Trials@uspto.gov
571-272-7822

Paper 12
Entered: February 16, 2021

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BIOCON PHARMA LIMITED,
Petitioner,

v.

NOVARTIS PHARMACEUTICALS CORPORATION,
Patent Owner.

IPR2020-01263
Patent 8,101,659 B2

Before ERICA A. FRANKLIN, ROBERT A. POLLOCK, and KRISTI L. R. SAWERT, *Administrative Patent Judges.*

SAWERT, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. §§ 314, 325(d)

I. INTRODUCTION

Biocon Pharma Limited ("Petitioner") filed a Petition (Paper 1, "Pet.") requesting *inter partes* review of claims 1–4 of U.S. Patent No. 8,101,659 B2 (Ex. 1001, "the '659 patent") pursuant to 35 U.S.C. § 311. Novartis Pharmaceuticals Corporation ("Patent Owner") timely filed a Preliminary Response (Paper 7, "Prelim. Resp."). On our authorization (Paper 9, "Order"), Petitioner filed a preliminary Reply (Paper 10, "Reply") and Patent Owner filed a preliminary Sur-Reply (Paper 11, "Sur-Reply").

We have the authority and discretion to determine whether to institute an *inter partes* review. 35 U.S.C. § 314; 37 C.F.R. § 42.4. We may not institute an *inter partes* review "unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). After considering the Petition, Preliminary Response, Reply, and Sur-Reply, as well as the associated evidence, we exercise our discretion to deny institution of *inter partes* review under 35 U.S.C. §325(d).

II. BACKGROUND

A. Real Parties-In-Interest

Petitioner identifies Biocon Limited, Biocon Pharma Limited, and Biocon Pharma, Inc. as the real parties-in-interest. Pet. 70. Patent Owner identifies Novartis Pharmaceuticals Corporation as the real party-in-interest. Paper 6, 1.

B. Related Matters

Petitioner and Patent Owner state the '659 patent has been, or is, at issue in several judicial proceedings. Pet. 7–9; Paper 6, 1. Patent Owner specifically identifies the following judicial proceedings as related matters: (1) *In Re: Entresto (Sacubitril/Valsartan) Patent Litig.*, No. 20-md-2930-

LPS; (2) *Novartis Pharm. Corp. v. Alkem Labs. Ltd.*, No. 19-cv-1979-LPS (D. Del.); (3) *Novartis Pharm. Corp. v. Alembic Pharm. Ltd.*, No. 19-cv-2021-LPS (D. Del.); (4) *Novartis Pharm. Corp. v. Dr. Reddy's Labs., Inc.*, No. 19-cv-2053-LPS (D. Del.); (5) *Novartis Pharm. Corp. v. Alembic Pharm. Ltd.*, No. 20-cv-74-LPS (D. Del.); (6) *Novartis Pharm. Corp. v. Lupin Atlantis Holdings, S.A.*, No. 20-cv-415-LPS (D. Del.); (7) *Novartis Pharm. Corp. v. Mylan Pharm. Inc.*, No. 20-cv-445-LPS (D. Del.); (8) *Novartis Pharm. Corp. v. Mylan Pharm. Inc.*, No. 19-cv-201-IMK (N.D. W.Va.); and (9) *Novartis Pharm. Corp. v. Macleods Pharm. Ltd.*, No. 19-cv-19345 (D.N.J.) (dismissed). Paper 6, 1.

C. The '659 Patent (Ex. 1001)

The '659 patent, titled "Methods of Treatment and Pharmaceutical Composition," issued January 24, 2012, based on an application filed June 27, 2008. Ex. 1001, codes (22), (45), (54). The '659 patent relates to a pharmaceutical composition comprising valsartan and an NEP inhibitor, namely, N-(3-carboxy-1-oxopropyl)-(4S)-(p-phenylphenylmethyl)-4-amino-2R-methylbutanoic acid ethyl ester ("sacubitril") or (2R,4S)-5-biphenyl-4-yl-4(3-carboxy-propionyl amino)-2-methyl-pentanoic acid. *Id.* at 3:19–22, 16:16–25. Valsartan is an AT 1-receptor antagonist. According to the '659 patent, AT 1-receptor antagonists "can be used, e.g., as anti-hypertensive's [*sic*] or for the treatment of congestive heart failure, among other conditions." *Id.* at 1:49–51. NEP inhibitors "lower blood pressure and exert ANF-like effects, such as diuresis and increased cyclic guanosine 3′,5′-monophosphate (cGMP) excretion." *Id.* at 2:39–43.[1]

