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Paper 17
Entered: October 27, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PAR PHARMACEUTICAL, INC.,
Petitioner,

v.

NOVARTIS AG,
Patent Owner.

Case IPR2016-01059
Patent 5,665,772

BRECKENRIDGE PHARMACEUTICAL, INC.,
Petitioner,

v.

NOVARTIS AG,
Patent Owner.

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

ROXANE LABORATORIES, INC.,
Petitioner,

v.

NOVARTIS AG,
Patent Owner.

Case IPR2016-01102
Patent 5,665,772

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,[1] "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,[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]

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[1] 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.

[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. 819–23 (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 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."[1]).

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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[1] 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.

II. THE PETITIONS WARRANT INSTITUTION

The controlling statute regarding joinder of *inter partes* reviews is 35 U.S.C. § 315(c), which reads as follows:

> (c) JOINDER.--If 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 that the Director, after receiving a preliminary response under section 313 or the expiration of the time for filing such a response, determines warrants the institution of an inter partes review under section 314.

The statute makes clear that joinder of a party to an instituted *inter partes* review is within the Board's[1] discretion. That discretion may only be exercised, however, if the party seeking joinder "files a petition . . . that the Director . . . determines warrants the institution of an inter partes review." 35 U.S.C. § 315(c). As a threshold issue, therefore, we must first determine whether the Par II, Breckenridge I, Breckenridge II, and Roxane Petitions warrant institution of an *inter partes* review.

A. Claims 1–3 and 8–10

The grounds of unpatentability asserted against claims 1–3 and 8–10 in the Breckenridge I Petition and the Roxane Petition are not materially different from those instituted in Par I.[2] Breckenridge I Mot. 5; Roxane

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[1] By regulation, the Director's discretion has been delegated to the Board. 37 C.F.R. § 42.4(a).

[2] Novartis notes that in the Par I case, Morris is identified as pre-AIA § 102(a) art, whereas Breckenridge and Roxane identify it as both § 102(a) and § 102(b) art. As such, Novartis argues, the grounds raised in the petitions are not "identical." Prelim. Resp. 5. Though this may be the case, Novartis does not allege that Morris is not prior art to the '772 patent, or that

Mot. 5. Roxane relies on the same expert witness, Dr. William L. Jorgensen, as Par does in Par I, and states that Roxane and Par have agreed to work together with respect to his testimony. Roxane Mot. 8. Although the Breckenridge I Petition relies instead on the testimony of Dr. Steven W. Baldwin, Breckenridge argues that "the conclusions and underlying reasoning of the experts are essentially identical. . . ." Breckenridge I Mot. 6. Furthermore, Breckenridge offers that it will rely on the testimony of Dr. Jorgensen if Par permits it to do so. *Id*.[1]

We previously determined, upon consideration of the Petition and Novartis' Preliminary Response in Par I, that the record in that proceeding established a reasonable likelihood that Par would prevail with respect to claims 1–3 and 8–10. Par I, Paper 10, 17. The arguments and evidence in favor of institution of trial as to claims 1–3 and 8–10 similarly support institution in the present cases, and we incorporate our analysis from the Par I Decision on Institution herein. In the Breckenridge I and Roxane cases, however, the Preliminary Responses filed by Novartis raise arguments and declaration evidence[2] not presented in Par I. We must, therefore, determine whether Novartis' newly presented arguments and evidence alter our prior determination regarding reasonable likelihood of success.

The Preliminary Response filed by Novartis in Breckenridge I and Roxane focuses on two prior art references relied upon in Petitioners' lead

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its prior art status differs under § 102(a) and § 102(b).

[1] During a conference call with the Board, counsel for Par agreed that Breckenridge could rely on the testimony of Dr. Jorgensen. Ex. 1031, 36.

