

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.

Case IPR2023-00724
Patent 10,335,462

**REPLY IN SUPPORT OF PATENT OWNER'S MOTION FOR
ADDITIONAL DISCOVERY 37 C.F.R. §42.51(b)(2)¹**

¹ Abbreviations and cites are from Pap.71 ("Br."), and emphasis/annotations added.

TABLE OF CONTENTS

I.	PO Did Not Delay in Seeking the Motion for Additional Discovery	1
II.	The <i>Garmin</i> Factors Weigh in Favor of Additional Discovery	2

I. PO Did Not Delay in Seeking the Motion for Additional Discovery²

The substantive value of PO’s discovery concerns sanctions, and—having tried but failed to secure it through lengthy negotiations—PO sought Board authorization for it at the same time PO sought it for sanctions briefing. Without permission to brief sanctions, the related additional discovery would not have been “useful.” *Garmin*, Pap.26, 7. Petitioner Mylan’s arguments that PO “unduly delayed” are tied to its arguments about sanctions timing (Opp.4), which PO addresses in its sanctions briefing. Pap.84; Pap.70, 2-6. In short, it was not PO’s obligation to police Petitioner’s compliance, and PO’s IPR counsel acted promptly after becoming aware Petitioner Mylan was improperly pursuing the overlapping grounds—drafting and serving the §42.11(d)(2) proposed motion, meeting and conferring, and then seeking a call with the Board for permission to file. Pap.84; *see Parse Biosciences, Inc. v. 10x Genomics, Inc.*, IPR2023-00955, Paper 28, 4 (Aug. 21, 2024). Mylan’s claim this “could have been resolved long ago” is belied by Mylan’s own continued violation of its stipulation in July, and Mylan’s late-concocted (July 2) argument that it had to serve expert reports to preserve those grounds for trial. Pap.80, 2; EX2655, 2.

Mylan’s “delay” cases are inapt. The request in *Douglas Dynamics, L.L.C. v.*

² Petitioner’s arguments about district courts deciding *Fintiv* compliance and the sanctions motion being “moot” are addressed in PO’s sanctions motion briefing.

Meyer Products LLC was denied primarily because petitioner failed to provide threshold **nexus** evidence, negating any “significan[ce]” of the requested commercial success evidence. IPR2015-01839, Paper 29, 5-7 (July 26, 2016). Delay was a secondary issue, and the Board found petitioner’s *awareness of the information for over a year* and *relying on that data* in its infringement contentions (after institution and before seeking additional discovery) made the delay significant. *Id.* at 8-9. And granting the discovery sought in *Deere & Co. v. Gramm* would have required delaying the schedule to permit its use in the POR. IPR2015-00898, Paper 17, 2-3 (Nov. 19, 2015). There are no similar gamesmanship concerns arising here: the requested discovery need not impact case schedule, as laid out in PO’s Motion (Br.10).

II. The *Garmin* Factors Weigh in Favor of Additional Discovery

Mylan doesn’t dispute that *Garmin* factors 2-4 favor **granting** additional discovery. Instead, Mylan argues PO “improperly lumps its arguments together” and contests whether *Garmin* factors 1 and 5 also favor additional discovery. Opp.5. (Mylan provides no authority requiring a separate *Garmin* factor analysis for **each request**, which PO broke out separately to the extent necessary. *See* Br.xxii, 6-10.)

In authorizing the briefing for this Motion, the Board recognized there was **no apparent dispute** that “Petitioner has some involvement in the invalidity case in the district court litigation that includes the grounds on which we instituted *inter partes* review.” Pap.69, 5. And Mylan still doesn’t dispute its participation here. Instead,

Mylan appears to refer to its involvement as “facts [PO] already knows.” Opp.6.

Notably, Mylan doesn’t dispute that it has in its possession evidence related to the **retention**, **direction**, and **payment** of the shared litigation experts on the 3 overlapping grounds that would be uncovered by this additional discovery. Instead of disputing its involvement or the existence of evidence, Petitioner argues the Motion does not contain “any explanation for why the discovery it seeks would have substantive value beyond the facts it already knows.” Opp.6. Not so: as the Board noted in authorizing this Motion, Mylan’s involvement, “on its face, appears to be in direct conflict with the stipulation Mylan included in its Petition” and thus PO’s requested briefing “may be helpful to the panel.” Br.3; Pap.69, 5. The substantive value of the additional discovery requested here is to establish “the extent of Mylan’s violation and the harm Mylan has imposed” (Br.3-6)—*i.e.*, its participation in pursuing the instituted grounds “in [apparent] direct conflict with the stipulation Mylan included in its Petition.” *Id.*; Pap.69, 5. The extent of Mylan’s participation and the harm it caused is relevant to Petitioner’s arguments that the sanctions sought are disproportionate and that PO suffered no harm. Pap.80, 12-15.

