

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

GILEAD SCIENCES, INC.	)	
	)	
Plaintiff	)	
	)	
v.	)	C.A. No. 22-cv-00615 (MN)
	)	
LUPIN LTD., LAURUS LABS LIMITED, AND	)	
CIPLA LIMITED,	)	
Defendants.	)	
_____	)	

DEFENDANT CIPLA LIMITED’S NOTICE OF *SOTERA*¹ STIPULATION

WHEREAS this civil action was first filed by Plaintiff on May 9, 2022, asserting infringement of U.S. Patent Nos. 9,708,342, 10,385,067, and 10,548,846 under 35 U.S.C. § 271 (e) arising from the filing by Defendant Cipla Limited (“Cipla”) of an Abbreviated New Drug Application (“ANDA”) with the United States Food and Drug Administration (“FDA”)(D.I. 1); and

WHEREAS Plaintiff first received notice of Cipla’s certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV) with respect to each of U.S. Patent Nos. 9,708,342, 10,385,067, and 10,548,846 on or about April 1, 2022 (D.I. 1 at ¶ 76); and

WHEREAS Plaintiff thereafter filed with the United States Patent Office continuation patent application No. 17/738,803 on May 6, 2022, which led to the issuance of U.S. Patent No. 11,744,802 (the “’802 Patent”) on September 5, 2023; and

WHEREAS the Plaintiff and Cipla agreed, by stipulation dated October 4, 2023 to permit

¹In *Sotera Wireless, Inc. v. Masimo Corp.*, “Petitioner filed a stipulation in District Court.” IPR2020-01019, Paper 12 at 13 (Dec. 1, 2020) (filing stipulation in *Masimo Corporation v. Sotera Wireless, Inc.*, No. 3:19-cv-01100-BAS-MSB, Dkt. 86 (S.D. Cal. Oct. 15, 2020)).

Plaintiff to serve and Amended Complaint, adding claims of infringement of the '802 Patent to the present litigation (D.I. 159); and

WHEREAS both Cipla and Plaintiff have agreed, based on a Paragraph III certification to U.S. Patent No. 9,216,996 (which is listed on the Orange Book with an expiration date of December 19, 2033) that “even if successful in this suit the earliest [Cipla] could launch a generic version of Biktarvy® would be upon expiration of the '996 patent—a date long after the end of the stay in this matter;” (D.I. 159, p. 1-2); and

WHEREAS Plaintiff served Cipla with an Amended Complaint, asserting the '802 patent on November 16, 2023 (D.I. 170); and

WHEREAS on October 28, 2024, Cipla filed a Petition for *Inter Partes* Review (“Petition”) with the Patent Trial and Appeal Board requesting that all claims of the '802 Patent be held unpatentable, and the *Inter Partes* Review (“IPR”) proceeding was assigned the number IPR2025-00033; and

WHEREAS Cipla’s Petition asserts the following grounds of invalidity:

IPR Petition No.	Patent No.	IPR Ground	Claims	Grounds of Unpatentability
IPR2025-00033	11,744,802	35 U.S.C. § 103 (Obviousness)	1–13	WO 2014/1003223 and WO 2015/022351
IPR2025-00033	11,744,802	35 U.S.C. § 103 (Obviousness)	1–13	WO 2014/1003223; WO 2015/022351; Michael J. Bowker, “A Procedure for Salt Selection and Optimization” <i>in</i> HANDBOOK OF PHARMACEUTICAL SALTS: PROPERTIES, SELECTION, AND USE 161–89 (P. Heinrich Stahl & Camille G. Wermuth eds., 2002); and Paulekuhn et al., “Trends in Active Pharmaceutical Ingredient Salt Selection Based on Analysis of the Orange Book

				Database,” 50 J. MED. CHEM. 6665–72 (2007)
IPR2025-00033	11,744,802	35 U.S.C. § 103 (Obviousness)	1–13	WO 2014/1003223; WO 2015/022351; and 2015/231079

NOW, THEREFORE, Cipla hereby gives notice of, and stipulates that:

- (1) if the Patent Trial and Appeal Board institutes IPR in IPR2025-00033, then:
 - a. Cipla will not pursue in this case a judgement of invalidity of any claims of the '802 patent on the specific grounds raised in the Petition as identified above; and
 - b. Cipla will not pursue in this case a judgment of invalidity of any claim of the '802 patent on any other ground that reasonably could have been raised in an IPR proceeding.

Because parties are frequently encouraged by this Court in Hatch-Waxman based matters to narrow the claims and defenses to be adjudicated at trial, this stipulation is not intended, and should not be construed, to limit Cipla's ability to assert invalidity defenses of any claims of the '802 Patent that remain asserted by Gilead after claim narrowing, or that remain asserted after conclusion of trial, on any other ground, regardless of whether IPR is instituted.

Further, because Cipla's stipulation does not take effect unless the above IPR petition is granted institution, no other relief is sought by Cipla at this time. Pursuant to 35 U.S.C. § 314(b), the Patent Trial and Appeal Board will issue its institution decision on the above *inter partes* review petition no later than May 19, 2025.

Dated: March 27, 2025

SEITZ, VAN OGTROP & GREEN, P.A.

OF COUNSEL:

Christopher J. Sorenson
MERCHANT & GOULD PC
150 South Fifth Street, Suite 2200
Minneapolis, Minnesota 55402
(612) 332-5300
csorenson@merchantgould.com

Andrew O. Larsen
MERCHANT & GOULD PC
500 Fifth Avenue, Suite 4100
New York, NY 10110
(212) 223-6520
alarsen@merchantgould.com

B. Jefferson Boggs
MERCHANT & GOULD PC
1900 Duke Street, Suite 600
Alexandria, Virginia 22314
(703) 684-2500
jboggs@merchantgould.com

/s/ James S. Green, Jr.

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

Attorneys for Cipla Limited