Filed on behalf of: Par Pharmaceutical, Inc. et al.

Entered: January 3, 2017

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]
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. RATAIN'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. Ratain's deposition (Paper 57, "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 sections 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 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 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. Fuel*, 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 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); *Zhonghan* 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. A POSA would not have….") and practically all of its observation as detailed in the following paragraphs with Petitioners' responses.

A. Mot. 1: "I. A POSA would not have reasonably expected…"

This section is a *de facto* unauthorized sur-reply on reasonable expectations.

Novartis paraphrases 11:15-24, 14:19-15:6 (Mot. 1), impermissibly characterizing two sections of testimony and its own expert declarations, arguing reasonable expectation of success. Contrary to Novartis's argument, Petitioners rebutted Novartis's legal and factual contentions. Reply 17-19 & n.6 (including cited exhibits, as do all citations to Petitioners' briefs or its experts' testimony). The cited testimony and Novartis's arguments are also relevant to Ex. 1119 ¶¶ 26-29, 32-36, 42-44, 47-48, 101-106; Ex. 2223 14:6-17, 16:11-22; 18:4-8; 20:17-21; 23:23-24:16, 77:7-15 (Kao '678 (Ex. 2130)); 80:13-25; 84:12-25 (Kao '447 (Ex. 2075)), 85:10-15 (same).

Novartis paraphrases 18:9-19:23, 21:18-20 (Mot. 1), characterizing two portions of testimony totaling nearly two pages and further arguing reasonable expectation of success. This testimony and Novartis's reasonable-expectation arguments are relevant to the items identified in the response above.

B. Mot. 2-4: "II. Petitioners have failed…[co-administration and half-life]"

The section continues Novartis's sur-reply on reasonable expectations.

Novartis paraphrases 204:18-205:19 (Mot. 2), characterizing a page of Dr. Ratain's testimony and another exhibit (Ex. 2132), and re-arguing its case. Novartis did not attempt to impeach Dr. Ratain with the trial testimony in Ex. 2132, but instead impermissibly attempts to do so here—after cross-examination is

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