduct of an unrelated party. DRL and Sun invested considerable resources in preparing and filing their petitions (*e.g.*, retaining experts, paying PTAB fees, briefing *Fintiv*, etc.)—all of which was done within the confines of the Board’s rules and regulations governing joinder petitions, as confirmed by the Federal Circuit and Supreme Court. *See, e.g.*, IPR2024-00009, Paper 19 at 3, n. 1 (rejecting Novo’s interpretation of § 315(b)). Novo cannot leverage its dispute with Mylan to impose sanctions that would violate the due process rights of DRL and Sun. As Novo expressly stipulated, DRL or Sun would cease to be an “understudy” if “Mylan is terminated.” *See, e.g.*, IPR2024-00009, Paper No. 12 at 2; IPR2024-00107, Paper No. 8 at 2. (agreeing to “understudy” role “[u]nless Mylan is terminated”). The parties did not qualify the circumstances that would permit DRL or Sun to act as lead petitioner. Accordingly, the Board should deny any relief that would be prejudicial to DRL and Sun.

Respectfully submitted,

Dated: August 16, 2024

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I hereby certify that on this 16th day of August 2024, I caused to be served a true and correct copy of the foregoing by electronic delivery to Novo's counsel of record:

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