[2] Declaration of Alexander M. Klibanov. Ex. 2401.

compound analysis: Yalkowski and Lemke. At a high level, Petitioners rely on Yalkowski's discussion of the entropy of fusion for drugs and molecules, and the effect of the addition of flexible side chains on solubility of compounds. Breckenridge I Pet. 34–35. Lemke is cited for its summary of the solubilizing potential of various functional groups. *Id*. at 35–36. Petitioners argue that both references would guide the person of ordinary skill in the art in selecting appropriate substituents for increasing solubility of rapamycin. *Id*. at 45–49.

Novartis argues that a person of ordinary skill in the art would not have relied on Yalkowski because its disclosure focuses on ideal solubility, and there is no evidence a person of ordinary skill in the art would have considered ideal solubility relevant to the actual water solubility of rapamycin. Prelim. Resp. 8. Novartis' expert witness, Dr. Klibanov, testifies that ideal solubility only applies when a solute and solvent have "nearly identical physiochemical properties"; water and rapamycin, however, have "polarities and hydrophobicities" which are "vastly dissimilar." Ex. 2401 ¶¶ 17–21. Novartis contends that the testimony of Petitioners' expert Dr. Jorgenson on this point—that Yalkowski is applicable to "all solvent systems"—is conclusory and should not be given weight. Prelim. Resp. 14.

With respect to Lemke, Novartis addresses Petitioners' reliance on Table 16-1 of the reference, particularly the solubilizing potential of various functional groups. *Id*. at 17–20. Novartis focuses on the fact that everolimus differs from rapamycin by the addition of two methyl groups and an ether oxygen, but that Dr. Jorgensen testifies that from Lemke's Table

16-1 a person of ordinary skill in the art would have reason to add "flexible side chains with solubilizing groups, *e.g.*, alkyl chains with *amino, hydroxyl, or carboxylate groups*." *Id*. at 19; Ex. 1003 ¶ 84 (emphasis added).

As with several of the arguments raised in Novartis' Preliminary Response in Par I, these arguments may have merit. At this time, however, we consider them to put facts into dispute that must be considered at the conclusion of trial, when viewed as part of the entirety of the record. With respect to Yalkowski, Dr. Klibanov's testimony calls into question the applicability of the reference to the lead compound analysis. But we disagree with Novartis that there is *no* evidence in support of Petitioners' case: Dr. Jorgenson testifies that Yalkowski discusses "fundamental physical chemistry of the dissolution of solids applicable to all solvent systems," and cites Bell[1] as applying Yalkowski's teachings to increase solubility of a molecule. Ex. 1003 ¶ 78. Although Novartis may dispute the applicability of these teachings, there is not a complete lack of evidence in Petitioners' favor.

Similarly, with Lemke, Novartis is correct that everolimus differs from rapamycin by two methyl groups and an ether group. But the modification being proposed by Petitioners is not the insertion of these groups behind the terminal hydroxyl group, but rather the substitution of two methyls and a hydroxyl at the pre-existing C40 hydroxyl group. Breckenridge I Pet. 15–16; Ex. 1003 ¶ 142 ("Chemical reactions of hydroxyl groups are among the most fundamental and elementary reactions taught in

[1] Thomas W. Bell, *Construction of a Soluble Heptacyclic Terpyridine*, 51 J. ORGANIC CHEMISTRY 764 (1986) (Ex. 1021).

beginning organic chemistry courses. As such, hydroxyl groups would have been, and still are, the first positions a person of ordinary skill in the art would modify on a lead compound . . .”). Dr. Jorgensen’s testimony that a person of ordinary skill in the art would focus on “alkyl chains with amino, hydroxyl, or carboxylate groups” (Ex. 1003 ¶ 84) is not, on its face, contrary to this modification.

Taking into account the newly raised arguments in the Preliminary Response, we remain persuaded that the Breckenridge I and Roxane Petitions establish a reasonable likelihood that claims 1–3 and 8–10 are unpatentable. The Petitions, therefore, warrant institution.

