

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

GILEAD SCIENCES, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 22-615 (MN)
	)	
LUPIN LTD., LAURUS LABS LIMITED,	)	
and CIPLA LIMITED,	)	
	)	
Defendants.	)	

**STIPULATION AND [PROPOSED] ORDER TO AMEND SCHEDULING ORDER**

WHEREAS, Defendants submitted Paragraph IV certifications for three patents listed in the Orange Book for Biktarvy® and Plaintiff timely filed suit for infringement of those three patents, resulting in a stay that runs until August 7, 2025;

WHEREAS, Plaintiff was recently granted another patent, U.S. Patent No. 11,744,802 (“the ’802 patent”), that claims, for example, a tablet comprising 50mg of bictegreavir (or a pharmaceutically acceptable salt thereof), 25 mg of tenofovir alefenamide (or a pharmaceutically acceptable salt thereof), and 200mg of emtricitabine (or a pharmaceutically acceptable salt thereof);

WHEREAS, by agreement of the parties, Plaintiff will be filing an amended complaint against Defendants adding counts for declaratory judgment of infringement of the ’802 patent;

WHEREAS, Plaintiff and Defendants agree that the interests of judicial efficiency weigh strongly in favor of trying the case for infringement of the ’802 patent together with the existing case for infringement currently pending, but that the addition of the ’802 patent to the case adds discovery burdens that make the current schedule untenable;

WHEREAS, Defendants assert that they each currently have submitted a Paragraph III certification to the U.S. Food & Drug Administration with respect to U.S. Patent 9,216,996 listed

in the Orange Book for Biktarvy®, with a listed expiration date of December 19, 2033. Defendants agree, based on these Paragraph III certifications, that even if successful in this suit the earliest they could launch a generic version of Biktarvy® would be upon the expiration of the '996 patent—a date long after the end of the stay in this matter. Defendants further agree, that if they were to convert their Paragraph III certifications with respect to the '996 patent to Paragraph IV certifications, doing so would give rise to a new 30-month stay.

NOW THEREFORE, IT IS HEREBY STIPULATED by the parties, subject to the approval of the Court, that the Scheduling Order is modified as set forth in the table below.

Event	Current Deadline	New Proposed Deadline
Plaintiff's Initial '802 Infringement contentions	N/A	Two weeks after filing amended complaint
Defendants' Initial '802 Invalidity contentions	N/A	Four weeks after filing amended complaint
Identification of additional claim terms for construction from the '802 patent	N/A	Four weeks after filing amended complaint
Deadline for service of additional written discovery requests specific to the '802 patent. The parties agree that defendants can serve the following additional discovery specific to the '802 patent: 3 joint Interrogatories, 2 individual Interrogatories (per defendant), 3 joint Requests for Admissions, 2 individual Requests for Admission (per defendant), and 5 joint Requests for Production.	N/A	Five weeks after filing amended complaint
Parties serve supplemental discovery responses, where relevant, to include responses specific to the '802 patent	N/A	Six weeks after filing amended complaint.

<b>Event</b>	<b>Current Deadline</b>	<b>New Proposed Deadline</b>
Supplementation of Accused Products and Invalidity References	September 18, 2023	February 2, 2024
Fact Discovery Cut Off	September 20, 2023	March 15, 2024
Final Infringement and Invalidity Contentions	October 6, 2023	April 5, 2024
Final Validity and Non-Infringement Contentions	October 20, 2023	April 26, 2024
Submission of Joint Claim Construction Chart	October 27, 2023	May 3, 2024
Plaintiff to Serve Opening Claim Construction Brief	November 10, 2023	May 31, 2024
Defendants to Serve Answering Claim Construction Brief	December 8, 2023	June 28, 2024
Plaintiff to Serve Reply Claim Construction Brief	January 8, 2024	July 26, 2024
Defendants to Serve Sur-Reply Claim Construction Brief	January 22, 2024	August 16, 2024
Parties to File Joint Claim Construction Brief	February 1, 2024	August 23, 2024
Hearing on Claim Construction	February 22, 2024	Weeks of September 3 or September 9, 2024, if convenient for the Court

Event	Current Deadline	New Proposed Deadline
Initial Expert Reports Due	April 5, 2024	October 4, 2024
Rebuttal Expert Reports Due	May 17, 2024	November 15, 2024
Reply Expert Reports Due	June 21, 2024	December 16, 2024
Expert Discovery Cut-Off	September 12, 2024	February 28, 2025
<i>Daubert</i> Motions with Opening Briefs Due	September 26, 2024	March 14, 2025
Pretrial Conference	December 2, 2024 at 4:30 p.m.	June 2025 at the Court's convenience
Trial (5 day bench)	December 9, 2024	June 2025 at the Court's convenience

Pursuant to D. Del. Local Rule 16.4, counsel for the parties hereby certify that they have provided a copy of this stipulation to their respective clients.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

*/s/ Jeremy A. Tigan*

---

Jeremy A. Tigan (#5239)  
Megan E. Dellinger (#5739)  
1201 North Market Street  
P.O. Box 1347  
Wilmington, DE 19899  
(302) 658-9200  
jtigan@morrisnichols.com  
mdellinger@morrisnichols.com

*Attorneys for Plaintiff*

PHILLIPS, McLAUGHLIN & HALL, P.A.

*/s/ David A. Bilson*

---

John C. Phillips, Jr. (#110)  
David A. Bilson (#4986)  
1200 North Broom Street  
Wilmington, DE 19806-4204  
(302) 655-4200  
jcp@pmhdelaw.com  
dab@pmhdelaw.com

*Attorneys for Lupin Ltd.*

SEITZ, VAN OGTROP & GREEN, P.A.

*/s/ James S. Green, Jr.*

---

James S. Green, Jr. (#4406)  
222 Delaware Avenue, Suite 1500  
Wilmington, DE 19801  
(302) 888-0600  
jsgreen@svglaw.com

*Attorneys for Laurus Labs Limited and  
Cipla Limited*

October 4, 2023

SO ORDERED this \_\_\_\_ day of \_\_\_\_\_, 2023.

---

Hon. Maryellen Noreika  
United States District Judge