

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.,
Petitioner,

v.

NOVO NORDISK A/S,
Patent Owner.

IPR2023-00724¹
Patent 10,335,462 B2

Before JOHN G. NEW, SUSAN L. C. MITCHELL, and
ROBERT A. POLLOCK, *Administrative Patent Judges*.

MITCHELL, *Administrative Patent Judge*.

ORDER
Conduct of the Proceeding
37 C.F.R. §§ 42.5

¹ IPR2024-00009 (Dr. Reddy's Laboratories) and IPR2024-00107 (Sun Pharmaceutical Industries) have been joined with this proceeding.

On July 22, 2024, in response to an email request from Patent Owner dated July 12, 2024 (Ex. 3005), Judges New, Mitchell, and Pollock conducted a conference call with counsel for the parties to discuss Patent Owner's request to file a motion for sanctions against Petitioner and a motion for additional discovery. A court reporter was present, and Patent Owner confirmed that it will file a copy of the transcript as an exhibit once it is available.

Patent Owner seeks authorization to file a motion for sanctions under 37 C.F.R. §§ 42.11 and 42.12 because Patent Owner alleges that Petitioner Mylan Pharmaceuticals Inc. ("Mylan") violated the stipulation it included in its Petition for *Inter Partes* Review (Paper 1, "Petition" or "Pet.") to support its position that there was no basis to deny institution under 35 U.S.C. § 314(a). *See* Pet. 65–66. Mylan stipulated that "if the Board institutes, Petitioner will not pursue in the district court any instituted grounds against the originally-issued claims unless a change in law otherwise permits." Pet. 66.

Patent Owner contends Mylan violated this stipulation "by actively pursuing three instituted grounds (Grounds 1, 2 and 4) in district court litigation—including in three expert reports expressly made on behalf of Mylan and its co-defendants and served by Mylan." Ex. 3005. According to Patent Owner, Mylan is actively pursuing instituted Grounds 1, 2, and 4 in the parallel district court litigation by continuing to engage and pay experts who submitted declarations in the instant proceeding and who were subsequently shared with co-defendants in the parallel district court proceeding, and by assisting the district court co-defendants in the preparation and service of invalidity contentions and expert reports that

contain equivalent invalidity positions authored by Mylan's experts in the instant proceeding.

Patent Owner contends it "seeks sanctions from the Board that are not available in the district court and are not being sought there." Ex. 3005. In particular, Patent Owner seeks its attorney fees and expenses under Rule 12, an adverse judgment against all Petitioners in this proceeding, "or, in the alternative, precluding arguments and excluding evidence" in this proceeding as to Grounds 1, 2, and 4. *Id.*

Patent Owner also seeks authorization to file a motion for additional discovery from Petitioner because "Petitioner has refused any discovery regarding its conduct in connection with the expert reports." Ex. 3005. Patent Owner seeks "limited additional discovery from Petitioners regarding their respective retention, direction, and payment of these three experts in connection with the instituted '462 grounds who, prior to institution, were experts in this IPR and only for Mylan." *Id.* Patent Owner represents that it met and conferred with Petitioner and requested this information, but Petitioner has refused to provide any discovery. *Id.*

Petitioner Mylan opposes Patent Owner's request to file a motion for sanctions because it asserts that it has not violated the stipulation it included in its Petition. Ex. 3005. Mylan contends it "has confirmed in writing to Patent Owner's district court counsel that Petitioner will not pursue in the district court litigation any invalidity ground instituted in this IPR." *Id.* Mylan argues further that its actions in the district court litigation are not inconsistent with the stipulation included in its Petition because the language "pursue in the district court" is limited to matters before the district court, such as motions or presentation at trial. Mylan contends contributing to

invalidity contentions and expert reports on invalidity in the district court case does not qualify as “pursuing” those positions, but instead is a way for Mylan to preserve the issues in case there is an intervening change in the law by having a developed record on these grounds that it may then “pursue.”

