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Paper 12
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BRECKENRIDGE PHARMACEUTICAL, INC.,
Petitioner,

v.

NOVARTIS PHARMACEUTICALS CORP.,
Patent Owner.

Case IPR2017-01592
Patent 8,410,131 B2

Before SHERIDAN K. SNEDDEN, ROBERT A. POLLOCK, and JACQUELINE T. HARLOW, *Administrative Patent Judges*.

POLLOCK, *Administrative Patent Judge.*

DECISION
Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

Breckenridge Pharmaceutical, Inc. ("Petitioner") filed a Petition for an *inter partes* review of claims 1–3 and 5–9 of U.S. Patent No. 8,410,131 B2 ("the '131 patent," Ex. 1001). Paper 1 ("Pet."). Novartis Pharmaceuticals Corp. ("Patent Owner" or "Novartis") timely filed a Preliminary Response. Paper 9 ("Prelim. Resp."). We review the Petition, Preliminary Response, and accompanying evidence under 35 U.S.C. § 314.

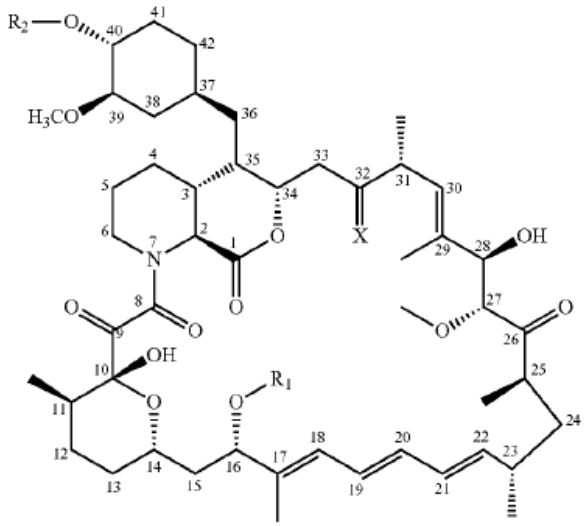
For the reasons provided below, we determine Petitioner has satisfied the threshold requirement set forth in 35 U.S.C. § 314(a). Because Petitioner has demonstrated a reasonable likelihood that at least claim 1 of the '131 patent is unpatentable, we institute an *inter partes* review of the challenged claims.

A. *Related Proceedings*

According to the parties, the '131 Patent is at issue in *Novartis Pharm. Corp. v. West-Ward Pharm. Int'l. Ltd.*, C.A. No. 15-0474-RGA (D. Del.); *Novartis Pharm. Corp. v. Breckenridge Pharm., Inc.*, C.A. No. 16-0431-RGA (D. Del.); *Novartis Pharm. Corp. v. Teva Pharm. USA, Inc.*, C.A. No. 17-0393-RGA (D. Del.); and *Novartis Pharm. Corp. v. Breckenridge Pharm., Inc.*, C.A. No. 17-0420-RGA (D. Del.). Pet. 4; Paper 3; Paper 6.

B. *The '131 Patent and Relevant Background*

The '131 patent relates to "a new use" for the macrolide antibiotic rapamycin and derivatives thereof, including compounds of formula I:



wherein
R_1 is CH_3 or $C_{3\text{-}6}$alkynyl, R_2 is H or -CH_2-CH_2OH, and
X is =0, (H, H) or (H, OH)
provided that R_2 is other than H when X is =0 and R_1 is CH_3.

Ex. 1001, 1–36. A preferred compound within the genus of formula I is 40-O-(2-hydroxyethyl)-rapamycin, also known as everolimus, which is depicted in claim 1 of the '131 Patent (subject to the Certificate of Correction dated October 20, 2015). *See id.* at 1:42–48; Pet. 14, 33; Prelim. Resp. 13.[1]

According to the Specification:

> Compounds of formula I have, on the basis of observed activity, e.g. binding to macrophilin-12 (also known as FK-506 binding protein or FKBP-12) . . . been found to be useful e.g. as immunosuppressant, e.g. in the treatment of acute allograft rejection. It has now been found that Compounds of formula I have potent antiproliferative properties which

[1] Petitioner notes, and Patent Owner does not dispute, that 40-O-(2-hydroxyethyl)-rapamycin is variously referred to as "Compound A" of the '131 Patent, "SDZ RAD, RAD, RAD001, and Certican®." Pet. 6, n.4. For consistency, we refer to this compound as everolimus.

