UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX INC., Petitioner

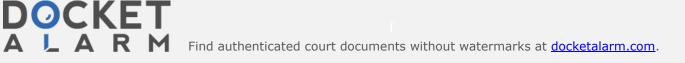
v.

NOVO NORDISK A/S, PATENT OWNER

CASE IPR2024-00631 U.S. PATENT NO. 10,335,462 ISSUED: JULY 2, 2019

TITLE: USE OF LONG-ACTING GLP-1 PEPTIDES

APOTEX'S MOTION TO SEAL AND FOR ENTRY OF A PROTECTIVE ORDER PURSUANT TO 37 C.F.R. § 42.54



I. INTROUDCTION

Pursuant to 37 C.F.R. §§ 42.14, 42.54, and 42.55, Petitioner Apotex Inc. ("Apotex") hereby moves for entry of the protective order (Appendix A below) and further moves to seal (1) its Motion for Joinder Under 35 U.S.C. § 315(c) and 37 C.F.R. §§ 42.22 and 42.122(b) to inter partes review of IPR2023-00724 (the "joinder motion") and (2) the Declaration of Robert Shapiro, Ex. 1507 (the "Shapiro declaration"). That order is the Board's default protective order. Patent Owner Novo Nordisk A/S ("Novo") has likewise moved for entry of the Board's default protective order in *Mylan Pharms. Inc.* v. *Novo Nordisk A/S*, IPR2023-00724 (the "Mylan IPR proceeding"). Good cause exists for sealing those documents. That is because they contain Apotex's confidential business information, which, if disclosed, would likely cause competitive harm to Apotex.

II. ENTRY OF A PROTECTIVE ORDER

Apotex moves for entry of the Board's default protective order, submitted here as Appendix A below. *See* Patent Trial and Appeal Board Consolidated Trial Practice Guide 117–22 (Nov. 2019). Novo has moved for entry of the same protective order in the Mylan IPR proceeding. *Mylan*, IPR2023-00724, Paper No. 28 (PTAB Jan. 17, 2024). The challenged patent in that proceeding is the same as in this proceeding: U.S. Patent No. 10,335,462. Apotex seeks joinder to that proceeding.

III. GOOD CAUSE EXISTS TO SEAL APOTEX'S JOINDER MOTION AND THE DECLARATION OF ROBERT SHAPIRO

Pursuant to the protective order and 37 C.F.R. §§ 42.54 and 42.55, Apotex moves to seal its joinder motion and the Shapiro declaration (Ex. 1507). As the Board has found in similar cases, "good cause" exists to seal these documents because they contain Apotex's non-public business information. Celltrion, Inc., v. Genentech, Inc., IPR2016-01667, Paper No. 20 at 4 (PTAB Aug. 18, 2017) (granting motion to seal non-public business information, including information) about drug development and regulatory strategies), Paper No. 31 at 4 (PTAB July 23, 2018) (granting motion to expunge that information from the record); Unified Patents Inc. v. Dragon Intellectual Prop., LLC, IPR2014-00216, Paper No. 40, 6-7 (PTAB Feb. 27, 2015) (granting motion to seal non-public business information, including information relating to business strategies); see also 37 C.F.R. § 42.54. Specifically, the entirety of the Shapiro declaration describes Apotex's confidential drug development and regulatory approval strategies. Ex. 1507. Certain portions of Apotex's joinder motion rely on the declaration and contain the same confidential information. If that confidential information were publicly disclosed, it would likely cause competitive business harm to Apotex.

Apotex has filed unredacted, nonpublic versions of its joinder motion and the Shapiro declaration concurrently with this motion and its petition for *inter*

-2-

partes review. Apotex has also concurrently filed a redacted version of its joinder motion redacting the limited portions of the motion that rely on the confidential Shapiro declaration. Because the entirety of the Shapiro declaration contains confidential information, Apotex has not filed a redacted version.

IV. CONCLUSION

For the foregoing reasons, Apotex respectfully requests that the Board grant this motion to seal and for entry of a protective order.



Dated: March 1, 2024 **STEPTOE LLP** 1114 Avenue of the Americas New York, NY 10036 Telephone: 212-506-3900 Fax: 212-506-3950 Email: Semaglutide@Steptoe.com Respectfully submitted,

/John J. Molenda/

John J. Molenda Reg. No. 47,804 *Lead Counsel for Apotex*

DOCKET A L A R M



Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.