

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' RESPONSE TO PATENT OWNER'S
MOTION FOR OBSERVATIONS
ON DR. JORGENSEN'S CROSS EXAMINATION**

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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I. The Board should deny Novartis’s motion because it exceeds the page limits and each observation is excessively long and argumentative

The Board should deny Novartis’s motion for observations of Dr. Jorgensen’s deposition (Paper 55, “Mot.”) in its entirety because Novartis impermissibly argues its case rather than concisely pointing out relevant testimony and its relevance as required by the Trial Practice Guide. 77 Fed. Reg. 48756, 48767-68 (Aug. 14, 2012). That is, Novartis’s argumentative observations impermissibly characterize the subject testimony rather than quoting it or accurately summarizing it, address multiple passages (and often extensive—covering *50 pages* of testimony) in a single observation, characterize other exhibits, and re-argue old arguments and introduce new ones. *Actelion Pharm. v. Icos*, IPR2015-00561, Paper 33 at 2-3 (Mar. 18, 2016) (examples of offending observations are in *Actelion Ex. 1049* at 14-15); *LG Elecs. v. ATI Techs.*, IPR2015-00325, Paper 52 at 3-4 (Jan. 25, 2016); *Medtronic v. Nuvasive*, IPR2013-00506, Paper 37 at 3-4 (Oct. 15, 2014). What is more, this motion would be improper even if it was an authorized sur-reply because it impermissibly raises new arguments.

Novartis also violated the Board’s scheduling order by filing two 15-page motions for observations, one for each expert, rather than a single motion as permitted. Paper 9 at 3, 4, 6; 37 C.F.R. § 42.24. Like a motion to exclude, the Scheduling Order authorizes only one motion for observations regardless of the number of exhibits addressed in the briefs, and there is no good reason to allow

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another 30 pages of briefing after a 15-page reply. *Zhongshan Broad Ocean Motor v. Nidec Motor*, IPR2014-01121, Paper 86 at 32-33 (May 9, 2016) (five-judge panel, with substantively identical scheduling order); *Neste Oil v. Reg Synth. Fuels*, IPR2013-00578, Paper 29 at 4-5 (Sept. 9, 2014). When the Board desires more than one 15-page motion for observations, it expressly orders it, unlike here. *Mylan Pharm. v. Allergan*, IPR2016-01127, Paper 9 at 6 (Dec. 8, 2016) (added sentence allowing one motion per witness). Although the Board has not typically expunged excess observations *sua sponte* when the issue is not raised, Petitioners raise it here and request the Board to do so.

Petitioners therefore bring Novartis's improper motion to the Board's attention in its response and ask the Board to dismiss or deny it in its entirety without leave to correct. *Green Cross v. Shire Human Genetic Therapies*, IPR2016-00258, Paper 78 (Dec. 21, 2016) (ordering petitioner to do the same); *Zhongshan* at 32-33 (no leave to correct); *LG Elecs.* at 3-4 (also no leave).

II. Responses to observations

Novartis's impermissible arguments and characterizations include all of its headers (*e.g.*, "I. Yalkowsky would not have motivated") and each observation as detailed in the following paragraphs with Petitioners' responses.

A. Mot. 1-7: “I. Yalkowsky would not...”

Novartis paraphrases 113:19-115:6 (Mot. 1), impermissibly characterizing nearly two pages of Dr. Jorgensen’s testimony, and along with a half-dozen other observations (Mot. 1-3, 6), impermissibly expanding a single mention of enthalpy at POR 25 into over three pages of new argument. Novartis also impermissibly characterizes and misquotes evidence other than the deposition transcript at hand (*e.g.*, Ex. 1118). In any event, the cited pages of Dr. Jorgensen’s testimony define the components of the formula $\Delta G = \Delta H - T\Delta S$ in his supplemental declaration, Ex. 1118 ¶ 95. This testimony and Novartis’s arguments and characterizations are relevant to Novartis’s new and expanded enthalpy theories at Reply 9-10 (“Lemke and Yalkowsky *together* taught that adding flexible side chains (to increase internal entropy) containing polar groups (to increase hydrophilicity) is likely to improve solubility”), 15-16 (“a POSA would have understood the same qualitative effects apply in real and ideal systems” and “[a]lthough a POSA would not have been interested in quantitatively calculating ideal solubility, a POSA would be very interested in the qualitative impact of entropy on solubility”); Ex. 2222, 115:7-21 (“one would expect...that a more polar compound will have a more negative enthalpy of solution. So that would be a known factor that would favor enthalpy of solution.”); Ex. 1118 ¶ 15 (Stella “illustrates precisely the impact on rapamycin’s water solubility of modifications with flexible side chains containing polar groups

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