RFPs. Mylan asserts PO has not shown how the RFP “documents would provide substantive value beyond what PO already knows (factor 1).” Opp.8. But each RFP seeks documents that would be useful for establishing the extent of Petitioner Mylan’s involvement in pursuing the overlapping grounds and the harm imposed on

PO, and are thus in the interests of justice. For example, documents responsive to RFP No. 1 (**retention**) may establish that Mylan entirely or primarily drove the work on the overlapping in the expert reports (if, *e.g.*, the other co-defendants did not retain the experts well in advance of the filing of the reports). Likewise, documents responsive to RFP No. 2 (**direction**) may establish that Mylan was the primary or sole party controlling the experts in litigation in connection with the overlapping grounds. And RFP No. 3 (**payment**) documents may establish Mylan was the only or primary funder of the litigation expert reports for the overlapping grounds (*e.g.*, others didn't reimburse Mylan). *See* EX2552, 65:1-7; 74:19-75:7. Petitioner's arguments about expert and cost sharing miss the point—while sharing is not prohibited *per se*, sharing can't be used to breach Mylan's *Sand Revolution* stipulation. By providing that stipulation, Mylan explicitly agreed **not** to pursue the overlapping grounds—including by substantive or financial contributions. Pap.69, 5; Pap.1, 66.

And with respect to *Garmin* factor 5, Mylan further argues the documents are “overly burdensome to provide or log (factor 5).” Opp.8. But RFP Nos. 1, 2, and 3 each minimize the burden on Mylan by seeking only “[d]ocuments **sufficient to show**,” and narrowing the requests to information related to the *specific overlapping grounds* asserted for one patent (the '462).³ Br.4-5. And each RFP is limited in time

³ Although Mylan never asked, PO would not object to Mylan redacting information

(starting when Mylan retained the shared experts) and does *not seek privileged or work product protected information*. PO merely seeks information about the **retention, payment, and frequency** of communications with experts—not the **substance** of such communications. Work product doesn’t protect factual information, such as the bases for an opinion, or compensation. *E.g., Apple Inc. v. Singapore Asahi Chem. & Solder Indus. PTE Ltd.*, IPR2019-00377, Paper 22, 10 (Oct. 21, 2019); *see also* Fed. R. Civ. P. 26(b)(4)(C); EX2552, 65:1-67:20; EX2553, 52:9-54:6. Mylan cites **no case** suggesting the frequency or times of counsel-expert interactions are privileged. *Cf.*, EX1140, 8:22-9:17 (Mylan asking similar questions). And Mylan may provide a privilege log as necessary. Br.4; *Cavium, LLC v. Alacritech, Inc.*, IPR2018-00401, Paper 24, 12-13 (Nov. 20, 2018).

Interrogatories. Interrogatory No. 1 (**retention**) satisfies *Garmin* factor 1 for the same reasons as RFP No. 1; Interrogatory Nos. 2 and 3 (**direction**) for the same reasons as RFP No. 2; and Interrogatory Nos. 4 and 5 (**payment**) for the same reasons as RFP No. 3. The Interrogatories (an alternative to the RFPs) impose minimal burden because they are directed to just three experts’ work on three invalidity arguments regarding the ’462 patent, and only concerning their retention, direction, and compensation over a limited time.

Respectfully submitted: /Megan Raymond/

August 23, 2024

unresponsive to the requested information on the *overlapping grounds*.

CERTIFICATE OF PAGE COUNT

The undersigned certifies that the foregoing REPLY IN SUPPORT OF PATENT OWNER'S MOTION FOR ADDITIONAL DISCOVERY 37 C.F.R. §42.51(b)(2) FROM PETITIONER MYLAN PHARMACEUTICALS INC. complies with the Board's July 26, 2024 (Pap.69) limiting this motion to 5 pages.

