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Paper 12
Date: October 5, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ARGENTUM PHARMACEUTICAL LLC,
Petitioner,

v.

NOVARTIS AG,
Patent Owner.

IPR2016-01479[1]
Patent 9,006,224 B2

Before CHRISTOPHER L. CRUMBLEY, ROBERT A. POLLOCK, and KRISTI L. R. SAWERT, *Administrative Patent Judges.*

CRUMBLEY, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining No Challenged Claims Unpatentable
35 U.S.C. § 318(a)

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[1] This proceeding as initially filed named Par Pharmaceutical, Inc. as the sole Petitioner. Argentum Pharmaceutical LLC was joined as a party to this proceeding via a Motion for Joinder in IPR2017-01063; West-Ward Pharmaceuticals International Limited was joined as a party via a Motion for Joinder in IPR2017-01078. Subsequently, Par and West-Ward separately requested termination of their participation in the proceeding pursuant to settlement. Argentum Pharmaceutical LLC is the sole remaining Petitioner.

I. INTRODUCTION

In this *inter partes* review, instituted pursuant to 35 U.S.C. § 314, Argentum Pharmaceutical LLC ("Argentum") challenges the patentability of claims 1–3 of U.S. Patent No. 9,006,224 B2 (Ex. 1001, "the '224 patent"), owned by Novartis AG ("Novartis").

We have jurisdiction under 35 U.S.C. § 6. This Final Written Decision, issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73, addresses issues and arguments raised during trial. For the reasons discussed below, we determine that Argentum has not shown by a preponderance of the evidence that claims 1–3 of the '224 patent are unpatentable.

A. Procedural History

On July 22, 2016, Par Pharmaceutical, Inc. ("Par") filed a Petition requesting an *inter partes* review of claims 1–3 of the '224 patent. Paper 1 ("Pet."). Novartis filed a Preliminary Response. Paper 7. On February 14, 2017, we instituted an *inter partes* review of the challenged claims. Paper 8 ("Dec."). Subsequent to institution, Argentum and West-Ward Pharmaceuticals International Limited ("West-Ward") filed separate petitions and motions for joinder with the instant proceeding. IPR2017-01063, Papers 1, 3; IPR2017-01078, Papers 1, 3. On September 25, 2017, we granted both motions for joinder, joining Argentum and West-Ward as petitioners to this *inter partes* review. Paper 33. As we noted at the time, both Argentum and West-Ward stated that their petitions include the same

grounds and arguments[2] as those in the Par proceeding, and both parties rely on the same evidence including the same expert witness testimony. *Id*. at 5.

Following institution, Novartis filed a Patent Owner Response (Paper 17, "PO Resp.") and Argentum filed a Reply (Paper 21, "Reply"). We granted Novartis authorization to file a Surreply (Paper 26, "Surreply") to address alleged new arguments made in Argentum's Reply, and permitted Argentum to file a short Response (Paper 29).

Argentum relies upon the declaration testimony of Dr. Mark J. Ratain (Ex. 1003), and with its Reply submitted a Supplemental Declaration of Dr. Ratain (Ex. 1119). Novartis took cross-examination of Dr. Ratain via deposition following the submission of each declaration, and filed the transcripts (Exs. 2040, 2111). Novartis filed observations on the cross-examination of Dr. Ratain (Paper 34) and Argentum filed a response to the observations (Paper 42).

Novartis relies upon the declaration testimony of Dr. Matthew H. Kulke. Ex. 2041. Argentum took cross-examination of Dr. Kulke via deposition and submitted the transcript. Ex. 1070.

Novartis filed a Motion to Exclude certain evidence submitted by Argentum (Paper 35, "Mot. Exclude"), after which Argentum filed an Opposition (Paper 41, "Opp. Exclude") and Novartis filed a Reply (Paper 43, "Reply Exclude").

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[2] For this reason, although we cite to Par's Petition in this decision because it is of record in this proceeding, we attribute all the contentions made therein to Argentum as the sole remaining Petitioner.

Oral argument was requested by both parties. Papers 31, 36. Argument was heard on November 1, 2017, and a transcript has been entered into the record. Paper 49 ("Tr.").

On January 23, 2018, Par and Novartis filed a joint motion to terminate Par as a petitioner due to settlement (Paper 50), which we granted on February 6, 2018 (Paper 52).

On February 14, 2018, counsel for Argentum contacted the Board via e-mail, requesting that the Board hold the Final Written Decision in abeyance in order to facilitate ongoing settlement discussions with Novartis. Ex. 3002. We notified the parties that, in light of the parties' request and because the proceedings involve joinder, pursuant to 35 U.S.C. § 316(a)(11) and 37 C.F.R. § 42.100(c) we would adjust the time for issuing a Final Written Decision. Counsel for West-Ward[3] e-mailed a similar request on February 15, 2018. Ex. 3003. West-Ward continued to provide updates to the Board via e-mail to notify us that settlement negotiations were ongoing and to request that we continue to hold this Decision in abeyance.

On October 2, 2020, West-Ward and Novartis jointly requested to terminate West-Ward as a petitioner due to settlement (Paper 57), which we granted (Paper 60). Argentum is the sole remaining Petitioner in this proceeding.

[3] West-Ward updated its Mandatory Notices on January 8, 2019, notifying us that it changed its name to Hikma Pharmaceuticals International Limited. IPR2017-01078, Paper 11. Because the majority of the filings in this case were made prior to the name change, for clarity of this Decision we will refer to the company using its prior name, West-Ward.

B. Related Proceedings

Claims 1 and 2 of the '224 patent were challenged by a different petitioner in IPR2016-01461; the Board denied institution of trial in that proceeding.

We are informed that the '224 patent has been asserted in two patent infringement actions in the United States District Court for the District of Delaware: *Novartis Pharm. Corp. et al. v. Roxane Labs., Inc*., No. 15-474-RGA, and *Novartis Pharm. Corp. et al. v. Par Pharm., Inc.,* No. 15-475-RGA. Pet. 3; Paper 4, 2–3.

While this *inter partes* review was pending, the District Court entered a decision in the former case, finding no invalidity of claim 1 the '224 patent, on December 14, 2017. *Novartis Pharm. Corp. v. West-Ward Pharm. Int'l Ltd.*, 287 F. Supp. 3d 505 (D. Del. 2017) ("District Court Decision"). That decision also found that certain claims of a related patent, U.S. Patent No. 8,410,131 ("the '131 patent") were not invalid. *Id*. West-Ward appealed the District Court's decision as to the '131 patent to the United States Court of Appeals for the Federal Circuit, but did not appeal the District Court's decision regarding the '224 parent at issue here. On May 13, 2019, the Federal Circuit affirmed. *Novartis Pharm. Corp. v. West-Ward Pharm. Int'l Ltd.*, 923 F.3d 1051 (Fed. Cir. 2019) ("Federal Circuit Decision").

C. The '224 Patent

The '224 patent, titled "Neuroendocrine Tumor Treatment," issued April 14, 2015, from U.S. Patent Application No. 12/094,173. Ex. 1001, codes (54), (45), (21). The patent describes treating neuroendocrine tumors using mTOR (mammalian target of rapamycin) inhibitors, including rapamycin and its derivatives. *Id*. at 1:2–5, 1:17–43. One specifically listed

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