B. Claim 7

Claim 7 depends from claim 1, and recites “[a] pharmaceutical composition comprising a therapeutically effective amount of a compound according to claim 1 and a pharmaceutically acceptable carrier therefor.” The Par II, Breckenridge II, and Roxane Petitions each contain similar challenges to claim 7. The Petitioners note that claims 8 and 9, on which trial has been instituted, recite methods of using the compounds of claim 1 as immunosuppressants or to prevent allograft rejection. Par II Pet. 50. Petitioners argue that “[t]here is no patentable distinction between the use of the compound for therapeutic effect and its formulation as a pharmaceutical composition in an effective amount with a pharmaceutically acceptable carrier.” *Id*.

Petitioners argue that the validity of pharmaceutical composition claims “rise or fall with the validity of” the underlying compound claim. Par II Pet. 2 (citing *Aventis Pharma Deutschland GmbH v. Lupin, Ltd.*, 499 F.3d

1293, 1303 (Fed. Cir. 2007)). We disagree that the Federal Circuit set any such *per se* rule. The cited portion of *Aventis* stands for the unremarkable proposition that when the added limitations of dependent claims "appear almost verbatim in virtually all the prior art patents," the validity of those claims "rise or fall with the validity of" the independent claim. *Aventis*, 499 F.3d at 1303.

Petitioners also cite *Geneva Pharm., Inc. v. Glaxosmithkline PLC*, 189 F. Supp. 2d 377, 384–85 (E. D. Va. 2002), *aff'd* 349 F.3d 1373 (Fed. Cir. 2003), for the proposition that a pharmaceutical composition claim is patentably indistinct from method claims of administering the compound. Par II Pet. 3. In *Geneva*, the court noted in the context of an obviousness-type double patenting case that a pharmaceutical composition claim was "strikingly similar" to a method of treatment claim, and therefore the composition claim was obvious over the method claim. *Geneva*, 189 F. Supp. 2d at 384. While such a comparison is appropriate in an obviousness-type double patenting case, the question before us is not whether claim 7 distinguishes over claims 8 and 9, but rather whether claim 7 would have been obvious over the cited prior art.

Portions of Petitioners' arguments as to claim 7—in particular, the lead compound analysis that allegedly results in the formation of everolimus—are the same as that raised in Par I as to claim 1. We, therefore, need not repeat our analysis herein. Having obtained everolimus, Petitioners argue, a person of skill in the art would have relied Hughes' disclosure that C40-rapamycin derivatives may be used in therapeutically effective amounts in pharmaceutical compositions. Pet. 52. Petitioners also

cite the ’772 patent’s statement that the claimed compounds may be administered by any conventional route. *Id*.

Novartis responds that Petitioners’ arguments regarding claim 7 conflict with those raised regarding the other claims. Specifically, Novartis notes that as part of the lead compound analysis, Petitioners argue that a person of ordinary skill would have had reason to modify rapamycin due to its low solubility in water, which limited its ability to be used in pharmaceutical formulations. Prelim. Resp. 22–23. This, Novartis argues, contradicts other statements—made in the context of claim 7—that rapamycin was known to have been formulated into pharmaceutical compositions. *Id.* at 23–25. Other than this alleged conflict, Novartis does not directly address the disclosure of Hughes or the merits of Petitioners’ argument.

We do not share Novartis’ concern regarding Petitioners’ arguments. It is not inconsistent to state that rapamycin had been included in pharmaceutical formulations (Par II Pet. 28–29 (citing Ex. 1005, Table 4, 49)) while at the same time arguing that such formulation was difficult because of rapamycin’s low solubility (Par II Pet. 20 (citing Ex. 1005, 46; Ex. 1003 ¶¶ 75–76)). Both facts can be simultaneously true; the fact that rapamycin was difficult to formulate into pharmaceutical compositions does not mean that such formulation was impossible. We do not take Petitioners’ arguments to be in conflict in the manner Novartis suggests. Institution of trial as to claim 7 on the Par II, Breckenridge II, and Roxane Petitions is warranted.

