

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.

IPR2023-00724
U.S. Patent No. 10,335,462

**PETITIONER DRL AND SUN'S RESPONSE TO PATENT OWNER'S
MOTION FOR ADDITIONAL DISCOVERY 37 C.F.R. §42.51(b)(2)**

LIST OF EXHIBITS

EXHIBIT No.	DESCRIPTION
1001	U.S. Patent No. 10,335,462
1002	Prosecution history excerpts for U.S. Patent No. 10,335,462
1003	Declaration of John Bantle, MD
1004	CV of John Bantle, MD
1005	Declaration of William J. Jusko, Ph.D.
1006	CV of William J. Jusko, Ph.D.
1007	Declaration of Paul Dalby, Ph.D.
1008	CV of Paul Dalby, Ph.D.
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1012	Lovshin, <i>Incretin-Based Therapies for Type 2 Diabetes Mellitus</i> , 5 NATURE REV. ENDOCRINOLOGY 262 (2009)
1013	Clinical Trial No. NCT00696657
1014	Clinical Trial No. NCT00851773
1015	WO 2006/097537
1016	U.S. Patent Application Pub. No. US2007/0010424
1017	U.S. Patent No. 5,512,549
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1088	<i>Markman</i> Hearing Transcript, <i>In Re: Ozempic (Semaglutide) Patent Litigation</i> , No. 22-MD-3038 (D. Del. July 13, 2023)
1089	Claim Construction Order, <i>In Re: Ozempic (Semaglutide) Patent Litigation</i> , No. 22-MD-3038 (D. Del. July 25, 2023), ECF No. 148
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1093	Declaration of Bryan D. Beel in Support of Motion for <i>Pro Hac Vice</i> Admission of Bryan D. Beel
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The additional discovery Patent Owner Novo Nordisk A/S (“Novo”) seeks from Petitioners Dr. Reddy’s Laboratories, Inc. (“DRL”) and Sun Pharmaceutical Industries Ltd. (“Sun”) should be denied because Novo has not met its significant burden to demonstrate the necessity, or even usefulness, of this discovery, particularly as to DRL and Sun. *See Garmin International, Inc. v. Cuozzo Speed Technologies LLC*, IPR2012-00001, Paper 26 (PTAB Mar. 5, 2013) (precedential). Indeed, the Board granted Novo authorization to file its motion for discovery “on condition that the motion explain *how such discovery would be useful* in light of the extant schedule” Paper 69, 5–6 (emphasis added). Novo has not even attempted to do so, nor could it.¹ Instead, Novo’s requests are nothing more than a fishing expedition that seek discovery duplicative of that sought from Mylan and from parties accused of no wrongdoing. *Mylan Pharm. v. St. Regis Mohawk Tribe*, IPR2016-01127, Paper 124 at 4 (denying discovery that “serves no purpose in these proceedings and amounts to a fishing expedition that is a waste of our time and resources.”). Moreover, the discovery sought by Novo is irrelevant because Mylan confirmed that it was preserving its rights to the extent there was a change in law. Accordingly, the Board should deny Novo’s burdensome discovery requests as to DRL and Sun in their entirety.

¹ The section of Novo’s brief that purports to address the required “useful[ness]” requirement only addresses a proposed discovery schedule. Paper 69, at 10.

I. ARGUMENT

Novo “seeks additional discovery from Petitioners regarding their respective *retention, direction, and payment* of these . . . experts” Paper 71 at 3 (emphasis added). “The test for a party seeking additional discovery in an *inter partes* review is a strict one.” *Symantec Corp. v. Finjan, Inc.*, Case IPR2015-01545, slip op. at 4 (PTAB Dec. 11, 2015) (Paper 9). Such discovery of **DRL and SUN** about their retention, direction, and payment of the shared experts is (1) not relevant to Novo’s assertions regarding **Mylan’s** wrongdoing, and (2) duplicative of discovery Mylan would be ordered to produce. Accordingly, and as demonstrated below, the balance of the *Garmin* factors weighs heavily against any discovery from DRL and Sun.

