

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SANDOZ INC.,
Petitioner,

v.

ACERTA PHARMA B.V.,
Patent Owner.

Case IPR2023-00478
Patent 10,272,083 B2

PETITION FOR *INTER PARTES* REVIEW

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C. “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” (claim 10)	17
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A. Ground 1: Claims 8-12 and 19-20 would have been obvious over Barf and Cheson.27

1. Claim 827

 a. “A method of treating a mantle cell lymphoma (MCL) in a human subject suffering therefrom comprising the step of”27

 b. “orally administering, to the human subject, ... a BTK inhibitor, wherein the BTK inhibitor is a compound of Formula (II) ... or a pharmaceutically-acceptable salt, hydrate, or solvate thereof.”28

 c. “a dose of 100 mg twice daily”28

 i. A 100 mg dose would have been obvious.....29

 (1) Barf discloses and claims a range that encompasses the claimed dose.....29

 (2) A POSA practicing Barf would have arrived at a 100 mg dose by conducting a routine dose-finding study.34

 ii. Twice-daily dosing would have been obvious....40

2. Claim 944

3. Claim 1044

4. Claim 1147

5. Claim 1248

6. Claim 1949

7. Claim 2049

B. Ground 2: Claims 8-12 and 19-20 would have been obvious over Barf-PCT and Cheson.49

1. Claim 850

 a. “A method of treating a mantle cell lymphoma (MCL) in a human subject suffering therefrom comprising the step of”50

 b. “orally administering, to the human subject, ... a BTK inhibitor, wherein the BTK inhibitor is a compound of Formula (II) ... or a pharmaceutically-acceptable salt, hydrate, or solvate thereof.”50

c. “a dose of 100 mg twice daily”51

2. Claim 952

3. Claim 1053

4. Claim 1153

5. Claim 1253

6. Claim 1954

7. Claim 2054

C. There are no probative secondary considerations.54

1. The results submitted during prosecution fail to demonstrate probative unexpected results.55

a. A daily dose of 200 mg acalabrutinib (100 mg BID) does not produce probative unexpected results.55

b. Acalabrutinib’s twice-daily dosing does not produce probative unexpected results.59

2. The results in the specification fail to demonstrate probative unexpected results.64

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A. The Board should not deny review under §314(a).67

B. The Board should not deny review under §325(d).67

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