III. DISCRETION TO GRANT JOINDER

Having determined that the newly-filed Petitions warrant institution, we must determine whether to exercise our discretion to join Breckenridge and Roxane as parties to Par I with respect to claims 1–3 and 8–10. With respect to claim 7, we must determine whether to join the ground of unpatentability raised by Par, Breckenridge, and Roxane to Par I.[1]

A. Claims 1–3 and 8–10

Breckenridge and Roxane contend that joinder is appropriate because a consolidated *inter partes* review procedure would avoid inefficiency and prevent inconsistencies. Breckenridge I Mot. 8; Roxane Mot. 8. The Petitioners also raise the prospect of prejudice, arguing that the decision in Par I will likely impact the district court actions to which they are party. Breckenridge I Mot. 8; Roxane Mot. 9–10. To simplify briefing and discovery, and avoid impact on the schedule of Par I, the Petitioners propose that they will work together with Par to manage questioning at depositions, and will rely on the same expert. Breckenridge I Mot. 5–6; Roxane Mot. 7–8. Breckenridge and Roxane suggest that they each be permitted to file seven additional pages to accompany any further briefs submitted by Par. Breckenridge I Mot. 5–6; Roxane Mot. 7.

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[1] Because we decide not to exercise our discretion as to claim 7, we need not address whether 35 U.S.C. § 315(c) permits a petitioner, otherwise barred under 35 U.S.C. § 315(b), to add a ground of unpatentability to a pending *inter partes* review trial through joinder. *See generally Target Corp. v. Destination Maternity Corp.*, Case IPR2014-00508 (PTAB Feb. 12, 2015) (Paper 28).

Novartis argues that we should exercise our discretion to deny Breckenridge's and Roxane's Motions, but then states that it will not oppose joinder if the Board orders Breckenridge and Roxane:

> (i) to rely solely on the petition and evidence filed by Par in [Par I];
>
> (ii) to share with Par the pages currently allotted to Par in [Par I] for any written work product; and
>
> (iii) to share with Par the time currently allotted to Par in [Par I] for the cross and redirect examination of any witness.

Breckenridge I, Paper 12, 8.[1]

During a conference call with the Board, counsel for Par confirmed that Par does not oppose the Motions for Joinder. Ex. 1031, 36.

Upon review, the Motions for Joinder demonstrate that joinder of Breckenridge and Roxane as parties to Par I is appropriate, and will lead to the more efficient resolution of the proceedings. With respect to claims 1–3 and 8–10, the Breckenridge I Petition and Roxane Petition do not assert any new ground of unpatentability that is not already being considered in Par I, rely on the same arguments and evidence, and do not require any modification to the existing schedule. We, therefore, determine that joinder will not unduly complicate or delay the proceedings, and exercise our discretion to join Breckenridge and Roxane as parties to the Par I *inter partes* review.

With respect to Novartis' proposed requirements that the Petitioners act in concert, we consider them appropriate and in keeping with procedures

[1] Novartis proposes similar requirements in the Opposition to Roxane's Motion, with slight alterations due to the presence of a challenge to claim 7.

followed by the Board in other cases of joinder where the joining parties filed identical Petitions with identical evidence. We do not consider it necessary at this time to permit Breckenridge and Roxane additional briefing beyond that already permitted Par. The Petitioners should work together to present consolidated briefing in Par I, with Par as the lead Petitioner. If some disagreement arises which prevents a unified position, the Petitioners may request a conference call with the Board.

B. Claim 7

The Petitioners generally repeat the same justifications for joinder of the ground challenging claim 7. Par II Mot. 9–12. Par makes the additional argument that because "there are no substantive differences between the instituted claims and claim 7," the validity of the claims "rise or fall" together and joinder would promote efficiency. *Id*. at 1–2, 7–9. Breckenridge requests joinder "[t]o the extent the Motion for Joinder filed on behalf of Par [in Par II] is granted." Breckenridge II Mot. 1. Because of this, and because of the similarities in the arguments made in the Motions, we consider all three together.