A. Factor 1: More Than a Possibility and Mere Allegation

“The mere possibility of finding something useful, and mere allegation that something useful will be found, are insufficient to demonstrate that the requested discovery is necessary in the interest of justice.” PTAB Consolidated Trial Practice Guide November 2019 (“TPG”) at 25. The party requesting discovery should have evidence to “show beyond speculation that in fact something useful will be uncovered.” *Garmin*, slip op. at 6. Additionally, “‘useful’ . . . does not mean merely ‘relevant’ and/or ‘admissible,’” but rather “means favorable in substantive value to a contention of the party moving for discovery.” *Garmin*, slip op. at 7.

Novo has made no showing any useful discovery resides uniquely with DRL or Sun. *First*, Novo repeatedly identifies DRL and Sun’s conduct as exemplary, *see* Paper 70, at 6, 10, so it is hard to imagine how anything useful can be obtained from DRL and Sun—indeed, there is not even a “mere allegation” that DRL and Sun have engaged in conduct requiring discovery. *Second*, any documents relevant to *Mylan’s* actions regarding the shared experts would be in *Mylan’s* possession, as there is no dispute that these are *Mylan’s* experts, *e.g.*, Paper 71, at 4 (“Mylan’s IPR experts”), and Novo never even asserts that anything relevant to its motion for sanctions would be uniquely found in the possession of DRL and Sun. And finally, the *only dispute* here is whether Mylan’s preservation of the overlapping grounds in the district court and agreement not to pursue them “by motion or at trial” is within the scope of its stipulation. But Mylan already confirmed that it was preserving those overlapping grounds in the event there is a change in law, so there is nothing left to discover. Thus, this factor weighs heavily against any discovery of DRL and Sun.

B. Factor 2: Litigation Positions and Underlying Basis

Asking for a party’s litigation positions and the underlying basis for those positions is not necessary in the interest of justice. TPG at 26. Novo’s pursuit of discovery from DRL and Sun, including communications between the parties (including other co-defendants in the district court litigation that are not even subject to this IPR proceeding) as well as three experts, *see* Paper 71, at 4–5 (seeking

communications in Request for Production No. 2), carries a significant risk of revealing the litigation positions of all of the defendants in the parallel district court proceeding. For example, the experts subject to the requests offered opinions on issues that are not subject to any stipulation offered by Mylan, DRL or Sun. Yet, Novo's requests are not limited to avoid discovery of such topics, which would directly violate the prohibition against discovery litigation positions. Thus, this factor weighs heavily against any discovery of DRL and Sun.

C. Factor 3: Ability To Generate Equivalent Info by Other Means

Production by another of “[i]nformation a party can reasonably figure out or assemble without a discovery request would not be in the interest of justice” *Garmin*, IPR2012-00001, slip op. at 6. Patent Owner concedes any discovery sought is “at [Petitioner Mylan’s] fingertips.” Paper 71, at 9; *see also id.* at 9 (“PO seeks factual information regarding Petitioner Mylan’s role”). Thus, any relevant discovery that may be in DRL and Sun’s possession is either already in Novo’s possession or is otherwise discoverable from Mylan. Duplicative information undermines *Garmin* factor three. *See CQV Co. Ltd. v. Merck Patent GmbH*, PGR2021-00054, Paper 36 at 10. Thus, this factor weighs heavily against any discovery of DRL and Sun.

D. Factors 4 and 5: Whether Easily Understandable and Burdensome

The requests must be easily understandable and not be overly burdensome to answer given the expedited nature of IPRs, TPG at 27, but these requests are neither. *First*, they are not easily understandable because they include vague phrases, *e.g.*, “sufficient to show the timing and frequency” and “relating to or reflecting any direction, instruction, or consultation,” that fail to place any meaningful restrictions on the scope of discovery sought. *Second*, they are overly burdensome because Novo requests require parsing through months of invoices for each of three experts and numerous joint defense communications, which is very time-consuming. *Third*, as Novo concedes there likely exist significant privilege issues that would require the added burden of generating a privilege list and/or completing line-by-line redactions. *Finally*, since there no allegations of misconduct against DRL and Sun, foisting a time-consuming and expensive exercise (including responding to Novo’s motion) is extremely burdensome and prejudicial. Thus, this factor weighs heavily against any discovery of DRL and Sun.

II. CONCLUSION

For the foregoing reasons, the Board should deny all of Novo’s requests for discovery from 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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