

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

ACERTA PHARMA B.V. et al.,

Plaintiffs,

v.

ALEMBIC PHARMACEUTICALS
LIMITED, et al.,

Defendants.

C.A. No. 22-154-GBW-SRF
(Consolidated)

**STIPULATION AND [PROPOSED] ORDER REGARDING CLAIM CONSTRUCTION
FOR U.S. PATENT NOS. 9,758,524; 10,239,883; 9,796,721; 10,167,291; 10,272,083**

WHEREAS, the Scheduling Order entered in this consolidated action sets forth a schedule for claim construction briefing, and the *Markman* hearing is currently set for August 31, 2023 at 9:00 a.m.;

WHEREAS, the parties exchanged claim terms and proposed constructions for U.S. Patent Nos. 9,758,524 (“’524 Patent”), 10,239,883 (“’883 Patent”), 9,796,721 (“’721 Patent”), 10,167,291 (“’291 Patent”), and 10,272,083 (“’083 Patent”) (collectively, the “Asserted Patents”) in accordance with the Scheduling Order, and have conferred and reached an agreement on the claims terms at issue;

WHEREAS, the parties agree that no terms of the Asserted Patents require a *Markman* construction by the Court at this time, *i.e.*, the parties are not proposing competing constructions for any terms; and

WHEREAS, the parties agree to defer the indefiniteness arguments that Defendants preserved in their invalidity contentions until a later stage in the litigation;

IT IS HEREBY STIPULATED AND AGREED, by and between Plaintiffs Acerta Pharma B.V., AstraZeneca UK Limited, AstraZeneca Pharmaceuticals LP, AstraZeneca AB, and Merck Sharp & Dohme B.V. and Defendants Alembic Pharmaceuticals Limited, Cipla Ltd. and Cipla USA Inc., MSN Pharmaceuticals Inc., MSN Laboratories Private Limited, Natco Pharma, Inc. & Natco Pharma Limited and Sandoz Inc., subject to the approval of the Court, that:

1. The Scheduling Order (D.I. 30) shall be amended to remove the following deadlines and the Claim Construction Hearing from the Court's calendar:

Event	Deadline
Joint Claim Construction Chart	March 13, 2023
Opening Claim Construction Brief	April 10, 2023
Answering Claim Construction Brief	May 15, 2023
Reply Claim Construction Brief	June 19, 2023
Sur-Reply Claim Construction Brief	July 24, 2023
Joint Claim Construction Brief	July 31, 2023
Claim Construction Hearing	August 31, 2023 at 9:00 a.m.

2. In light of the requested cancellation of the claim construction deadlines, including the joint claim construction chart, the parties wish to memorialize their agreed-upon constructions as set forth below, which would have otherwise been presented in a joint claim construction chart:

	Claim Terms/Phrases	Agreed-Upon Construction
1.	“A method of treating Mantle Cell Lymphoma (MCL) in a human subject, the method comprising administering to the human subject” ’524 Patent (claim 1; required limitation of all asserted claims)	The quoted preamble language is limiting as to the intentional purpose for which the method must be performed, i.e., treating Mantle Cell Lymphoma (MCL) in a human subject, which requires treating MCL in a human subject, but does not require a particular level of efficacy.
2.	“A method of treating chronic lymphocytic leukemia (CLL) in a human subject, the method comprising administering to the human subject” ’883 Patent (claim 1; required limitation of all asserted claims)	The quoted preamble language is limiting as to the intentional purpose for which the method must be performed, i.e., treating chronic lymphocytic leukemia (CLL) in a human subject, which requires treating CLL in a human subject, but does not require a particular level of efficacy.

3.	“characterized by a reflection X-ray powder diffraction pattern comprising peaks at $6.4^{\circ}\pm 0.2^{\circ} 2\theta$, $8.6^{\circ}\pm 0.2^{\circ} 2\theta$, $10.5^{\circ}\pm 0.2^{\circ} 2\theta$, $11.6^{\circ}\pm 0.2^{\circ} 2\theta$ and $15.7^{\circ}\pm 0.2^{\circ} 2\theta$” ’721 Patent (claim 1; required limitation of all asserted claims) ’291 Patent (claims 1 and 14; required limitation of all asserted claims)	characterized by a reflection X-ray powder diffraction pattern that includes, but is not limited to, each of the following peaks at $6.4^{\circ}\pm 0.2^{\circ} 2\theta$, $8.6^{\circ}\pm 0.2^{\circ} 2\theta$, $10.5^{\circ}\pm 0.2^{\circ} 2\theta$, $11.6^{\circ}\pm 0.2^{\circ} 2\theta$ and $15.7^{\circ}\pm 0.2^{\circ} 2\theta$. The peaks identified in the specification, including the claims, of the ’721 and ’291 Patents, were measured using Cu—Kα radiation. The source of radiation, Cu—Kα, is not a limitation of this claim, and the use of Cu—Kα radiation is not required to prove infringement of this claim.
4.	“$\pm 0.2^{\circ} 2\theta$” ’721 Patent (claims 1-4; required limitation of all asserted claims) ’291 Patent (claims 1-3 and 15-16; required limitation of all asserted claims)	within a maximum of $0.2^{\circ} 2\theta$ above or below the recited peak.
5.	“95-105 mg of a crystal form of (S)-4-(8-amino-3-(1-(but-2-ynoyl)pyrrolidin-2-yl)imidazo[1,5-a]pyrazin-1-yl)-N-(pyridin-2-yl)benzamide characterized by” ’291 Patent (claims 1 and 14; required limitation of all claims)	at least 95 mg and no more than 105 mg must be in a crystal form of (S)-4-(8-amino-3-(1-(but-2-ynoyl)pyrrolidin-2-yl)imidazo[1,5-a]pyrazin-1-yl)-N-(pyridin-2-yl)benzamide where the crystal form is characterized by
6.	“A method of treating chronic lymphocytic leukemia (CLL) or small lymphocytic leukemia (SLL) in a human subject suffering therefrom comprising the step of orally administering, to the human subject” ’083 Patent (claim 1; required limitation of claims 2-7 and 15-18)	The quoted preamble language is limiting as to the intentional purpose for which the method must be performed, i.e., treating chronic lymphocytic leukemia (CLL) or small lymphocytic leukemia (SLL) in a human subject suffering therefrom, which requires treating CLL or SLL in a human subject, but does not require a particular level of efficacy.

7.	“A method of treating a mantle cell lymphoma (MCL) in a human subject suffering therefrom comprising the step of orally administering, to the human subject” ’083 Patent (claim 8; required limitation of claims 9-14, 19-20)	The quoted preamble language is limiting as to the intentional purpose for which the method must be performed, i.e., treating Mantle Cell Lymphoma (MCL) in a human subject suffering therefrom, which requires treating MCL in a human subject suffering therefrom, but does not require a particular level of efficacy.
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DATED: March 13, 2023

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IT IS SO ORDERED this _____ day of _____, 2023.

United States District Judge