

IPR2025-00033
U.S. Patent No. 11,744,802

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CIPLA LIMITED
Petitioner,

v.

GILEAD SCIENCES, INC.,
Patent Owner.

Case No. IPR2025-00033
U.S. Patent No. 11,744,802

**PATENT OWNER'S UNOPPOSED COMBINED MOTION TO SEAL AND
MOTION FOR PROTECTIVE ORDER**

I. Introduction

Patent Owner Gilead Sciences, Inc. hereby moves to seal Exhibits 2021 and 2022 in their entirety, as well as portions of the Patent Owner Preliminary Response directly quoting Exhibit 2021. Good cause exists for granting the instant motion to seal because these documents include confidential information relating to Patent Owner's research and development of Biktarvy®, its three-drug combination containing bicitgravir. Petitioner Cipla does not oppose Gilead's request to seal these documents. In addition, Gilead requests that the Board enter the parties' agreed-on protective order. *See* 37 C.F.R. §§ 42.14, 42.54.

II. Good Cause Exists For Sealing Certain Confidential Information

The standard governing the Board's determination of whether to grant a motion to seal is "good cause." *Garmin v. Cuozzo*, IPR2012-00001, Paper 36 (April 5, 2013). In that regard, the Board must "strike a balance between the public's interest in maintaining a complete and understandable file history and the parties' interest in protecting truly sensitive information." *Id.*

Gilead provides the following non-confidential description of the nature of the confidential information that is under seal and the reasons why the information should not be made available to the public:

- Exhibit 2021 is an excerpt of the deposition of Dr. Hal Martin, a Director at Gilead involved in the bicitgravir clinical trials. Dr. Martin

testified in the district court litigation regarding the development of Gilead's drug product containing bicittegravir. This testimony includes sensitive and confidential information regarding the properties and development of Gilead's drug product containing bicittegravir. Gilead also moves to seal direct quotes from Dr. Martin's deposition that are included in the Patent Owner Preliminary Response.

- Exhibit 2022 is an internal Gilead document reporting the status of development of Gilead's drug product containing bicittegravir (GS-9883). This document includes sensitive and confidential information regarding the properties and development of Gilead's drug product containing bicittegravir.

To Gilead's knowledge, these documents have not been published or otherwise made available to the public. The confidential information disclosed in Exhibits 2021 and 2022 has been produced on a confidential basis under the parties' agreed-on protective order in the co-pending district court litigation, and Gilead has maintained these documents and the information they contain as confidential and proprietary. If such confidential information is made public, it would create a competitive disadvantage for Gilead and provide competitors with knowledge of Gilead's proprietary drug-development research.

The Board has found good cause to seal proprietary scientific research information under similar circumstances. For example, the Board found good cause to grant a patent owner's motion to seal a document containing non-public research data, noting that it was subject to a protective order in a related district court litigation. *See Illumina, Inc. v. Cornell Rsch. Found., Inc.*, No. IPR2016-00549, 2017 WL 2312917, at *2-3 (PTAB May 26, 2017). The Board also found good cause to seal portions of the Patent Owner Preliminary Response that cited such non-public data. *Id.* Similarly, the Board has found good cause to grant a patent owner's motion to seal copies of documents that contained "proprietary technical and product development information," as well as deposition transcripts and papers discussing that confidential information. *Intelligent Bio-Systems, Inc. v. Illumina Cambridge Ltd.*, No. IPR2013-00517, Paper 83 at 4-5 (PTAB Jan. 29, 2015).

In addition, the information in the documents identified above are being submitted to support Gilead's argument that the "efficiency and integrity of the system are best served by denying" review under the *Fintiv* factors, given (among other reasons) the advanced stage of the co-pending district court litigation. *Apple Inc. v. Fintiv, Inc.*, No. IPR2020-00019, 2020 WL 2126495, at *3 (PTAB Mar. 20, 2020) (informative). Exhibits 2021 and 2022 are exemplars of fact and documentary evidence developed in the district court that will be better assessed by the district

court, which will have the benefit of a fuller context under which to assess credibility and relevance of such evidence, including through live and/or deposition testimony.

Therefore, the public's interest in having access to these particular documents is not outweighed by the fact that they are confidential and proprietary to Gilead. Gilead therefore respectfully requests that Exhibits 2021 and 2022 be sealed in their entirety, as well as the portions of the Patent Owner Preliminary Response directly quoting Exhibit 2021.

III. Proposed Protective Order

The parties have met and conferred and agreed on a protective order, which is appended as Addendum A. The proposed protective order provides the protections of the Default Protective Order of this Board, plus additional protections. The additional protections include a prosecution bar and a statement that the protective order applicable to the IPR proceedings does relieve or change the obligations that apply due to the protective order in the co-pending litigation, including for documents produced in both matters. The protective order also makes changes to align with the protections of the district court protective order, including renaming "PROTECTIVE ORDER MATERIAL" as "CONFIDENTIAL – ATTORNEYS' EYES ONLY."

