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Paper 9
Entered: February 13, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ROXANE LABORATORIES, INC.,
Petitioner,

v.

NOVARTIS AG,
Patent Owner.

Case IPR2016-01461
Patent 9,006,224 B2

Before LORA M. GREEN, CHRISTOPHER L. CRUMBLEY, and ROBERT A. POLLOCK, *Administrative Patent Judges*.

CRUMBLEY, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 314(a) and 37 C.F.R. § 42.108

I. INTRODUCTION

Roxane Laboratories, Inc. filed a Petition requesting an *inter partes* review of claims 1 and 2 of U.S. Patent No. 9,006,224 B2 (Ex. 1001, "the '224 patent"). Paper 2 ("Pet."). Novartis AG, the owner of the '224 patent, filed a Preliminary Response to the Petition. Paper 6 ("Prelim. Resp.").

Pursuant to 35 U.S.C. § 314(a), an *inter partes* review may not be instituted unless the information presented in the Petition and any Preliminary Response shows "there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." Taking into account the information presented, we conclude that the record does not establish a reasonable likelihood that Roxane will prevail in proving that claims 1 and 2 of the '224 patent are unpatentable. Accordingly, we do not institute an *inter partes* review.

A. Related Matters

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. 4–5; Paper 4, 2. Claims 1–3 of the '224 patent have been challenged by a different petitioner in IPR2016-01479, currently pending before the Board.

B. 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,

(54), (45), (21). Specifically, 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 rapamycin derivative is 40-O-(2-hydroxyethyl)-rapamycin, also known as everolimus. *Id*. at 1:46–47; 11:50.

The '224 patent discloses that mTOR inhibitors have activity as immunosuppressants, and have also been found useful for the treatment of solid tumors, particularly advanced solid tumors, including pancreatic neuroendocrine tumors (PNETs). *Id*. at 2:35–67. PNETs are particularly lethal, having a 5-year patient survival rate of 55.3%; the '224 patent states that most are malignant at the time of diagnosis, and 60% or more present with liver metastases. *Id*. at 3:1–10. The '224 patent concludes that there is an unmet need for treatment of PNETs in patients whose disease has progressed following one or more courses of chemotherapy. *Id*. at 3:10–12.

The '224 patent describes a method of treatment using mTOR inhibitors, specifically with everolimus ("compound A"). *Id*. at 11:66–67. The patent proposes a clinical study in which patients with advanced PNETs are treated with 10 mg/day of everolimus after failure of cytotoxic chemotherapy. *Id*. at 26:56–60.

C. Illustrative Claim

Of the challenged claims, claims 1 is independent and illustrative of the challenged claims:

> 1. A method for treating pancreatic neuroendocrine tumors, comprising administering to a human subject in need thereof a therapeutically effective amount of 40-0-(2-hydroxyethyl)-

rapamycin as a monotherapy and wherein the tumors are advanced tumors after failure of cytotoxic chemotherapy.

Ex. 1001, 26:66–27:4.

D. Asserted Grounds of Unpatentability

Roxane challenges claims 1 and 2 of the '224 patent on the following grounds of unpatentability:

References	**Basis**[1]	**Challenged Claims**
Lane[2] and Tabernero[3]	§ 103(a)	1 and 2
von Wichert,[4] Dutcher,[5] Cottens,[6] and Tabernero	§ 103(a)	1 and 2

[1] The relevant sections of the Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112–29, took effect on March 16, 2013. Because the application from which the '224 patent issued was filed before that date, our citations to Title 35 are to its pre-AIA version.

[2] U.S. Published Patent Application 2004/0147541 A1 to Lane *et al.* (published July 29, 2004) (Ex. 1005).

[3] J. Tabernero et al., *A phase I study with tumor molecular pharmacodynamics (MPD) evaluation of dose and schedule of the oral mTOR-inhibitor Everolimus (RAD001) in patients (pts) with advanced solid tumors*, DEVELOPMENTAL THERAPEUTICS: MOLECULAR THERAPEUTICS, Abstract 3007, 193s (2005) (Ex. 1006).

[4] Götz von Wichert et al., *Insulin-like Growth Factor-I is an Autocrine Regulator of Chromogranin A Secretion and Growth in Human Neuroendocrine Tumor Cells*, 60 CANCER RES. 4573–4581 (Aug. 15, 2000) (Ex. 1007).

[5] Janice P. Dutcher, *Mammalian Target of Rapamycin (mTOR) Inhibitors*, 6 CURRENT ONCOLOGY REP. 111–115 (2004) (Ex. 1008).

[6] U.S. Patent 5,665,772 to Cottens et al. (Sept. 9, 1997) (Ex. 1009).

Roxane contends that all asserted references are prior art to the '224 patent under 35 U.S.C. § 102(b). Pet. 27–32. Novartis does not, at this stage of the proceeding, challenge the prior art status of any reference.

II. ANALYSIS

A. Claim Construction

In an *inter partes* review, we construe claims by applying the broadest reasonable interpretation in light of the specification. 37 C.F.R. § 42.100(b); *see also In re Cuozzo Speed Techs., LLC*, 136 S. Ct. 2131, 2144–46 (2016). Under the broadest reasonable interpretation standard, and absent any special definitions, claim terms are given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech. Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Any special definitions for claim terms or phrases must be set forth with reasonable clarity, deliberateness, and precision. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

Roxane does not set forth an explicit construction for any claim term, asserting instead that all terms should be "accorded their broadest reasonable interpretation as understood by" a person of ordinary skill in the art. Pet. 17. In response, Novartis asks that we construe the claim term "advanced," alleging that Roxane's arguments in the Petition are based on an improper interpretation of the term. Prelim. Resp. 6. Novartis asks that we construe an "advanced" tumor, as used in claim 1, to mean a tumor that is metastatic or unresectable. *Id*. at 6–8. Furthermore, Novartis contends, "advanced" is not synonymous with "after failure of cytotoxic chemotherapy." *Id*. at 8–13.

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