

Filed On Behalf Of: Novartis AG

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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

**NOVARTIS AG,**  
Patent Owner

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Case IPR2016-00084<sup>1</sup>

U.S. Patent 5,665,772

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**PATENT OWNER'S REPLY IN SUPPORT  
OF ITS MOTION TO EXCLUDE EVIDENCE**

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<sup>1</sup> The Board on October 27, 2016 joined Breckenridge's IPR2016-01023 and Roxane's IPR2016-01103 with Par's IPR2016-00084 challenging claims 1-3 and 8-10 of the '772 patent.

**TABLE OF AUTHORITIES**

**Cases**

*Belden, Inc. v. Berk-Tek, LLC*  
805 F.3d 1064 (Fed. Cir. 2015) .....3, 5

*Facebook, Inc. v. Software Rights Archive, LLC*,  
IPR2013-00479, Paper 54 (P.T.A.B. Feb. 2, 2015) .....3

*Genzyme Therapeutic Prods. Limited Partnership v. Biomarin  
Pharms. Inc.*,  
825 F.3d 1360 (Fed. Cir. 2016) .....3, 5

*In re Nomiya*,  
509 F.2d 566 (C.C.P.A. 1975).....2

*In re NuVasive, Inc.*,  
841 F.3d 966 (Fed. Cir. 2016) .....5

*InTouch Techs. Inc. v. VGO Comms., Inc.*,  
751 F.3d 1327 (Fed. Cir. 2014) .....2

*PharmaStem Therapeutics, Inc. v. ViaCell, Inc.*,  
491 F.3d 1342 (Fed. Cir. 2007) .....2

**Statutes**

35 U.S.C. § 132 .....2

**Other Authorities**

77 Fed. Reg. 48,612 .....4

**Regulations**

37 C.F.R. § 42.123(b) .....4

37 C.F.R. § 42.64(b) .....4

37 C.F.R. § 42.64(c).....1, 3

Novartis submits this reply in support of its December 20, 2016 motion to exclude evidence (Paper 54, “Motion”) and in response to Petitioners’ opposition thereto (Paper 60, “Op.”). For the reasons set forth herein and in the Motion, the Motion should be granted.

Petitioners complain that the Motion does not identify with “required specificity” where Novartis timely objected to certain evidence. Op. at 1, 7-8, 12, 14. Not true. Novartis fully complied with the requirement of § 42.64(c) that its Motion “identify the objections in the record in order and . . . explain the objections.” Motion at 1-2, *pin-citing* Novartis’s December 12, 2016 objections, Paper 50 at, *inter alia*, 16 (objecting to specific paragraphs of Jorgensen reply declaration because they make new *prima facie* arguments), 20 (same for Ratain reply declaration), 17-18 (objecting to specific paragraphs of Ratain reply declaration because they are based on non-prior art documents), 2, 4-14, 18 and 21 (objecting to specific evidence in because it was not cited in the reply).<sup>2</sup>

Petitioners cite no authority to suggest that Novartis’s December 12 objections must be more specific than they are. And regardless of the specificity of the

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<sup>2</sup> Ex. 1087 was not previously objected to on the ground that it was not cited in the reply. Novartis thus withdraws § III.6 of the Motion as to Ex. 1087.

objections, Petitioners could not have been prejudiced by the eight days that elapsed between the December 12 objections and the December 20 Motion.

Petitioners rely on a statement from the '772 patent to identify an alleged motivation to modify rapamycin, and—in contrast to Petitioners' cited authorities *PharmaStem* and *Nomiya*—do not explain how that statement constitutes an admission that the matter therein was also in the prior art. *PharmaStem v. ViaCell*, 491 F.3d 1342, 1362 (Fed. Cir. 2007) (“the inventors cited several prior art references”); *In re Nomiya*, 509 F.2d 566, 570-71 (C.C.P.A. 1975) (figures in specification were “labeled prior art, ipsissimis verbis”). Indeed, Petitioners fail to identify any prior art cited in their petition to support their alleged motivation. *See Op.* at 2 (citing only their reply). Petitioners' reliance on the statement in the '772 patent to support their alleged motivation thus is improper. Motion, § III.1; *see also InTouch Techs. v. VGO Comms.*, 751 F.3d 1327, 1351-52 (Fed. Cir. 2014) (rejecting obviousness analysis that relied on patent itself).<sup>3</sup>

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<sup>3</sup> Contrary to Petitioners' misrepresentations (*Op.* at 1), Novartis has never argued that the statement was 35 U.S.C. § 132 “new matter” or was added to “maintain a priority date to which it was not entitled.” And Petitioners have never disputed the October 9, 1992 priority date.

Petitioners try to salvage the new *prima facie* evidence they served on December 5, 2016 by contending that a § 42.64(c) motion to exclude is not a “proper vehicle” for excluding reply evidence and that Novartis did not seek the Board’s permission to use the Motion for that purpose. Op. at 3-4. Though some panels have asserted that a motion to exclude “normally is not the proper vehicle for resolution of a dispute regarding reply arguments and evidence exceeding the proper scope of a reply,” *Facebook v. Software Rights Archive*, IPR2013-00479, Paper 54 at 37 (P.T.A.B. Feb. 2, 2015), no statute or regulation prohibits such use. Indeed, the Federal Circuit suggests that patent owners can (and should) use motions to exclude for that purpose. *Belden v. Berk-Tek*, 805 F.3d 1064, 1081 (Fed. Cir. 2015) (“[I]f the petitioner submits a new expert declaration with its Reply, the patent owner . . . can move to exclude the declaration.”); *Genzyme v. Biomarin*, 825 F.3d 1360, 1368 (Fed. Cir. 2016) (“If Genzyme had wanted the Board to disregard those [reply] references, it could have filed a motion to exclude them.”).<sup>4</sup>

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<sup>4</sup> Petitioners moreover admit that exclusion is warranted where a petitioner changes its invalidity theory on reply. Op. at 4. That is what happened here. Novartis will provide citations to Petitioners’ improper reply arguments, as authorized by the Board on January 6, 2017.

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