Under ¶ 5(A)(ii) of the protective order, Gilead has filed a confidential, non-redacted version of the Patent Owner Preliminary Response, as well as a redacted

version of the Patent Owner Preliminary Response to remove the confidential information.

IV. Conclusion

For the foregoing reasons, Gilead respectfully requests for the Board to enter the parties' agreed on protective order and seal Exhibits 2021 and 2022, as well as portions of the Patent Owner Preliminary Response directly quoting Exhibit 2021.

Dated: February 19, 2025

Respectfully submitted,

By: Meg E. Fasulo

Meg E. Fasulo (Reg. No. 75,820)

J. Scott McBride (*pro hac vice* requested)

Rebecca T. Horwitz (*pro hac vice*
requested)

BARTLIT BECK LLP

54 West Hubbard Street, Suite 300

Chicago, IL 60654

(312) 494-4400

Taylor Kelson (*pro hac vice* to be
requested)

BARTLIT BECK LLP

1801 Wewatta Street, Suite 1200

Denver, CO 80202

(303) 592-3100

Counsel for Patent Owner

CERTIFICATE OF SERVICE

The undersigned certifies, that on this 19th day of February, 2025, the foregoing document is being served by e-mail on counsel of record for Petitioner as follows:

alarsen@merchantgould.com
csorenson@merchantgould.com
CiplaBictegravirIPR@merchantgould.com

By: Meg E. Fasulo
Meg E. Fasulo (Reg. No. 75,820)
BARTLIT BECK LLP
54 West Hubbard Street, Suite 300
Chicago, IL 60654

Counsel for Patent Owner

Addendum A

Protective Order

IPR2025-00033
U.S. Patent No. 11,744,802

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CIPLA LIMITED
Petitioner,

v.

GILEAD SCIENCES, INC.,
Patent Owner.

Case No. IPR2025-00033
U.S. Patent No. 11,744,802

PROTECTIVE ORDER

This protective order governs the treatment and filing of confidential information, including documents and testimony.

1. Confidential information shall be clearly marked “CONFIDENTIAL – ATTORNEYS’ EYES ONLY.”

2. Access to confidential information marked “CONFIDENTIAL – ATTORNEYS’ EYES ONLY” is limited to the following individuals who have executed the acknowledgment appended to this order:

- A. Party Representatives. Representatives of record for a party in the proceeding.
- B. Experts. Retained experts of a party in the proceeding who further certify in the Acknowledgement that they are not a competitor to any party, or a consultant for, or employed by, such a competitor with respect to the subject matter of the proceeding.
- C. In-house counsel. The four in-house representatives for each party who have been disclosed under the protective order in the co-pending district court litigation. *See Gilead Sciences, Inc. v. Lupin Ltd.*, 1:22-cv-00615-MN, Dkt. 40 at ¶ 5(f).
- D. Support Personnel. Administrative assistants, clerical staff, court reporters and other support personnel of the foregoing persons who

are reasonably necessary to assist those persons in the proceeding shall not be required to sign an Acknowledgement, but shall be informed of the terms and requirements of the Protective Order by the person they are supporting who receives confidential information.

- E. The Office. Employees and representatives of the United States Patent and Trademark Office who have a need for access to the confidential information shall have such access without the requirement to sign an Acknowledgement. Such employees and representatives shall include the Director, members of the Board and their clerical staff, other support personnel, court reporters, and other persons acting on behalf of the Office.

3. The individuals specified in Paragraphs 2(A), 2(B), and 2(C) who have received access to “CONFIDENTIAL – ATTORNEYS’ EYES ONLY” material shall not engage or be involved in the substance of prosecution (including but not limited to drafting claims, editing claims, amending claims, and any discussions regarding the claim scope to pursue as part of prosecution) of patent applications claiming bictegravir or the combination of bictegravir, emtricitabine, and tenofovir alafenamide, including any methods of manufacture,

use, administration, or formulation, for a period beginning when such individual first accesses “CONFIDENTIAL – ATTORNEYS’ EYES ONLY” material and ending twenty-four (24) months from the end of this action IPR2025-00033 (including any appeals thereof), without prior approval to do so by agreement of the parties. For the avoidance of doubt, nothing herein shall preclude any such individual from any work relating to any post-grant proceeding before the Patent Trial and Appeal Board under 35 U.S.C. §§ 311 et seq. or 35 U.S.C. §§ 321 et seq. or corresponding post-grant proceedings before any foreign patent authority; provided, however, that no such individual that has accessed “CONFIDENTIAL – ATTORNEYS’ EYES ONLY” material shall provide any input, or otherwise participate in any way, in drafting or submitting any amendments to any claims in any reexamination, post-grant review or inter partes review proceeding or corresponding post-grant proceedings before any foreign patent authority (including providing recommendations regarding drafting, crafting, or amending claims to persons engaged on behalf of the receiving party in such activities) relating to bictegravir or the combination of bictegravir, emtricitabine, and tenofovir alafenamide, including any methods of manufacture, use, administration, or formulation. This paragraph shall not apply to any post-grant proceeding before the Patent Trial and Appeal Board under 35 U.S.C. §§ 311 et