[1] The written description of the '659 patent explains that ANFs (atrial natriuretic factors), "also known as ANPs, brain natriuretic peptide (BNP), met and leu enkephalin, bradykinin, neurokinin A and substance P . . . . are a

The '659 patent states that "combination therapy with valsartan and a NEP inhibitor results in a more effective anti-hypertensive therapy . . . through improved efficacy, as well as a greater responder rate." *Id.* at 6:65–7:3. In particular, the '659 patent states that "[i]t has surprisingly been found that, a combination of valsartan and a NEP inhibitor achieves greater therapeutic effect than the administration of valsartan, ACE inhibitors or NEP inhibitors alone and promotes less angioedema than is seen with the administration of a vasopeptidase inhibitor alone." *Id.* at 6:41–45. The '659 patent states that the combination therapy "is also useful in the treatment or prevention of heart failure." *Id.* at 7:3–4.

D. Illustrative Claim

Of the challenged claims, claim 1 is independent. Ex. 1001, 16:16–33. Claims 2–4 depend, directly or indirectly, from claim 1. *Id.* at 16:34–47. Claim 1, reproduced below, illustrates the claimed subject matter:

> 1. A pharmaceutical composition comprising:
>
> (i) the AT 1-antagonist valsartan or a pharmaceutically acceptable salt thereof;
>
> (ii) the NEP inhibitor N-(3-carboxy-1-oxopropyl)-(4S)-(p-phenylphenylmethyl)-4-amino-2R-methylbutanoic acid ethyl ester or (2R,4S)-5-biphenyl-4-yl-4(3-carboxy-propionyl amino)-2-methyl-pentanoic acid or a pharmaceutically acceptable salt thereof, and
>
> (iii) a pharmaceutically acceptable carrier;
>
> wherein said (i) AT 1-antagonist valsartan or pharmaceutically acceptable salt thereof and said (ii) NEP inhibitor N-(3-carboxy-1-oxopropyl)-(4S)-(p-phenylphenylmethyl)-4-amino-2R-methylbutanoic acid ethyl ester or (2R,4S)-5-

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family of vasodilator, diuretic and anti-hypertensive peptides," and among the substrates for the zinc-metalloprotease, NEP (neutral endopeptidase). *Id.* at 2:10–21.

biphenyl-4-yl-4(3-carboxy-propionylamino)-2-methyl-pentanoic acid or pharmaceutically acceptable salt thereof, are administered in combination in about a 1:1 ratio.

Id. at 16:16–33.

E. Asserted Evidence

Petitioner submits the following evidence:

Evidence	**Exhibit No.**
EP 0 726 072 A2 (published Aug. 14, 1996) ("EP '072")	1002
Shetty and DelGrande, *Differential Inhibition of the Prejunctional Actions of Angiotensin II in Rat Atria by Valsartan, Irbesartan, Eprosartan, and Losartan*, J. PHARMACOL. EXP. THER. 294:179–186 (2000) ("Shetty")	1004
Gomez-Monterrey et al., *New Thiol Inhibitors of Neutral Endopeptidase EC 3.4.24.11: Synthesis and Enzyme Active-Site Recognition*, J. MED. CHEM. 37:1865–1873 (1994) ("Gomez-Monterrey")	1005
Ksander et al., *Dicarboxylic Acid Dipeptide Neutral Endopeptidase Inhibitors*, J. MED. CHEM. 38:1689–1700 (1995) ("Ksander")	1006
U.S. Pat. No. 5,217,996 (issued June 8, 1993) ("the '996 patent")	1009
Physicians' Desk Reference, Edition 54 (2000) ("PDR").	1012
Declaration of Y.W. Francis Lam, Pharm.D.	1018

F. Asserted Grounds of Unpatentability

Petitioner asserts that claims 1–4 are unpatentable under 35 U.S.C. § 103(a)[2] based on the following grounds:

[2] The Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) ("AIA"), amended several provisions of 35 U.S.C., including § 103. Because the '659 patent claims priority to an application that has an effective filing date prior to the effective date of the applicable AIA amendments, we refer herein to the pre-AIA version of § 103.

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