

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 ORDER TO AMEND SCHEDULING ORDER

WHEREAS, Defendant Cipla submitted to the U.S. Food and Drug Administration Cipla's ANDA No. 218766, seeking approval to engage in the commercial manufacture, use, importation, offer for sale, and/or sale of Cipla's Pediatric B/F/TAF ANDA Product;

WHEREAS, on or about November 21, 2023, Plaintiff Gilead received from Defendant Cipla a letter ("Notice Letter") pursuant to 21 U.S.C. § 355(j)(2)(B) relating to Cipla's ANDA No. 218766, which includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to Gilead's U.S. Patent Nos. 9,708,342 and 10,385,067;

WHEREAS, on December 29, 2023, Plaintiff filed a lawsuit against Defendant Cipla for infringement of the '342 and '067 patents by Cipla's Pediatric B/F/TAF ANDA Product, *see Gilead Sciences, Inc. v. Cipla Limited*, No. 23-1480 (D. Del. Dec. 29, 2023) ("Pediatric ANDA Litigation");

WHEREAS, the '342 and '067 patents are asserted against all Defendants in the present litigation, and are also asserted against Defendant Cipla in the Pediatric ANDA Litigation;

WHEREAS, Plaintiff and Defendant Cipla expect that the disputed issues of the validity of the '342 and '067 patents and of Defendant Cipla's infringement of those patents will be

substantially similar, and potentially identical, in the present litigation and in the Pediatric ANDA Litigation;

WHEREAS, Plaintiff and Defendant Cipla intend to move to consolidate the Pediatric ANDA Litigation with the present litigation after Defendant Cipla answers Plaintiff's complaint in the Pediatric ANDA Litigation;

WHEREAS, Plaintiff and Defendants agree that the interests of judicial efficiency weigh strongly in favor of litigating and trying the present litigation concurrently with the Pediatric ANDA Litigation, but that the limited additional document production and fact discovery required in the Pediatric ANDA Litigation cannot be completed within the currently scheduled deadlines in the present litigation;

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
Supplementation of Accused Products and Invalidity References	February 2, 2024	May 3, 2024
Fact Discovery Cut Off	March 15, 2024	June 14, 2024
Final Infringement and Invalidity Contentions	April 5, 2024	July 2, 2024
Final Validity and Non-Infringement Contentions	April 26, 2024	July 26, 2024
Submission of Joint Claim Construction Chart	May 3, 2024	August 2, 2024
Plaintiff to Serve Opening Claim Construction Brief	May 31, 2024	August 30, 2024
Defendants to Serve Answering Claim Construction Brief	June 28, 2024	September 27, 2024
Plaintiff to Serve Reply Claim Construction Brief	July 26, 2024	October 25, 2024
Defendants to Serve Sur-Reply Claim Construction Brief	August 16, 2024	November 15, 2024
Parties to File Joint Claim Construction Brief	August 23, 2024	November 22, 2024
Hearing on Claim Construction	September 13, 2024 at 10:00 am	December 18, 2024 at 10:00 a.m.

Event	Current Deadline	New Proposed Deadline
Initial Expert Reports Due	October 4, 2024	January 17, 2025
Rebuttal Expert Reports Due	November 15, 2024	February 28, 2025
Reply Expert Reports Due	December 16, 2024	April 4, 2025
Expert Discovery Cut-Off	February 28, 2025	May 30, 2025
<i>Daubert</i> Motions with Opening Briefs Due	March 14, 2025	Vacated. The parties shall not separately brief or file <i>Daubert</i> motions. The parties shall file any <i>Daubert</i> motions as motions <i>in limine</i> , consistent with the Court's requirements, including page requirements, for such motions.
Pretrial Conference	September 29, 2025 at 4:30 pm	September 29, 2025 at 4:30 pm [no change]
Trial (5 day bench)	October 6–10, 2025	October 6–10, 2025 [no change]

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.

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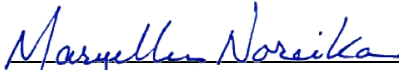
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*Attorneys for Defendants Cipla Limited and
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January 26, 2024

SO ORDERED this 29th day of January 2024.



The Honorable Maryellen Noreika
United States District Judge