seq. or 35 U.S.C. §§ 321 et seq. pertaining to U.S. Patent No. 11,744,802 or any patent within the same family as the '802 patent, including IPR2025-00033.

4. Employees (e.g., corporate officers), consultants, or other persons performing work for a party, other than those persons identified above in (2)(A)–(E), shall be extended access to confidential information only upon agreement of the parties or by order of the Board upon a motion brought by the party seeking to disclose confidential information to that person and after signing the Acknowledgment. The party opposing disclosure to that person shall have the burden of proving that such person should be restricted from access to confidential information.

5. Persons receiving confidential information shall use reasonable efforts to maintain the confidentiality of the information, including:

- A. Maintaining such information in a secure location to which persons not authorized to receive the information shall not have access;
- B. Otherwise using reasonable efforts to maintain the confidentiality of the information, which efforts shall be no less rigorous than those the recipient uses to maintain the confidentiality of information not received from the disclosing party;
- C. Ensuring that support personnel of the recipient who have access to

the confidential information understand and abide by the obligation to maintain the confidentiality of information received that is designated as confidential; and

- D. Limiting the copying of confidential information to a reasonable number of copies needed for conduct of the proceeding and maintaining a record of the locations of such copies.

6. Persons receiving confidential information shall use the following procedures to maintain the confidentiality of the information:

A. Documents and Information Filed With the Board.

- i. A party may file documents or information with the Board along with a Motion to Seal. The Motion to Seal should provide a non-confidential description of the nature of the confidential information that is under seal, and set forth the reasons why the information is confidential and should not be made available to the public. A party may challenge the confidentiality of the information by opposing the Motion to Seal. The documents or information shall remain under seal unless the Board determines that some or all of it does not qualify for confidential treatment.

ii. Where confidentiality is alleged as to some but not all of the information submitted to the Board, the submitting party shall file confidential and non-confidential versions of its submission, together with a Motion to Seal the confidential version setting forth the reasons why the information redacted from the non-confidential version is confidential and should not be made available to the public. A party may challenge the confidentiality of the information by opposing the Motion to Seal. The non-confidential version of the submission shall clearly indicate the locations of information that has been redacted. The confidential version of the submission shall be filed under seal. The redacted information shall remain under seal unless the Board determines that some or all of the redacted information does not qualify for confidential treatment.

B. Documents and Information Exchanged Among the Parties.

iii. Documents (including deposition transcripts) and other information designated as confidential that are disclosed to another party during discovery or other proceedings before

the Board shall be clearly marked as “CONFIDENTIAL – ATTORNEYS’ EYES ONLY” and shall be produced in a manner that maintains its confidentiality.

7. Within 60 days after the final disposition of this action, including the exhaustion of all appeals and motions, each party receiving confidential information must return, or certify the destruction of, all copies of the confidential information to the producing party.

8. Nothing in this protective order should be understood as relieving or changing the confidentiality obligations of any person bound by the district court protective order, *Gilead Sciences, Inc. v. Lupin Ltd.*, 1:22-cv-00615-MN, Dkt. 40, including with respect to any confidential document produced in that litigation. Such persons must satisfy their obligations towards the confidentiality of any document produced in both matters consistent with their obligations under the protective orders in both matters.

9. Standard Acknowledgement of Protective Order. The following form may be used to acknowledge a protective order and gain access to information covered by the protective order:

CIPLA LIMITED v. GILEAD SCIENCES, INC.

IPR2025-00033

U.S. Patent No. 11,744,802

Acknowledgment for Access to Protective Order Material

I _____, affirm that I have read the Protective Order; that I will abide by its terms; that I will use any information marked “CONFIDENTIAL – ATTORNEYS’ EYES ONLY” only in connection with this proceeding and for no other purpose; that I will only allow access to support staff who are reasonably necessary to assist me in this proceeding; that prior to any disclosure to such support staff I informed or will inform them of the requirements of the Protective Order; that I am personally responsible for the requirements of the terms of the Protective Order and I agree to submit to the jurisdiction of the Office and the United States District Court for the Eastern District of Virginia for purposes of enforcing the terms of the Protective Order and providing remedies for its breach.

By: _____

Date: _____