

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX INC.,
PETITIONER

v.

NOVO NORDISK A/S,
PATENT OWNER

CASE IPR2023-00724¹
U.S. PATENT NO. 10,335,462
ISSUED: JULY 2, 2019

TITLE:
USE OF LONG-ACTING GLP-1 PEPTIDES

APOTEX’S MOTION TO EXPUNGE

¹ IPR2024-00009 (Dr. Reddy’s Laboratories), IPR2024-00107 (Sun Pharmaceutical Industries), and IPR2024-00631 (Apotex Inc.) have been joined with this proceeding.

I. INTRODUCTION

Pursuant to the Trial Practice Guide and 37 C.F.R. § 42.56, Petitioner Apotex Inc. (“Apotex”) requests that the Board expunge certain confidential papers and exhibits from the records of IPR2023-00724 and IPR2024-00631. Pursuant to the Board’s Institution Decision in IPR2024-00631, Apotex files this motion in the joined proceeding, IPR2023-00724. IPR2024-00631, Paper No. 22 at 14. The Board granted authorization to Apotex to file this motion in an email dated October 15, 2024.

Notably, Patent Owner Novo Nordisk A/S (“Novo”) has indicated that it does not intend to oppose this motion. For the reasons set forth below, Apotex respectfully requests that the following documents currently under seal be expunged from the record of IPR2024-00631, as these documents contain Apotex’s confidential business information:

Document	Description
Paper No. 5	Motion for Joinder
Ex. 1507	Declaration of Robert Shapiro
Paper No. 9	Patent Owner's Opposition to Petitioner's Motion for Joinder
Paper No. 10	Apotex’s Reply to Patent Owner's Opposition to Petitioner's Motion for Joinder
Paper No. 15	Patent Owner’s Preliminary Response (“POPR”)

Paper No. 17	Apotex's Reply to Patent Owner's Preliminary Response
Ex. 2010	June 10, 2024 Email from Counsel for Petitioner re: IPR2024-00631
Paper No. 21	Patent Owner's Reply to Petitioner's Reply to Patent Owner's Preliminary Response

Additionally, for the reasons set forth below, Apotex respectfully requests that Paper No. 100, Patent Owner's Request for Director Review, currently under seal, be expunged from the record of IPR2023-00724, as this document contains Apotex's confidential business information.

II. STATEMENT OF FACTS

On March 16, 2023, Mylan filed the first IPR petition challenging U.S. Patent No. 10,335,462 (the "'462 patent"). IPR2023-00724, Paper No. 1. On October 4, 2023, the Board issued its decision to institute *inter partes* review. IPR2023-00724, Paper No. 10; *see also* n.1, *supra* (noting joinder of Dr. Reddy's and Sun).

On March 1, 2024, Apotex filed an IPR petition challenging the '462 patent. IPR2024-00631, Paper No. 1. On that date, Apotex also filed a motion to join its proceeding with Mylan's proceeding and Ex. 1507, along with an unopposed motion to seal describing the confidential information in both documents. IPR2024-00631, Paper Nos. 3, 5. On April 1, 2024, Novo filed its opposition to

the joinder motion. IPR2024-00631, Paper No. 9. On April 15, 2024, Apotex filed its reply, as well as an unopposed motion to seal both the opposition and the reply. IPR2024-00631, Paper Nos. 10, 11. On June 12, 2024, Novo filed its POPR and Ex. 2010, along with an unopposed motion to seal. IPR2024-00631, Paper Nos. 14, 15. On July 1, 2024, Apotex filed its reply to the POPR along with an unopposed motion to seal. IPR2024-00631, Paper Nos. 17, 19. On July 15, 2024, Novo filed its sur-reply, along with an unopposed motion to seal. IPR2024-00631, Paper Nos. 20, 21. On September 11, 2024, the Board instituted Apotex's IPR petition and granted Apotex's motion to join Mylan's IPR proceeding. IPR2024-00631, Paper No. 22. Concurrently, the Board asked Apotex and Novo to identify any confidential information in the Institution Decision. IPR2024-00631, Paper No. 23. The parties identified no confidential information in that decision. On September 25, 2024, Novo requested Director Review of the Institution Decision and filed an unopposed motion to seal. IPR2023-00724, Paper Nos. 100, 101. On October 24, 2024, Novo's request for Director Review was denied. IPR2023-00724, Paper No. 116.

The confidential information originates in the two confidential exhibits (IPR2024-00631, Exs. 1507, 2010), which are entirely confidential. The subsequent confidential papers (IPR2024-00631, Paper Nos. 5, 9, 10, 15, 17, 21;

IPR2023-00724, Paper No. 100) rely on these exhibits and the prior papers. The parties have already filed public, redacted versions of each of the confidential papers.

On October 7, 2024, Apotex and Novo filed a joint motion to terminate the IPR proceedings with respect to Apotex due to settlement. IPR2023-00724, Paper No. 110.

III. LEGAL STANDARD

Ordinarily, confidential information subject to a Protective Order that is submitted in PTAB proceedings becomes public 45 days after final judgment. Trial Practice Guide at 21-22. But a party may preserve the confidentiality of confidential information by filing a motion to expunge under 37 C.F.R. § 42.56. *Id.* That rule “balances the needs of the parties to submit confidential information with the public interest in maintaining a complete and understandable file history for public notice purposes.” *Id.* A party seeking expungement of its papers or exhibits from the record must show good cause by demonstrating “that any information sought to be expunged constitutes confidential information, and that [the party’s] interest in expunging it outweighs the public’s interest in maintaining a complete and understandable history of this *inter partes* review.” *Atlanta Gas Light Co. v. Bennett Regulator Guards, Inc.*, IPR2013-00453, Paper No. 97 at 2 (PTAB Apr. 15, 2015).

