

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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PAR PHARMACEUTICAL, INC.,  
Petitioner,

v.

NOVARTIS AG,  
Patent Owner.

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Case IPR2016-01059  
Patent 5,665,772

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BRECKENRIDGE PHARMACEUTICAL, INC.,  
Petitioner,

v.

NOVARTIS AG,  
Patent Owner.

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Cases IPR2016-01023, IPR2016-01103  
Patent 5,665,772

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ROXANE LABORATORIES, INC.,  
Petitioner,

v.

NOVARTIS AG,  
Patent Owner.

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Case IPR2016-01102  
Patent 5,665,772

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

CRUMBLEY, *Administrative Patent Judge*.

DECISION

Granting, Granting-In-Part, and Denying Motions for Joinder  
*35 U.S.C. § 315(c); 37 C.F.R. § 42.122(b)*

## I. INTRODUCTION

On April 29, 2016, the Board instituted an *inter partes* review trial of claims 1–3 and 8–10 of U.S. Patent No. 5,665,772 (Ex. 1001,<sup>1</sup> “the ’772 patent”). *Par Pharm. v. Novartis AG*, Case IPR2016-00084 (“Par I”), Paper 8. Trial in that matter is pending on the following grounds of unpatentability:

1. Whether claims 1–3 and 10 are unpatentable under 35 U.S.C. § 103(a) as having been obvious over Morris,<sup>2</sup> Van Duyne,<sup>3</sup> Rossmann,<sup>4</sup> Yalkowski,<sup>5</sup> and Lemke;<sup>6</sup> and
2. Whether claims 8 and 9 are unpatentable under 35 U.S.C. § 103(a) as having been obvious over Morris, Van Duyne, Rossmann, Yalkowski, Lemke, and Hughes.<sup>7</sup>

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<sup>1</sup> Unless otherwise indicated, when essentially identical documents have been filed in each of the cases, for simplicity we will cite only to the docket of IPR2016-01023.

<sup>2</sup> Randall Ellis Morris, *Rapamycins: Antifungal, Antitumor, Antiproliferative, and Immunosuppressive Macrolides*, 6 TRANSPLANTATION REVIEWS 39–87 (1992) (Ex. 1005).

<sup>3</sup> Gregory D. Van Duyne et al., *Atomic Structure of the Rapamycin Human Immunophilin FKBP-12 Complex*, 113 J. AM. CHEM. SOC’Y 7433–35 (1991) (Ex. 1006).

<sup>4</sup> Michael G. Rossmann et al., *Three-Dimensional Coordinates from Stereodiagrams of Molecular Structures*, B36 ACTA CRYST. 819–23 (1980) (Ex. 1024).

<sup>5</sup> Samuel H. Yalkowsky, *Estimation of Entropies of Fusion of Organic Compounds*, 18 INDUS. ENG’G CHEM. FUNDAM. 108–11 (1979) (Ex. 1007).

<sup>6</sup> Thomas L. Lemke, *Chapter 16: Predicting Water Solubility*, REVIEW OF ORGANIC FUNCTIONAL GROUPS 113–21 (2d ed. 1988) (Ex. 1008).

<sup>7</sup> U.S. Patent 5,233,036 (Aug. 3, 1993) (Ex. 1009).

Four additional petitions have now been filed with the Board, each seeking joinder with Par I. We summarize these petitions below.

In IPR2016-01059 (“Par II”), Par Pharmaceuticals, Inc. filed a Petition requesting *inter partes* review of claim 7 of the ’772 patent. Par II, Paper 1, “Par II Pet.” Concurrently with its Petition, Par filed a Motion for Joinder (Paper 3, “Par II Mot.”), seeking joinder with the Par I case. The owner of the ’772 patent, Novartis AG, filed an Opposition to the Motion for Joinder (Paper 11) and a Patent Owner Preliminary Response (Paper 16, “Prelim. Resp.”<sup>1</sup>).

In IPR2016-01023 (“Breckenridge I”), Breckenridge Pharmaceuticals, Inc. filed a Petition requesting *inter partes* review of claims 1–3 and 8–10 of the ’772 patent. Breckenridge I, Paper 4, “Breckenridge I Pet.” Concurrently with its Petition, Breckenridge filed a Motion for Joinder (Paper 5, “Breckenridge I Mot.”), seeking joinder with the Par I case. Novartis filed an Opposition to the Motion for Joinder (Paper 12) and a Patent Owner Preliminary Response (Paper 17).

In IPR2016-01103 (“Breckenridge II”), Breckenridge filed a Petition requesting *inter partes* review of claim 7 of the ’772 patent. Breckenridge II, Paper 1, “Breckenridge II Pet.” Concurrently with its Petition, Breckenridge filed a Motion for Joinder (Paper 4, “Breckenridge II Mot.”), seeking joinder with the Par I case. Novartis filed an Opposition to the Motion for Joinder (Paper 10) and a Patent Owner Preliminary Response (Paper 15).

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<sup>1</sup> Novartis filed identical Preliminary Responses in each of the four cases. We will cite to them generally as “Prelim. Resp.”

In IPR2016-01102 (“Roxane”), Roxane Laboratories, Inc. filed a Petition requesting *inter partes* review of claims 1–3 and 7–10 of the ’772 patent. Roxane, Paper 2, “Roxane Pet.” Concurrently with its Petition, Roxane filed a Motion for Joinder (Paper 3, “Roxane Mot.”), seeking joinder with the Par I case. Novartis filed an Opposition to the Motion for Joinder (Paper 11) and a Patent Owner Preliminary Response (Paper 14).

The grounds of unpatentability asserted, and the claims challenged, in all five proceedings may be summarized as follows:

Ground of Unpatentability	Challenged Claim(s)	Case
Morris, Van Duyne, Rossmann, Yalkowski, and Lemke	1–3, 10	Par I (instituted)
		Breckenridge I
		Roxane
Morris, Van Duyne, Rossmann, Yalkowski, Lemke, and Hughes	8, 9	Par I (instituted)
		Breckenridge I
		Roxane
	7	Par II
		Breckenridge II
		Roxane

As a threshold matter, we determine that the Motions for Joinder were timely. Our Rules provide that a request for joinder must be filed “no later than one month after the institution date of any *inter partes* review for which joinder is requested.” 37 C.F.R. § 42.122(b). The Motions were filed on or before May 26, 2016, less than one month after the April 29, 2016 institution date of the Par I *inter partes* review, and are thus timely.

For the reasons explained below, we grant the Breckenridge I Motion, grant-in-part the Roxane Motion, and deny the Par II and Breckenridge II Motions.

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