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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.

IPR2022-01102
Patent 9,610,321 B2

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

SNEDDEN, *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

A. Background and Summary

Mylan Pharmaceuticals, Inc. ("Petitioner") filed a Petition requesting an *inter partes* review of claims 1–16 of U.S. Patent No. 9,610,321 B2 ("the '321 patent," Ex. 1001). Paper 2 ("Pet."). Bausch Health Ireland Limited ("Patent Owner") filed a Preliminary Response to the Petition. Paper 7 ("Prelim. Resp.").

To institute an *inter partes* review, we must determine that the information presented in the Petition shows "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) (2018). The Supreme Court has held that a decision to institute under 35 U.S.C. § 314 may not institute on less than all claims challenged in the petition. *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1359–60 (2018). After considering the evidence and arguments presented in the Petition, we determine that Petitioner has not demonstrated a reasonable likelihood of success in proving that claims 1–16 of the '321 patent is unpatentable.

B. Real Parties-in-Interest

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

Patent Owner identifies itself and Salix Pharmaceuticals, Inc. as real parties-in-interest. Paper 3, 2.

C. Related Matters

Petitioner has filed petitions for *inter partes* review involving patents related to the '321 patent in IPR2022-00722 (Patent 7,041,786); IPR2022-

01103 (Patent 9,616,097), IPR2022-01104 (Patent 9,919,024), and IPR2022-01105 (Patent 9,925,231). Pet. 4; Paper 3, 3–4.

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.

D. The '321 patent (Ex. 1001)

The '321 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.[1] Ex. 1001, code (54), 1:30–32, 3:19–20, 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 3:24–28.

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 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

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

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.

E. Representative Claims

Independent claims 1 and 3, reproduced below, are representative of the claims challenged in this proceeding.

> 1. A method for treating chronic constipation in a human subject comprising
>
> > orally administering to said human subject a composition consisting of a per unit dose of 3 mg or 6 mg of a peptide consisting of SEQ ID NO:1
> >
> > wherein the peptide is a [4,12; 7,15] bicycle, an inert low moisture carrier, and a lubricant, and
> >
> > wherein the peptide has a chromatographic purity of no less than 91% after storage for at least three months.
>
> 3. A method of treating or alleviating a symptom associated with chronic idiopathic constipation or irritable bowel syndrome in a human subject comprising
>
> > orally administering to said human subject a composition consisting of a per unit dose of 3 mg or 6 mg of a peptide consisting of SEQ ID NO:1
> >
> > wherein the peptide is a [4,12; 7,15] bicycle, an inert low moisture carrier, and a lubricant, and
> >
> > wherein the peptide has a chromatographic purity of no less than 91% after storage for at least three months.

Ex. 1001, 253:12–19, 23–30.

Challenged dependent claims 2, 5–7, and 11–13 depend directly or indirectly from claim 1. Challenged dependent claims 4, 8–10, and 14–16 depend directly or indirectly from claim 3.

F. Asserted Grounds of Unpatentability

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

Ground	Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1	1–6, 8–9, 11–16	103(a)	Shailubhai,[2] Camilleri,[3] Remington,[4] Mihranyan[5]
2	7, 10	103(a)	Shailubhai, Camilleri, Remington, Mihranyan, Currie[6]

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

[3] Camilleri et al., *Challenges to the Therapeutic Pipeline for Irritable Bowel Syndrome: End Points and Regulatory Hurdles*, GASTROENTEROL., 135, 1877–1891 (2008) ("Camilleri," Ex. 1031).

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

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

[6] Currie et al., *Methods and Compositions for the Treatment of Gastrointestinal Disorders*, U.S. Patent Publication No. 2005/0020811 (2005) ("Currie," Ex. 1032).

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