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Paper 73
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PAR PHARMACEUTICAL, INC.,
BRECKENRIDGE PHARMACEUTICAL, INC., AND
ROXANE LABORATORIES, INC.,
Petitioners,

v.

NOVARTIS AG,
Patent Owner.

Case IPR2016-00084[1]
Patent 5,665,772

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

CRUMBLEY, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
35 U.S.C. § 318 and 37 C.F.R. § 42.73

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[1] Breckenridge Pharmaceutical, Inc. was joined as a party to this proceeding via a Motion for Joinder in IPR2016-01023; Roxane Laboratories, Inc. was joined as a party via a Motion for Joinder in IPR2016-01102.

I. INTRODUCTION

In this *inter partes* review trial, instituted pursuant to 35 U.S.C. § 314, Petitioners Par Pharmaceutical, Inc., Breckenridge Pharmaceutical, Inc., and Roxane Laboratories, Inc. (collectively, "Par") challenge the patentability of claims 1–3 and 8–10 of U.S. Patent No. 5,665,772 ("the '772 patent," Ex. 1001), owned by Novartis AG.

We have jurisdiction under 35 U.S.C. § 6(b). This Final Written Decision, issued pursuant to 35 U.S.C. § 318(a), addresses issues and arguments raised during trial. For the reasons discussed below, we determine that Par has not proven, by a preponderance of the evidence, that claims 1–3 and 8–10 of the '772 patent are unpatentable.

A. Procedural History

On October 26, 2015, Par requested an *inter partes* review of claims 1–3 and 8–10 of the '772 patent. Paper 2, "Pet." Novartis filed a Patent Owner Preliminary Response. Paper 7. In a Decision on Institution of *Inter Partes* Review (Paper 8, "Dec. on Inst."), we instituted trial as to claims 1–3 and 8–10 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,[2] Van Duyne,[3] Rossmann,[4] Yalkowski,[5] and Lemke[6]; 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.[7]

Dec. on Inst. 18.

Novartis filed a Request for Rehearing of our decision to institute trial (Paper 10), which we denied (Paper 21).

Breckenridge filed a Petition and Motion for Joinder in IPR2016-01023, and Roxane filed a Petition and Motion for Joinder in IPR2016-01102. We granted Breckenridge's Motion and granted-in-part Roxane's Motion, and joined Breckenridge and Roxane as parties to this proceeding. Paper 37. We denied-in-part Roxane's Motion to the extent it sought to add

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[2] Randall Ellis Morris, *Rapamycins: Antifungal, Antitumor, Antiproliferative, and Immunosuppressive Macrolides*, 6 TRANSPLANTATION REVIEWS 39-87 (1992) (Ex. 1005).

[3] 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).

[4] Michael G. Rossmann *et al.*, *Three-Dimensional Coordinates from Stereodiagrams of Molecular Structures*, B36 ACTA CRYST. 819–823 (1980) (Ex. 1024).

[5] Samuel H. Yalkowsky, *Estimation of Entropies of Fusion of Organic Compounds*, 18 INDUS. ENG'G CHEM. FUNDAM. 108–11 (1979) (Ex. 1007).

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

[7] U.S. Patent No. 5,233,036 to Hughes (Aug. 3, 1993) (Ex. 1009).

claim 7 of the '772 patent to the instituted trial, and also denied Par's Motion for Joinder in IPR2016-01059 and Breckenridge's Motion for Joinder in IPR2016-01103, both of which sought joinder of claim 7. *Id.* Par, Breckenridge, and Roxane filed requests for rehearing of these denials. IPR2016-01059, Paper 20; IPR2016-01102, Paper 19; IPR2016-01103, Paper 19. As set forth in a Decision entered today in the related cases, these requests for rehearing are moot in view of our determination herein that claim 1 has not been proven unpatentable.

Novartis filed a Patent Owner Response (Paper 27, "PO Resp."), and Par filed a Reply (Paper 46, "Pet. Reply").

Par supported its Petition with the Declaration of William L. Jorgensen, Ph.D. Ex. 1003. Novartis took cross-examination testimony of Dr. Jorgensen via deposition and submitted the transcript of that deposition. Ex. 2091.

With its Response, Novartis submitted three declarations: the Declaration of Alexander M. Klibanov (Ex. 2092); the Declaration of William R. Roush, Ph.D. (Ex. 2093); and the Declaration of Howard A. Burris, III, M.D. (Ex. 2095). Par cross-examined Novartis's experts via deposition, and submitted the transcripts. Exs. 1114 (Klibanov), 1115 (Roush), 1035 (Burris).

With its Reply, Par submitted a Supplemental Declaration of Dr. Jorgensen (Ex. 1118), and submitted the declaration testimony of a second witness, Mark J. Ratain, M.D. (Ex. 1119). Novartis took cross-examination testimony via deposition of Drs. Jorgensen and Ratain, and

submitted the transcripts to the Board. Exs. 2222 (Jorgensen), 2223 (Ratain).

Novartis filed separate Observations on the Cross-Examination of Drs. Jorgensen and Ratain (Papers 55, 57), and Par filed Responses to the Observations (Papers 58, 59).[8] As authorized by the Board, Novartis also filed an Identification of Portions of Petitioner's Reply that allegedly exceed the proper scope of reply (Paper 63), and Par filed a Response to that list (Paper 65).

Novartis filed a Motion to Exclude various exhibits and papers submitted by Par (Paper 54, "Mot."), to which Par filed an Opposition (Paper 60) and Novartis filed a Reply (Paper 62).

Oral hearing was requested by both parties (Papers 51, 52), and argument before the Board was held February 2, 2017. A transcript of the oral hearing is included in the record. Paper 71, "Tr."[9] Both parties filed

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[8] In its responses to Novartis' Observations, Par contends that by filing two, 15-page observations, Novartis has exceeded the Board's page limits. Paper 60, 2–3. We agree that our Scheduling Order only authorized a single filing of observations; thus, Novartis exceeded the page limit by 15 pages. Furthermore, as Par argues, Novartis' Observations are impermissibly argumentative because they characterize the witnesses' testimony rather than simply setting forth the testimony itself. Per our Trial Practice Guide, excessively long or argumentative observations may be refused entry. *See* 77 Fed. Reg. 48,756, 48,768. In view of Novartis' failure to comply with our rules, we have not considered the Observations in reaching our conclusions in this Decision.

[9] With the authorization of the Board, Novartis filed an Unopposed Notice of Transcription Error (Paper 72) regarding an alleged error on page 48 of the transcript.

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