Though we recognize the arguments in favor of joining the claim 7 ground to the pending *inter partes* review, two factors weigh strongly against such joinder. The first is that no explanation has been given for why claim 7—the validity of which, according to the Petitioners, is so closely related to claims 1, 8, and 9—was not raised in the Par I Petition. During a conference call with the Board, Par's counsel was directly asked this question, and could only respond that it was an "inadvertent omission." Ex. 1031, 19. Novartis contends that Par has been on notice of Novartis'

assertion of claim 7 since at least February 19, 2015, well before the filing of the Par I Petition.

Petitioners cite various cases in which the Board granted joinder of later-raised grounds of unpatentability. Par II Pet. 7–8, 11–12. In those cases, however, the petitioner provided at least *some* justification for the delay in raising the grounds. *See Ariosa Diagnostics, Inc. v. Isis Innovation Ltd.*, Case IPR2013-00250 (PTAB Sept. 3, 2013) (Paper 24) (new claims asserted against petitioner's newly-launched product); *Samsung Elecs. Co. v. Va. Innovation Scis., Inc.*, Case IPR2014-00557 (PTAB June 13, 2014) (Paper 10) (Board partially denied first petition, second petition responded to Board's reasoning); *Enzymotec Ltd. v. Neptune Techs. & Bioresources, Inc.*, Case IPR2014-00556 (PTAB July 9, 2014) (Paper 19) (same); *Zhongshan Broad Ocean Motor Co. v. Nidec Motor Corp.*, Case IPR2015-00762 (PTAB Oct. 5, 2015) (Paper 16) (denial of first petition on procedural deficiency addressed by second petition); *Target*, Case IPR2014-00508 (PTAB Feb. 12, 2015) (Paper 28) (new art asserted in co-pending district court action).

In contrast, the case at hand is analogous to other cases in which the Board has declined to exercise its discretion to join. As we stated in *Micro Motion, Inc. v. Invensys Sys., Inc.*:

> We exercise our discretion and deny joinder of this proceeding. . . . In [the first petition], Petitioner neglected to include an analysis of claim 43 and offers now the analysis it could have offered then. . . . This is not a case where circumstances have changed that would make joinder an equitable remedy for Petitioner.

Case IPR2014-01409 (PTAB Feb. 18, 2015) (Paper 14), 14.

There is merit in encouraging a petitioner to raise in its first petition all grounds and claims that reasonably could be raised, to avoid serial attacks against a patent and reduce the burden on patent owners of defending multiple proceedings. *Cf. Conopco, Inc. v. The Procter & Gamble Co.*, Case IPR2014-00628 (PTAB Mar. 20, 2015), 3 ("a grant of review, under the particular circumstances presented here, would incentivize petitioners to hold back prior art for successive attacks, should a first petition be denied"). Granting joinder of petitions raising additional grounds, without sufficient justification from Petitioner regarding the reasons why the claims were not previously raised, would give petitioners incentive to raise fewer than all claims in a first petition. This concern is especially heightened after the expiration of the one-year 35 U.S.C. § 315(b) period, where but for joinder, the petition would be barred. Taking these considerations into account, we do not consider "inadvertent omission" of a ground of unpatentability to be sufficient justification for the grant of joinder.

Second, we consider the effect joinder would have on the already-instituted trial. Though the statute provides that the one-year deadline for rendering a final written decision may be adjusted in the case of joinder (35 U.S.C. § 316(a)(11)), we are hesitant to do so in cases where joinder will unduly complicate the existing proceeding, or "cause lengthy delays in an ongoing review." *Sony Corp. v. Network-1 Security Solutions, Inc.*, Case IPR2013-00386 (PTAB July 29, 2013) (Paper 16), 8.

In Par I, Novartis filed its Patent Owner's Response on September 16, 2016, a date already extended by agreement of the parties from that set in the Board's Scheduling Order. The parties are, therefore, over a month into

Par's discovery period, and the Petitioner's Reply is due December 5, 2016. The Patent Owner Response in Par I does not address claim 7, for obvious reasons. If we were to join grounds challenging claim 7 to Par I, we would either have to maintain two different schedules for two different sets of claims, or stay the proceedings as to claims 1–3 and 8–10 for several months until Novartis takes discovery on claim 7 and files a Response as to that ground. Although introducing such complications may be justified in some cases, it is not here, especially given the lack of a sufficient justification why claim 7 was not challenged in Par I.

