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Paper 15
Date: January 4, 2023

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner,

v.

BAUSCH HEALTH IRELAND LIMITED,
Patent Owner.

IPR2022-01105
Patent 9,925,231 B2

Before SHERIDAN SNEDDEN, CYNTHIA M. HARDMAN, and MICHAEL A. VALEK, *Administrative Patent Judges.*

HARDMAN, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 314
Granting Patent Owner's Motion to Seal and Enter Default Protective Order
37 C.F.R. §§ 42.14, 42.54

I. INTRODUCTION

Petitioner Mylan Pharmaceuticals Inc. requests *inter partes* review of claims 1–12 of U.S. Patent No. 9,925,231 B2 ("the '231 patent," Ex. 1001). Paper 2 ("Pet."). Patent Owner Bausch Health Ireland Limited filed a Preliminary Response. Paper 7 ("Prelim. Resp."); Paper 3, 1. The parties also filed authorized additional briefing concerning discretionary denial under 35 U.S.C. § 325(d). Papers 12, 14.

Considering the arguments and evidence of record, we determine that the Petition does not demonstrate "a reasonable likelihood that [P]etitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). Accordingly, we do not institute an *inter partes* review.

A. Real Parties in Interest

Petitioner identifies itself, Mylan Laboratories Ltd., Mylan Inc., and Viatris Inc. as real parties in interest. Pet. 3–4.

Patent Owner identifies itself and Salix Pharmaceuticals, Inc. as real parties in interest. Paper 3, 1.

B. Related Matters

The parties state that the '231 patent is involved in *Bausch Health Ireland Ltd. v. Mylan Laboratories Ltd.*, 1-22-cv-00020 (N.D. W.Va.); 2-21-cv-00573 (W.D. Pa. (administratively closed)); and *Bausch Health Ireland Ltd. v. MSN Laboratories Pvt. Ltd.*, 2-21-cv-10057 (D.N.J.). Pet. 4; Paper 3, 2–3. Patent Owner additionally identifies *Bausch Health Ireland Ltd. v. Mylan Laboratories Ltd.*, 1-21-cv-00611 (D. Del.) (closed), and 2:21-cv-10403 (D.N.J.) (transferred to N.D. W.Va.). Paper 3, 2–3.

Patent Owner also identifies the following *inter partes* reviews involving patents related to the '231 patent: IPR2022-00722 (U.S. Patent

No. 7,041,786 B2); IPR2022-01102 (U.S. Patent No. 9,610,321 B2); IPR2022-01103 (U.S. Patent No. 9,616,097 B2); and IPR2022-01104 (U.S. Patent No. 9,919,024 B2).

C. The '231 Patent[1]

The '231 patent, titled "Formulations of Guanylate Cyclase C Agonists and Methods of Use," relates to pharmaceutical formulations containing guanylate cyclase-C ("GCC") agonist peptides, including those described in U.S. Patent No. 7,041,786.[2] Ex. 1001, code (54), 1:30–32, 3:20–22, 7:15–16. According to the Specification, formulating "peptides for pharmaceutical delivery presents a number of special problems," including chemical and physical stability problems due to the peptides degrading by a variety of mechanisms. *Id.* at 3:24–29.

The Specification describes exemplary pharmaceutical formulations containing "GCC agonist peptides formulated with one or more excipients such that the peptide is stabilized against chemical degradation." *Id.* at 8:34–36. "The ideal excipient or combination of excipients will be non-hygroscopic, have few or no reducing sugars, and be substantially free of

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[1] The '231 patent claims priority to a series of applications, including PCT/US2011/051805, filed September 15, 2011, and three provisional applications filed in 2010. Ex. 1001, codes (63), (60). Petitioner asserts that during prosecution, the Examiner concluded that the provisional applications did not disclose all claim limitations, and that effective filing date of the claims under examination was September 15, 2011, the filing date of the PCT application. Pet. 10–11. Here, Petitioner assumes, and Patent Owner does not dispute, that the priority date of the challenged claims is September 15, 2011. *Id.*; Prelim. Resp. 40. We similarly assume that the priority date of the challenged claims is September 15, 2011.