IV. GOOD CAUSE EXISTS TO EXPUNGE THE DOCUMENTS CONTAINING APOTEX'S CONFIDENTIAL INFORMATION FROM THE RECORD

Good cause exists to expunge the documents containing Apotex's confidential information from the record. Not surprisingly, Novo has indicated that it does not intend to oppose this motion.

The information sought to be expunged constitutes Apotex's confidential business information. *See Atlanta*, IPR2013-00453, Paper No. 97 at 2. As has been explained in the motions to seal, that information describes Apotex's confidential drug development and regulatory approval strategies. *See, e.g.*, IPR2024-00631, Paper No. 3 at 2. As has also been explained in the motions to seal, if Apotex's confidential information were publicly disclosed, it would likely cause competitive business harm to Apotex. *See, e.g.*, IPR2024-00631, Paper No. 3 at 2; *see also Atlanta*, IPR2013-00453, Paper No. 97 at 2. That is because that information would allow competitors to gain an informational advantage regarding Apotex's strategies. Notably, each of those motions to seal were unopposed.

Further, the public has little interest in the confidential information. *See Atlanta*, IPR2013-00453, Paper No. 97 at 2. That is because the public has sufficient information to understand the nature of the confidential information without access to it. *Cf. Unified Patents Inc., v. Velos Media, LLC*, IPR2019-00763, Paper No. 50, at 5 (PTAB Mar. 8, 2021) (expunging confidential

information cited by final written decision, reasoning that “the Decision is written such that the public can understand the parties’ arguments and the bases for the Board’s determinations without access to the underlying confidential information.”). The public has sufficient information to understand both the confidential papers and exhibits from (1) the Institution Decision, which is entirely non-confidential and (2) the public, non-confidential versions of the confidential papers. Namely, those non-confidential documents show that Apotex’s confidential information explains Apotex’s business decision regarding the timing of Apotex’s IPR petition and joinder motion. *See, e.g.*, IPR2024-00631, Paper No. 4 at 10. While no redacted versions have been filed for the two confidential exhibits, that is because those exhibits are entirely confidential.

Moreover, the final judgment will not rely on the confidential information. The parties seek termination due to settlement. IPR2023-00724, Paper No. 110. So a final written decision on the merits will not issue. But even if the Board were to issue a final written decision, there would still be no need to rely on the confidential information. That is because the confidential information is unrelated to the proceeding’s merits, but rather related to institution and joinder. *See, e.g.*, IPR2024-00631, Paper No. 5, at 3-5, 10. Even in the Institution Decision, the Board addressed the subject matter of the confidential information without relying

on the specific confidential information itself or citing the confidential exhibits. IPR2024-00631, Paper No. 23 at 12-13; *see Red Diamond, Inc. v. Southern Visions, LLP*, IPR2020-00001, Paper 41 at 4 (PTAB Jan. 14, 2022) (expunging confidential exhibit relied upon by final written decision, reasoning that it “did not rely on the specific confidential information” in the exhibit). Apotex’s interest in expunging the confidential information thus outweighs the public’s interest in maintaining a complete and understandable history of this *inter partes* review proceeding. *See Atlanta*, IPR2013-00453, Paper No. 97 at 2.

V. CONCLUSION

For the foregoing reasons, Apotex respectfully requests that the Board grant this motion to expunge.

Dated: November 15, 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

CERTIFICATE OF SERVICE

The undersigned certifies that electronic service of APOTEX'S MOTION TO
EXPUNGE was made on counsel of record to the following email addresses:

J. Steven Baughman
Megan Raymond
Jenny C. Wu
Michael Milea
Philip S. May
Joshua Reich
GROOMBRIDGE, WU, BAUGHMAN & STONE LLP
steve.baughman@groombridgewu.com
megan.raymond@groombridgewu.com
jenny.wu@groombridgewu.com
mike.milea@groombridgewu.com
philip.may@groombridgewu.com
Joshua.reich@groombridgewu.com
Novo-SemaglutideIPR@groombridgewu.com

Brandon M. White
Emily J. Greb
Courtney Prochnow, Ph.D.
Christopher D. Jones
Jonathan I. Tietz, Ph.D.
Matthew A. Lembo
Shannon M. Bloodworth
David L. Anstaett
Bryan D. Beel
Nathan Kelley
Rodney Swartz
Jessica Kaiser
PERKINS COIE LLP
white-ptab@perkinscoie.com
greb-ptab@perkinscoie.com
prochnow-ptab@perkinscoie.com
jones-ptab@perkinscoie.com
tietz-ptab@perkinscoie.com
lembo-ptab@perkinscoie.com

sbloodworth@perkinscoie.com
danstaett@perkinscoie.com
bbeel@perkinscoie.com
kelley_nathan-ptab@perkinscoie.com
rswartz@perkinscoie.com
kaiser-ptab@perkinscoie.com
Semaglutide-Ozempic@perkinscoie.com

Jovial Wong
Scott Border
Sharon Lin McIntosh
WINSTON & STRAWN LLP
jwong@winston.com
sborder@winston.com
slin@winston.com

Brian Sodikoff
Christopher B. Ferenc
KATTEN MUNCHIN ROSENMAN LLP
brian.sodikoff@katten.com
christopher.ferenc@katten.com

Dated: November 15, 2024

/s/ John J. Molenda
John J. Molenda (Reg. No. 47,804)
Lawrence Kass (Reg. No. 40,671)
Tyler Doh (Reg. No. 80,274)
Michael I. Green (Reg. No. 80,436)
STEPTOE LLP
1114 Avenue of the Americas
New York, NY 10036
Tel: (212) 506-3900

Counsel for Apotex