For these reasons, we decline to exercise our discretion to join the grounds of unpatentability challenging claim 7 to the Par I proceeding.

IV. DENIAL OF INSTITUTION

Petitioners acknowledge that the Par II, Breckenridge I and II, and Roxane Petitions were each filed outside the one-year time period set forth in 35 U.S.C. § 315(b). Ex. 1031, 18–19. The one-year bar does not apply, however, to a request for joinder under 35 U.S.C. § 315(c). Because we deny joinder as to the Par II Petition, the Breckenridge II Petition, and the Roxane Petition as to claim 7, those grounds are barred and we deny institution of trial on the grounds of unpatentability raised as to claim 7. We grant joinder as to the Breckenridge I Petition and the Roxane Petition as to claims 1–3 and 8–10, and therefore join Breckenridge and Roxane as parties to the Par I proceeding.

V. ORDER

Accordingly, it is:

ORDERED that Par's Motion for Joinder (IPR2016-01059, Paper 3) is *denied*;

FURTHER ORDERED that trial is not instituted as to the ground of unpatentability set forth in Par's Petition (IPR2016-01059, Paper 1);

FURTHER ORDERED that Breckenridge's Motion for Joinder (IPR2016-01103, Paper 4) is *denied*;

FURTHER ORDERED that trial is not instituted as to the ground of unpatentability set forth in Breckenridge's Petition (IPR2016-01103, Paper 1);

FURTHER ORDERED that Roxane's Motion for Joinder (IPR2016-01102, Paper 3) is *granted-in-part* and *denied-in-part*;

FURTHER ORDERED that trial is not instituted as to the ground of unpatentability challenging claim 7, as set forth in Roxane's Petition (IPR2016-01102, Paper 2);

FURTHER ORDERED that Breckenridge's Motion for Joinder (IPR2016-01023, Paper 5) is *granted*;

FURTHER ORDERED that Breckenridge and Roxane are joined as Petitioners to IPR2016-00084;

FURTHER ORDERED that the grounds on which IPR2016-00084 was instituted are unchanged;

FURTHER ORDERED that, within one week of this Decision, any party may request a conference call with the Board to discuss changes to the Scheduling Order; in the absence of such changes, the Scheduling Order in

place for IPR2016-00084, as modified by the parties' stipulation, shall continue to govern the joined proceeding;

FURTHER ORDERED that, throughout IPR2016-00084, any paper, except for a motion that does not involve the other party, shall be filed by Par as a single, consolidated filing on behalf of Par, Breckenridge, and Roxane, pursuant to the page limits set forth in 37 C.F.R. § 42.24, and Par will identify each such filing as a consolidated filing;

FURTHER ORDERED that except as otherwise agreed by the Petitioners, counsel for Par will conduct cross-examination and other discovery on behalf of Par, Breckenridge, and Roxane, and that Novartis is not required to provide separate discovery responses or additional deposition time as a result of the joinder;

FURTHER ORDERED that Par, Breckenridge, and Roxane collectively will designate attorneys to present at the oral hearing (if requested) as a consolidated presentation;

FURTHER ORDERED that IPR2016-01023 and IPR2016-01102 are terminated under 37 C.F.R. § 42.72, and all further filings these proceeding are to be made in IPR2016-00084;

FURTHER ORDERED that a copy of this Decision will be entered into the record of IPR2016-00084; and

FURTHER ORDERED that the case caption in IPR2016-00084 shall be changed to reflect the joinder, in accordance with the attached example.

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PAR PHARMACEUTICAL, INC.,
BRECKENRIDGE PHARMACEUTICAL, INC., AND
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v.

NOVARTIS AG,
Patent Owner.

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

[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.