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Filed On Behalf Of: Novartis AG

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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 5,665,772

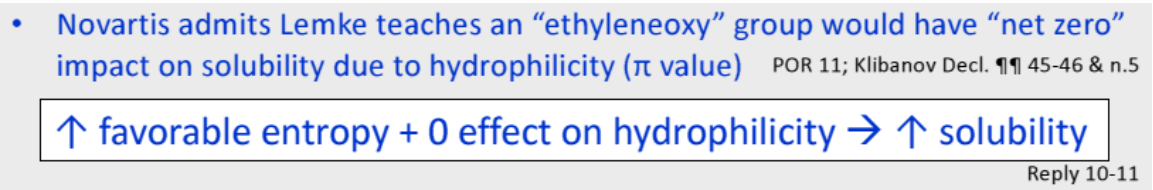
PATENT OWNER'S OBJECTIONS TO PETITIONERS' DEMONSTRATIVE EXHIBITS FOR ORAL HEARING

[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.

Pursuant to the Board's January 17, 2017 Order regarding the Trial Hearing, Patent Owner Novartis AG ("Novartis") objects to the following demonstratives served on January 24, 2017, by Petitioners Par Pharmaceuticals, Inc., Roxane Laboratories, Inc., and Breckenridge Pharmaceutical, Inc. ("Petitioners") on the grounds set forth below. Pursuant to the Board's Order, the parties held a meet and confer on January 30, 2017, to discuss their respective objections to demonstrative exhibits, but were unable to resolve the objections set forth below.

I. Novartis's Objections To Petitioners' Slides Containing New Arguments Not Presented In The Petition Or Reply

Slide 35: Novartis objects to the second bullet and the box that follows thereafter in Slide 35, set forth below:



Novartis objects to this bullet and box as an improper new argument because Petitioners have not previously argued in the Petition or Reply, nor has Novartis admitted in the Patent Owner Response (Paper 27 at 11) or Klibanov Declaration (Ex. 2092 ¶¶ 45-46 & n.5), that Lemke's solubility teachings are limited to "hydrophilicity," Petitioners have not previously included the equation in the box above in the Petition or Reply, and the Petitioners have not previously cited or relied on Klibanov Decl. ¶ 46 & n.5.

Slides 43, 51, 53: Novartis objects to item number 2 in Slides 43, 51, and 53, set forth below:

2. Everolimus did not satisfy any long-felt but unmet need

Novartis objects to item number 2 as an improper new argument because Petitioners have not disputed that everolimus satisfied a long-felt but unmet need for an immunosuppressant regimen for liver transplant recipients, as set forth in the Patent Owner Response, Paper 27 at 68.

Slide 49: Novartis objects to the first bullet in Slide 49, set forth below:

- Cyclosporine interferes with metabolism of everolimus and rapamycin, leading to increase in plasma concentrations

Reply 25; Ratain Decl. ¶ 46

Novartis objects to this bullet as an improper new argument because Petitioners have not previously argued in the Petition or Reply that "[c]yclosporine interferes with metabolism of everolimus and rapamycin, leading to increase in plasma concentrations," and Petitioners' citation to Ratain Decl. ¶ 46 as support for their reliance on these exhibits would constitute an improper incorporation by reference.

Slide 52: Novartis objects to the bullets under the second heading in Slide 52, set forth below:

- Need remains for breast and renal cell cancer treatments
- Other treatments explicitly have been shown to be superior to everolimus

Reply 26-27; Ratain Decl. ¶ 111

Novartis objects to each of these bullets as improper new arguments because Petitioners have not previously argued in the Petition or Reply that a need remains for breast cancer treatment or that other treatments for breast cancer are superior to everolimus.

II. Novartis's Objections To Petitioners' Slides Citing New Evidence Not Previously Cited In The Petition Or Reply

Slide 37: Novartis objects to the second sub-bullet in Slide 37, set forth below:

- Increase in internal entropy leads to increase in solubility in examples of nonideal solutions (Ex. 1117 Schwartz at 254, Table II, Table III)

Reply 16; Jorgensen Supp. Decl. ¶¶ 96-99

Novartis objects to this sub-bullet and citation to Ex. 1117 as an improper new argument because Petitioners have not previously cited Ex. 1117 in the Petition or Reply.

Slide 46: Novartis objects to the sub-bullets listed under the third main bullet in Slide 46, set forth below:

- Rapamycin *has* clinical activity in each of the approved tumor indications

Reply 22-23; Ratain Decl. ¶¶ 62-100

  - Breast cancer (*E.g.*, Ex. 2178, Ex. 2177) — Ratain Decl. ¶¶ 64-75
  - Renal cell carcinoma (Ex. 2173, Ex. 1087) — Ratain Decl. ¶¶ 83-87
  - NETs (Ex. 1088, Ex. 2163) — Ratain Decl. ¶¶ 76-82
  - SEGA (Ex. 1098, Ex. 1099) — Ratain Decl. ¶¶ 96-100
  - Renal angiomyolipoma (Ex. 1093) — Ratain Decl. ¶¶ 88-95

Novartis objects to Petitioners' citation to and discussion of Exs. 2178, 2177, 2173, 1087, 1088, 2163, 1098, 1099, and 1093 in these sub-bullets as an improper new argument because Petitioners have not previously cited these exhibits in the Petition or Reply to assert that everolimus's antitumor activity is no different than rapamycin's, and Petitioners' citation to Ratain Decl. ¶¶ 62-100 as support for their reliance on these exhibits constitutes an improper incorporation by reference.

Slide 48: Novartis objects to Petitioners' citation of Ex. 1120 and Fig. 1 in Slide 48, set forth below:

Novartis objects to Petitioners' citation of Ex. 1120 and reliance on Fig. 1 of Ex. 1120 as an improper new argument because Petitioners have not previously cited Ex. 1120 in the Petition or Reply, and Petitioners' citation to Ratain Decl. ¶¶ 101-108 as support for their reliance on these exhibits constitutes an improper incorporation by reference.

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