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Paper No. 10
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

WEST-WARD PHARMACEUTICALS INTERNATIONAL LIMITED,
Petitioner,

v.

NOVARTIS PHARMACEUTICALS CORPORATION,
Patent Owner.

Case IPR2018-00507
Patent US 8,410,131 B2

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

POLLOCK, *Administrative Patent Judge*.

DECISION
Instituting *Inter Partes* Review and Granting Motion for Joinder
37 C.F.R. § 42.108; 37 C.F.R. § 42.122(b)

I. INTRODUCTION

West-Ward Pharmaceuticals International Limited ("West-Ward") filed a Petition requesting an *inter partes* review of claims 1–3 and 5–9 of U.S. Patent No. 8,410,131 B2 ("the '131 patent"). Paper 1 ("Pet.").[1] Patent Owner Novartis Pharmaceutical Corporation ("Novartis") waived its right to file a Preliminary Response to the Petition. Paper 9.

Along with its Petition, West-Ward filed a Motion for Joinder to join this proceeding with IPR2017-01592. Paper 3 ("Mot."). West-Ward filed the Petition and Motion for Joinder in the present proceeding on January 17, 2018, within one month after we instituted trial in IPR2017-00737. Novartis timely filed a response to West-Wards's Motion for Joinder. Paper 7.

As explained further below, we institute trial on the same grounds as instituted in IPR2017-01592 and grant West-Ward's Motion for Joinder.

II. DISCUSSION

In IPR2017-01592, Breckenridge Pharmaceuticals, Inc. ("Breckenridge") challenged claims 1–3 and 9 of the '131 patent on the following grounds:

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[1] According to the Petition, "as a result of ongoing integration and reorganization activities, Petitioner identifies Hikma Pharmaceuticals PLC ("Hikma") and West-Ward Pharmaceuticals Corp. as real-parties-in-interest who, going forward, may have control over this proceeding." We also note that, in contrast to the identification of West-Ward in, for example, the Petition caption and Power of Attorney (Paper 1), the entity entering the Petition in the E2E electronic filing system identified Hikma as Petitioner. In the event West-Ward is not, or ceases to be the Petitioner, the new entity must promptly file an updated mandatory notice to that effect along with a new power of attorney.

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]
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

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[2] WO 01/51049 A1, published July 19, 2001. Ex. 1002.
[3] WO 00/33878 A2, published June 15, 2000. Ex. 1003.
[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.

After considering the Petition and Patent Owner's Preliminary Response, we instituted trial in IPR2017-01592 on each of the above-asserted grounds. IPR2017-01592, Paper 12, 35.

As asserted in Petitioner's Motion for Joinder, "West-Ward's Petition is substantively identical to the petition in the Breckenridge IPR," challenging the same claims based on the same art and the same grounds. *See* Mot. 6; *compare* IPR2018-00507, Paper 2, *with* IPR2017-01592, Paper 1. West-Ward also relies on the same expert testimony as Breckenridge. *See* Pet. 7 n.1 (asserting that Petitioner would withdraw the declaration of Dr. Cho and rely on the testimony of Dr. Pantuck submitted in IPR2017-01592 if it could retain Dr. Pantuck); Ex. 3001 (email correspondence to the Board stating, "West-Ward has retained Dr. Pantuck and will rely solely on Dr. Pantick if IPR2018-00507 is instituted").

For the same reasons stated in our Decision on Institution in IPR2017-01592, we institute trial in this proceeding on the same five grounds.

Having determined that institution is appropriate, we now turn to West-Ward's Motion for Joinder. 35 U.S.C. § 315(c). Section 315(c) provides, in relevant part, that "[i]f the Director institutes an inter partes review, the Director, in his or her discretion, may join as a party to that inter partes review any person who properly files a petition under section 311." *Id*. When determining whether to grant a motion for joinder we consider factors such as timing and impact of joinder on the trial schedule, cost, discovery, and potential simplification of briefing. *Kyocera Corp. v. SoftView, LLC*, Case IPR2013-00004, slip op. at 4 (PTAB Apr. 24, 2013) (Paper 15). Under the circumstances of this case, we determine that joinder is appropriate.

West-Ward avers that joinder will "not create any additional burden on Patent Owner," as it "raises no issues that are not already before the Board in the Breckenridge IPR." Mot. 6, 10. In particular, West-Ward argues that "the present Petition challenges the same instituted claims on the same grounds, and is supported by the same prior art, prior art combinations, and arguments as relied upon in Breckenridge's IPR petition and considered by the Board in instituting review in the Breckenridge IPR." *Id.* at 6.[10] West-Ward further asserts that it will:

> Effectively . . . act as a "silent understudy" unless, and until such time as, Breckenridge drops out of the proceedings for any reason. If the Breckenridge IPR is terminated with respect to the Breckenridge, Petitioner intends to "step into the shoes" of Breckenridge and materially participate in the remainder of the proceedings. Only if Breckenridge drops out of the proceedings for any reason, will Petitioner cease its understudy role.

Id. at 8–9.

Novartis responds that does not oppose joinder on conditions that, absent termination by Breckenridge, West-Ward "acts as a silent understudy in the joint proceedings," consents to consolidated filings not exceeding Breckenridge's allotted word and page counts, and consents to consolidated discovery that does not increase the allotted time for cross-examination or redirect examination. Paper 7, 8–9. While we generally agree with Novartis's position, an overly-strict adherence to its proposed conditions would be at odds with our discretion to managing this case. *See generally,* 37 C.F.R. § 42.71(a). Accordingly, we retain our discretion to entertain

[10] As discussed above, West-Ward also relies on the same expert as Breckenridge.

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