

**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)
CONFIDENTIAL

**PLAINTIFFS' INITIAL INFRINGEMENT CONTENTIONS
TO DEFENDANT SANDOZ INC.**

Pursuant to Paragraph 4 of the Court's Scheduling Order (D.I. 30) Plaintiffs Acerta Pharma B.V., AstraZeneca UK Limited, AstraZeneca Pharmaceuticals LP, AstraZeneca AB ("AstraZeneca"), and Merck Sharp & Dohme B.V. ("Merck") (collectively "Plaintiffs") disclose the following initial infringement contentions regarding U.S. Patent No. 9,290,504 ("the '504 patent"); U.S. Patent No. 9,758,524 ("the '524 patent"); U.S. Patent No. 10,239,883 ("the '883 patent"); U.S. Patent No. 9,796,721 ("the '721 patent"); U.S. Patent No. 10,167,291 ("the '291 patent"); and U.S. Patent No. 10,272,083 ("the '083 patent") to Defendant Sandoz Inc. ("Sandoz").

Plaintiffs' initial infringement contentions are based on the information currently available to, and known by, Plaintiffs. These initial infringement contentions are necessarily preliminary, as discovery is only just beginning. Plaintiffs have only received a limited set of documents from Sandoz, and have not obtained other discovery, such as other documents concerning Sandoz's ANDA Product and the active ingredient contained therein, samples of Sandoz's ANDA Product and the active ingredient contained therein, responses to written discovery, or

deposition testimony. Furthermore, the Court has not yet construed any of the asserted claims of the asserted patents. As a result, Plaintiffs reserve the right to modify, amend, or otherwise supplement these initial infringement contentions (including to add additional claims) as the pre-trial phase of the litigation proceeds and as additional information comes to light, and as provided in the Case Scheduling Order, the Federal Rules of Civil Procedure, and the Local Rules of the United States District Court for the District of Delaware.

These initial claim charts are provided without prejudice to Plaintiffs' right to introduce expert opinions and demonstratives as expert discovery progresses, and to produce and introduce at trial all evidence, whenever discovered, relating to the proof of currently known and subsequently discovered facts. In addition, the division of each claim into individual limitations is for convenience only and is without prejudice to Plaintiffs' right to argue for a different division at a later date.

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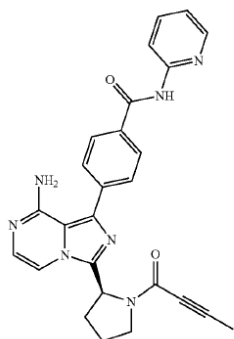
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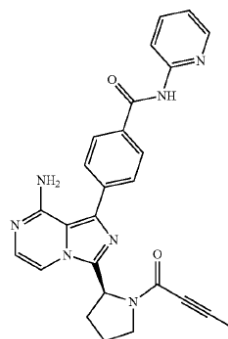
9. The method of claim 8, wherein the BTK inhibitor is a compound of Formula (II):



or a pharmaceutically acceptable salt thereof.

Sandoz's ANDA Product meets the limitations of claim 8 as set forth above. Plaintiffs incorporate by reference their contentions with respect to claim 8.

Sandoz's ANDA Product contains a pharmaceutical composition comprising the compound of Formula (II), specifically acalabrutinib, having the structure:



SDZACAL-00000650 at *754, *799; SDZACAL-00001232 at *233–234.

In addition, Sandoz in its December 28, 2021 Notice Letter does not substantively contest that its proposed labeling provides for a method of treating MCL that meets the limitations of claim 9, despite that Sandoz was required in its Notice Letter to state its bases for any contention that its ANDA Product would not infringe the '083 patent.

To the extent the use of Sandoz's ANDA Product in accordance with its proposed label does not literally infringe this claim, any differences are insubstantial. For each claim limitation, there is a corresponding aspect of the use of Sandoz's ANDA Product in accordance with its proposed labeling that performs substantially the same function in substantially the same way to achieve substantially the same result. Therefore Sandoz's ANDA Product infringes under the doctrine of equivalents, even assuming it does not infringe literally.

