

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 IPR2016-00084¹
U.S. Patent No. 5,665,772

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

**PETITIONERS' OPPOSITION TO
PATENT OWNER'S MOTION TO EXCLUDE**

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.

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The Board should deny Novartis's procedurally and substantively deficient motion to exclude, which is largely a *de facto* sur-reply and motion to strike. Novartis failed to point to where it timely objected with the required specificity, and in many cases, it did not so object. Moreover, Novartis did not seriously attempt to demonstrate that any evidence should be excluded because it is not admissible under the Federal Rules of Evidence. Instead, it alleges procedural defects or argues relevancy, contending that the Board should not give the cited evidence and argument any weight. Given Novartis's repeated procedural violations and its frivolous motion, Petitioners reserve the right to seek sanctions under 37 C.F.R. § 42.12.

I. Topic 1 – The Board should deny Novartis's motion to exclude evidence and argument pointing to relevant applicant-admitted prior art

In describing the known problems with rapamycin, the '772 patent states "rapamycin is highly insoluble, making it difficult to formulate stable galenic compositions." '772 patent at 1:39-40. Novartis argues that it later added this information to its original disclosure in violation of 35 U.S.C. § 132 (forbidding addition of new matter) in an effort to maintain a priority date to which it was not entitled, and therefore Petitioners cannot rely on it as evidence of the state of the art as of that earlier, undeserved priority date. Mot. 3-4; *see also* POR 52 n.6. However, it does not matter when Novartis added the admission. "Admissions in the specification regarding the prior art are binding on the patentee for purposes of

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a later inquiry into obviousness.” *PharmaStem Therapeutics v. ViaCell*, 491 F.3d 1342, 1362 (Fed. Cir. 2007); *In re Nomiya*, 509 F.2d 566, 571 & n.5 (CCPA 1975) (the admission is binding whether made “in the application or in other papers submitted during prosecution”). Moreover, this admission easily clears the “very low bar for relevance” because it corroborates Petitioners’ own evidence showing that rapamycin was known to be difficult to formulate because of its low solubility. Reply 6; *United States v. Rodríguez-Soler*, 773 F.3d 289, 293 (1st Cir. 2014).

II. Topic 2 – Novartis’s improper motion to consider its Lemke exhibits is moot because that evidence is already of record

Novartis seeks to admit Lemke Chapters 6 and 10-12 into evidence on the basis that Petitioners submitted Chapter 16, “Predicting Water Solubility.” Mot. 4-5 (citing Fed. R. Evid. 106). Novartis’s request is moot because those Lemke chapters are already of record and petitioners have not moved to exclude. Petitioners do not acquiesce that anything else is required out of “fairness” or for any other reason.

III. Topics 3, 4, 7 – The Board should deny Novartis’s motion to exclude evidence that allegedly exceeds the scope of a permissible reply

Novartis seeks to exclude as “untimely” two exhibits, multiple portions of two expert declarations, and “any evidence that does not appear in instituted Grounds 1 or 2” that Petitioners relied upon to establish obviousness. Mot. 5-12, 15. As explained in the following paragraphs, Novartis’s improperly raised

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arguments fail because all of the complained-of evidence properly replies to Novartis's response—a point that Novartis does not even bother to dispute.

A. Absent Board permission, a motion to exclude is not the proper vehicle for addressing Novartis's contentions

As an initial matter, the Board should deny Novartis' motion rather than reward Novartis's repeated efforts to engage in self-help to garner additional briefing on the merits, encouraging future parties to do the same. To be clear, Novartis's *prima-facie* arguments are addressing whether the evidence submitted with the petition is sufficient *by itself* to demonstrate obviousness and Novartis is impermissibly taking another shot at the merits of the petitions. *Liberty Mutual Ins. v. Progressive Cas. Ins.*, CBM2012-00002, Paper 66 at 62 (Jan. 23, 2014) (motion to exclude “is not a mechanism to argue that a reply contains new arguments or relies on evidence necessary to make out a prima facie case.”).

Thus, a motion to exclude is not the “proper vehicle” for addressing the scope of a reply or reply evidence, absent Board permission—permission Novartis lacks. *Torrent Pharms. v. Novartis*, IPR2014-00784, Paper 112 at 49 (Sept. 24, 2015); *Facebook v. Software Rights Archive*, IPR2013-00479, Paper 54 at 37 (Feb. 2, 2015) (citing cases); *Corning v. DSM IP Assets*, IPR2013-00052, Paper 88 at 22 n.13 (May 1, 2014) (motion to exclude “not an appropriate vehicle,” but granting permission in that instance). Further, Novartis's experienced counsel cannot claim that it is unaware of the requirement to seek Board permission before making such

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