Dated: August 23, 2024

Respectfully Submitted,

By: /Megan Raymond/
Megan Raymond (Reg. No. 72,997)
Groombridge, Wu, Baughman & Stone
LLP
801 17th Street, NW, Suite 1050
Washington, DC, 20006
P: (202)-505-5878
megan.raymond@groombridgewu.com

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of REPLY IN SUPPORT OF PATENT OWNER'S MOTION FOR ADDITIONAL DISCOVERY 37 C.F.R. §42.51(b)(2) FROM PETITIONER MYLAN PHARMACEUTICALS INC. has been served in its entirety by causing the aforementioned document to be electronically mailed to the following attorneys of record for the Petitioners listed below:

Petitioner's Counsel of Record:

Lead Counsel:	Brandon M. White Reg. No. 52,354 White-ptab@perkinscoie.com Perkins Coie LLP 700 13th Street, NW Washington, DC 20005 Telephone: (202) 654-6200 By Electronic Mail
Backup Counsel:	Emily J. Greb Reg. No. 68,244 Greb-ptab@perkinscoie.com Perkins Coie LLP 33 East Main Street Madison, WI 53703 Telephone: (608) 663-7460 Courtney Prochnow, PhD Reg. No. 67,639 Prochnow-ptab@perkinscoie.com Perkins Coie LLP 633 W. 5th St., Ste 5850 Los Angeles, CA 90071 Telephone: (310) 788-9900 Christopher D. Jones

	<p>Reg. No. 76,472 Jones-ptab@perkinscoie.com Perkins Coie LLP 700 13th Street, NW Washington, DC 20005 Telephone: (202) 654-6200</p> <p>Jonathan I. Tietz, PhD Reg. No. 76,753 Tietz-ptab@perkinscoie.com Perkins Coie LLP 700 13th Street, NW Washington, DC 20005 Telephone: (202) 654-6200</p> <p>Matthew A. Lembo Reg. No. 75,633 Lembo-ptab@perkinscoie.com Perkins Coie LLP 1155 Avenue of the Americas Floor 22 New York, NY 10036 Telephone: (212) 262-6900</p> <p>Shannon M. Bloodworth SBloodworth@perkinscoie.com Perkins Coie LLP 700 13th Street, NW Washington, DC 20005 Telephone: (202) 654-6200</p> <p>David L. Anstaett DAnstaett@perkinscoie.com Perkins Coie LLP 33 East Main Street Madison, WI 53703 Telephone: (608) 663-7460</p> <p>Bryan D. Beel BBeel@perkinscoie.com</p>
--	--

	<p>Perkins Coie LLP 1120 NW Couch St. Portland, OR 97209 Telephone: (503) 727-2000</p> <p>Nathan Kelley Kelley_nathan-ptab@perkinscoie.com Perkins Coie LLP 700 13th Street, NW Washington, DC 20005 Telephone: (202) 654-6200</p> <p>Rodney Swartz Reg. No. 73,343 RSwartz@perkinscoie.com Perkins Coie LLP 1120 NW Couch St. 10th Floor Portland, OR 97209 Telephone: (503) 727-2000</p> <p>Jessica Kaiser Reg No. 58,937 kaiser-ptab@perkinscoie.com Perkins Coie LLP 1900 Sixteenth St., Suite 1400 Denver, CO 80202-5255 Tel: (303) 291-2300</p> <p><u>Semaglutide-Ozempic@perkinscoie.com</u> By Electronic Mail</p>
--	--

Lead Counsel for Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Labor- atories. Ltd.:	Jovial Wong Reg. No. 60,115 Winston & Strawn LLP 1901 L Street NW Washington, DC 20036 Telephone: (202) 282-5867 jwong@winston.com By Electronic Mail
Backup Coun- sel:	Scott Border Reg. No. 77,744 Winston & Strawn LLP 1901 L Street NW Washington, DC 20036 Telephone: (202) 285-5054 sborder@winston.com Sharon Lin McIntosh (<i>pro hac vice</i> to be submitted) Winston & Strawn LLP 1901 L Street NW Washington, DC 20036 Telephone: (202) 285-5756 slin@winston.com By Electronic Mail

Lead Counsel for Sun Phar- maceutical In- dustries Ltd. and Sun Phar- maceutical In- dustries, Inc.:	Brian Sodikoff Katten Munchin Rosenman LLP 525 West Monroe Street Chicago, IL 60661 P: (312) 902-5200 brian.sodikoff@katten.com By Electronic Mail
Backup Coun- sel:	Christopher B. Ferenc Katten Munchin Rosenman LLP 1919 Pennsylvania Ave., N.W. Suite 800 Washington, DC 20006 P: (202) 625-3500 christopher.ferenc@katten.com By Electronic Mail

Dated: August 23, 2024

Respectfully submitted,

By: /Sayem Osman/
Sayem Osman