10. The method of claim 9, wherein the Mantle Cell Lymphoma (MCL) increases monocytes and NK cells in peripheral blood after treatment with Formula (II) for a period selected from the group consisting of about 14 days, about 28 days, and about 56 days.

Sandoz's ANDA Product meets the limitations of claim 9 as set forth above. Plaintiffs incorporate by reference their contentions with respect to claim 9.

The proposed labeling for Sandoz's ANDA Product directs, encourages, recommends, and promotes a

	method of treating MCL wherein the MCL increases monocytes and NK cells in peripheral blood after treatment with the compound of Formula (II) for a period selected from the group consisting of about 14 days, about 28 days, and about 56 days. One known salutary effect of the treatment of MCL with the compound of Formula (II) is to increase the levels of monocytes and natural killer cells in peripheral blood. '083 patent, col. 4, ll. 34–52; col. 67, l. 64–col. 68, l. 41. Moreover, the proposed labeling for Sandoz's ANDA Product directs, encourages, recommends, and promotes a method of treating MCL wherein the BTK inhibitor compound of Formula (II) is administered to the human subject for a period selected from the group consisting of about 14 days, about 28 days, and about 56 days. <i>See</i> SDZACAL-00004047 at *051 (describing clinical trials where MCL patients received acalabrutinib for a period ranging from “0.1 to 26.6[] months”). In addition, Sandoz in its December 28, 2021 Notice Letter does not substantively contest that its proposed labeling provides for a method of treating MCL that meets the limitations of claim 10, despite that Sandoz was required in its Notice Letter to state its bases for any contention that its ANDA Product would not infringe the '083 patent. To the extent the use of Sandoz's ANDA Product in accordance with its proposed label does not literally infringe this claim, any differences are insubstantial. For each claim limitation, there is a corresponding aspect of the use of Sandoz's ANDA Product in accordance with its proposed labeling that performs substantially the same function in substantially the same way to achieve substantially the same result. Therefore Sandoz's ANDA Product infringes under the doctrine of equivalents, even assuming it does not infringe literally.
11. The method of claim 9, wherein the MCL is selected from the group consisting of mantle zone MCL, nodular MCL, diffuse MCL, and blastoid MCL.	Sandoz's ANDA Product meets the limitations of claim 9 as set forth above. Plaintiffs incorporate by reference their contentions with respect to claim 9. The proposed labeling for Sandoz's ANDA Product directs, encourages, recommends, and promotes a

	method of treating MCL wherein the MCL is selected from the group consisting of mantle zone MCL, nodular MCL, diffuse MCL, and blastoid MCL. The subtypes of MCL commonly treated with acalabrutinib include mantle zone MCL, nodular MCL, diffuse MCL, and blastoid MCL. In addition, Sandoz in its December 28, 2021 Notice Letter does not substantively contest that its proposed labeling provides for a method of treating MCL that meets the limitations of claim 11, despite that Sandoz was required in its Notice Letter to state its bases for any contention that its ANDA Product would not infringe the '083 patent. To the extent the use of Sandoz's ANDA Product in accordance with its proposed label does not literally infringe this claim, any differences are insubstantial. For each claim limitation, there is a corresponding aspect of the use of Sandoz's ANDA Product in accordance with its proposed labeling that performs substantially the same function in substantially the same way to achieve substantially the same result. Therefore Sandoz's ANDA Product infringes under the doctrine of equivalents, even assuming it does not infringe literally.
15. The method of claim 2, the method comprising treating chronic lymphocytic leukemia (CLL) in a human subject suffering from CLL.	Sandoz's ANDA Product meets the limitations of claim 2 as set forth above. Plaintiffs incorporate by reference their contentions with respect to claim 2. The proposed labeling for Sandoz's ANDA Product directs, encourages, recommends, and promotes a method of treating chronic lymphocytic leukemia (CLL) and/or small lymphocytic leukemia (SLL) in a human subject suffering therefrom for the reasons detailed in Plaintiffs' contentions with respect to claim 1. Plaintiffs incorporate by reference their contentions with respect to claim 1. To the extent the use of Sandoz's ANDA Product in accordance with its proposed label does not literally infringe this claim, any differences are insubstantial. For each claim limitation, there is a corresponding aspect of the use of Sandoz's ANDA Product in accordance with its proposed labeling that performs