[2] U.S. Patent No. 7,041,786 appears in this record as Shailubhai, Ex. 1005.

contaminants." *Id.* at 8:39–42. Excipients may include carriers and lubricants. *Id.* at 9:33–65, 12:10–14, 13:3. One example formulation includes a GCC agonist peptide, an inert carrier, e.g., low-moisture microcrystalline cellulose (Avicel PH 112), and a lubricant, e.g., magnesium stearate. *Id.* at 18:13–30, 94:20–33 (Example 14).

The exemplary formulations include the GCC agonist peptide designated SP-304. *Id.* at 94:10. SP-304, also known as plecanatide, has the amino acid sequence shown in SEQ ID NO:1. *Id.* at 6:63–64, 7:21–25, 21:37, 23:20–23.

D. The Challenged Claims

Petitioner challenges all 12 claims of the '231 patent. Claim 1, the only independent claim, reads:

> 1. An oral dosage formulation of a Guanylate Cyclase-C (GCC) agonist peptide consisting of SEQ ID NO:1, wherein said peptide is a (4,12; 7,15) bicycle, an inert low moisture carrier and a lubricant, wherein the peptide has a chromatographic purity of no less than 91% after storage for at least three months.

Ex. 1001, 249:31–36.

Challenged dependent claims 2–12 depend directly from claim 1 and recite additional features. For example, claims 2, 3, and 5 add limitations regarding purity, stability, and excluding acids. *Id.* at 249:37–42, 249:46–250:32. Claims 4, 6, and 7 further limit the formulation and its packaging. *Id.* at 249:43–45, 250:33–36. Claims 8–9 and 10–12 further limit the lubricant and inert carrier, respectively. *Id.* at 250:37–46.

E. The Asserted Grounds of Unpatentability

Petitioner asserts that claims 1–12 are unpatentable on the following five grounds:

Ground	Claim(s) Challenged	35 U.S.C. §[3]	Reference(s)/Basis
1	1, 2, 4–12	103(a)	Shailubhai,[4] Remington,[5] Mihranyan[6]
2	3	103(a)	Shailubhai, Remington, Mihranyan, Aulton[7]
3	1, 2, 4–6, 8–12	103(a)	2009 Abstract,[8] Doelker[9]
4	3	103(a)	2009 Abstract, Doelker, Aulton
5	7	103(a)	2009 Abstract, Doelker, Zimmer[10]

[3] 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 assumed priority date for the challenged claims of September 15, 2011 (*see supra* n.1) is before the effective date of the applicable AIA amendments, we refer to the pre-AIA version of 35 U.S.C. § 103.

[4] Shailubhai et al., U.S. Patent No. 7,041,786 B2, issued May 9, 2006 ("Shailubhai," Ex. 1005).

[5] Rudnic, *Chapter 45: Oral Solid Dosage Forms*, in REMINGTON: THE SCIENCE AND PRACTICE OF PHARMACY 21st ed. (2005) ("Remington," Ex. 1006).

[6] Mihranyan et al., *Moisture Sorption by Cellulose Powders of Varying Crystallinity*, 269(2) Int. J. Pharm. 433–442 (2004) ("Mihranyan," Ex. 1007).

[7] Aulton, *Pharmaceutics: The Science of Dosage Form Design* (2nd ed. 2001) ("Aulton," Ex. 1029).

[8] Shailubhai et al., *SP-304 to Treat GI Disorders – Effects of a Single, Oral-Dose of SP-304 on Safety, Tolerability, Pharmacokinetics and Pharmacodynamics in Healthy Volunteers*, 136(5) Gastroenterol. A641, Abstract W1041 (2009) ("2009 Abstract," Ex. 1009).

[9] Doelker et al., *Morphological, Packing, Flow and Tableting Properties of New Avicel Types*, 21(6) Drug Dev. Ind. Pharm. 643–661 (1995) ("Doelker," Ex. 1010).

[10] Zimmer et al., WO 2008/106429, published Sept. 4, 2008 ("Zimmer," Ex. 1011).

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