Mylan pointed out that the papers in this proceeding, including the expert reports, were publicly available information and indicated that the arguments in the expert reports in the parallel litigation appear similar to this publicly available information. Mylan, however, would not acknowledge whether it was involved in the defendants’ invalidity case in the parallel district court litigation because it contends this information is protected under the work product doctrine. Accordingly, Mylan also opposes Patent Owner’s request to file a motion for additional discovery.

Petitioners Sun Pharmaceutical Industries (“Sun”) and Dr. Reddy’s Laboratories (“DRL”) oppose Patent Owner’s request to file a motion for sanctions and Patent Owner’s request to file a motion for additional discovery because Patent Owner is seeking relief against Sun and DRL “in the absence of any allegations of misconduct as to those parties.” Ex. 3005. Sun and DRL argue that any relief Patent Owner may receive should not affect Sun’s and DRL’s petitions because neither Sun nor DRL were under any restrictions, such as those to which Mylan had agreed in its Petition, in the parallel district court litigation when the expert reports were filed. Accordingly, Sun and DRL request the opportunity to respond to Patent Owner’s motions, and request that the Board separately consider whether any relief Patent Owner may receive should apply to Sun and DRL.

Patent Owner responds that Sun and DRL are bound by Mylan’s stipulation because Sun and DRL chose to join this proceeding as silent

understudies. Therefore, any relief Patent Owner may receive should similarly apply to Sun and DRL.

Having heard the parties' arguments, we determine that Patent Owner alleged sufficient credible facts for us to authorize a motion for sanctions. Mylan's position that its stipulation permits it to develop a record in the district court proceeding involving grounds upon which we instituted an *inter partes* review, and that such actions do not constitute "pursuing" those grounds in the district court as long as Mylan does not present them in a motion or at trial, deserves exploration in a motion for sanctions. Mylan also takes the position that admitting to the simple fact of any involvement in the development of the overlapping grounds with its experts in the district court litigation endangers Petitioner's alleged work product. It appears from Mylan's positions that it is undisputed that Petitioner Mylan has some involvement in the invalidity case in the district court litigation that includes grounds on which we instituted *inter partes* review. This action, on its face, appears to be in direct conflict with the stipulation Mylan included in its Petition. We determine that Patent Owner's requested briefing may be helpful to the panel and authorize such briefing as set forth below in the Order.

Order

Accordingly, it is:

ORDERED that Patent Owner's request for authorization to file a motion for sanctions is *granted*;

FURTHER ORDERED that Patent Owner's request to file a motion for additional discovery is granted on condition that the motion explain how

such discovery would be useful in light of the extant schedule, including the schedule for briefing set forth below;

FURTHER ORDERED that Patent Owner is authorized to file a motion for sanctions of no more than fifteen (15) pages by July 31, 2024;

FURTHER ORDERED that Patent Owner is authorized to file a motion for additional discovery of no more than ten (10) pages by July 31, 2024;

FURTHER ORDERED that Petitioner Mylan is authorized to file an opposition to Patent Owner's motion for sanctions of no more than fifteen (15) pages by August 16, 2024;

FURTHER ORDERED that Petitioner Mylan is authorized to file an opposition to Patent Owner's motion for additional discovery of no more than ten (10) pages by August 16, 2024;

FURTHER ORDERED that Petitioners Sun and DRL are authorized to jointly file an opposition to Patent Owner's motion for sanctions of no more than five (5) pages by August 16, 2024;

FURTHER ORDERED that Petitioners Sun and DRL are authorized to jointly file an opposition to Patent Owner's motion for additional discovery of no more than five (5) pages by August 16, 2024;

FURTHER ORDERED that Patent Owner is authorized to file a reply brief to respond to each of Petitioner Mylan's and Petitioners' Sun and DRL's oppositions to Patent Owner's motion for sanctions of no more than five (5) pages each by August 23, 2024; and

FURTHER ORDERED that Patent Owner is authorized to file a reply brief to respond to each of Petitioner Mylan's and Petitioners' Sun and

IPR2023-00724
Patent 10,335,462 B2

DRL's oppositions to Patent Owner's motion for additional discovery of no more than five (5) pages each by August 23, 2024.

IPR2023-00724
Patent 10,335,462 B2

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