> make them useful for cancer chemotherapy, particularly of solid tumors, especially of advanced solid tumors.

Id. at 1:49–58. The Specification defines "solid tumors" as "tumors and/or metastasis (wherever located) other than lymphatic cancer," including excretory system tumors (e.g. kidney, renal pelvis, ureter, bladder, and unspecified urinary organs). *Id.* at 2: 20–29.

C. *Challenged Claims*

Petitioner challenges claims 1–3 and 5–9 of the '131 Patent, of which only claim 1 is independent. Claim 1 recites:

> 1. A method for inhibiting growth of solid excretory system tumors in a subject, said method consisting of administering to said subject a therapeutically effective amount of [everolimus].

Depending from claim 1, claims 2 and 3, respectively, specify that the solid excretory system tumor is "an advanced solid excretory system tumor," or "a kidney tumor." Claim 5 specifies that the everolimus is administered orally. Claims 6–9 recite amounts of everolimus administered, most narrowly specified in claim 9 as "a unit dosage form of 10 mg.

D. *Asserted Grounds of Unpatentability*

Petitioner asserts the following grounds of unpatentability (Pet. 6–7):

Ground	Claim(s)	Basis	Reference(s)
1	1–3 and 5–9	§ 102(a)/102(e)(1)	Wasik[2]
2	1–3 and 5–9	§ 103(a)	Wasik alone or in combination with Navarro[3]

[2] WO 01/51049 A1, published July 19, 2001. Ex. 1002.
[3] WO 00/33878 A2, published Dec. 6, 1999. Ex. 1003.

Ground	Claim(s)	Basis	Reference(s)
3	1–3 and 5–9	§ 103(a)	Wasik, Navarro, Crowe,[4] and Luan[5]
4	1–3 and 5–9	§ 103(a)	Alexandre,[6] Crowe, Hidalgo,[7] Schuler,[8] Neumayer, and Navarro, [9]
5	1–3 and 5–9	§ 103(a)	Alexandre, Crowe, Hidalgo, Schuler, Neumayer, Navarro, and Luan

In support of its patentability challenges, Petitioner relies on the Declaration of Allan J. Pantuck, M.D. Ex. 1010. Patent Owner relies on the Declaration of Howard A. Burris, III, M.D. Ex. 2001.

[4] Crowe et al., *Absorption and Intestinal Metabolism of SDZ-RAD and Rapamycin in Rats*, 27(5) Drug Metab. Disp. 627-632 (1999). Ex. 1004.
[5] Luan et al., *Sirolimus Prevents Tumor Progression: mTOR Targeting for the Inhibition of Neoplastic Progression*, 1 Suppl. 1 Am. J. Transplant. 243, Abstr. No. 428 (2001). Ex. 1005.
[6] Alexandre et al., *CCI-779, A new Rapamycin Analog, Has Antitumor Activity at Doses Including Only Mild Cutaneous Effects and Mucositis: Early Results of an Ongoing Phase I Study*, 5(suppl.), Clin. Cancer Res. 3730s, Abstr. No. 7 (1999). Ex. 1007.
[7] Hidalgo et al., *The Rapamycin-sensitive Signal Transduction Pathway as a Target for Cancer Therapy*, 19(56) Oncogene 6680-6686 (2000). Ex. 1006.
[8] Schuler et al., *SDZ RAD, A New Rapamycin Derivative*, 64(1) Transplantation 36–42 (1997). Ex. 1008.
[9] Neumayer et al., *Entry-into-human Study with the Novel Immunosuppressant SDZ RAD in Stable Renal Transplant Patients*, 48(5) Br. J. Clin. Pharmacol. 694–703 (1999). Ex. 1009.

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