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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]
Patent No. 5,665,772

PATENT OWNER'S REQUEST FOR ORAL ARGUMENT PURSUANT TO 37 C.F.R. § 42.70(a)

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[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 April 29, 2016 Scheduling Order (Paper 9) in this proceeding, as modified by the Order dated December 2, 2016 (Paper 45), and 37 C.F.R. § 42.70(a), Patent Owner Novartis AG requests that the Patent Trial and Appeal Board hear oral argument on the issues below. As set forth in the December 2, 2016 Order, and the Board's email of the same date, oral argument is scheduled for February 2, 2017, and the Board has confirmed the availability of Hearing Room A on the morning of February 2, 2017.

Patent Owner respectfully requests 60 minutes of argument time.

Pursuant to 37 C.F.R. § 42.70(a), Patent Owner specifies the following issues to be argued, without intent to waive consideration of any issue not requested:

(1) Petitioners' failure to meet their burden of establishing obviousness of challenged claims 1-3 and 8-10 under either of the instituted Grounds, particularly where:

(a) Neither Lemke nor Yalkowsky, alone or in combination, provides a motivation to replace rapamycin's C40 hydroxyl (-OH) group with a different hydroxyl-containing group that additionally has an ether oxygen and two methylenes ($-OCH_2CH_2OH$), with a reasonable expectation that the modification will increase water solubility, because, *inter alia*:

(i) Lemke teaches that the addition of an ether oxygen (-O-) and two methylene groups (-CH_2CH_2-), *i.e.*, the groups present in everolimus but not rapamycin, will have a net zero impact on water solubility;

(ii) Petitioners' declarant Dr. Jorgensen admitted that Yalkowsky is not analogous art;

(iii) Yalkowsky's teachings about the ideal solubility of long-chain derivatives of rigid molecules of intermediate size are not applicable to the non-ideal solubility of rapamycin or everolimus in water; and

(iv) Yalkowsky's entropy teachings (*i.e.*, adding long flexible side chains increases the change in *entropy*, which may increase *ideal solubility*) cannot predict solubility in *non-ideal solutions*, as solubility in non-ideal solutions requires consideration of how a given modification impacts both entropy *and enthalpy*.

(b) A POSA seeking to increase rapamycin's water solubility while maintaining immunosuppressive activity would have pursued approaches likely to meaningfully impact water solubility, such as formulation, prodrugs, and water-soluble salts—not chemical synthesis of everolimus.

(c) The prior art contradicts Petitioners' unsupported suggestion that a POSA would consider only three specific compounds with "small" groups.

(d) Petitioners failed to apply the proper legal analysis and consider the art as a whole prior to selecting a lead compound.

(e) The prior art fails to establish that rapamycin's water solubility for immunosuppressive use was a known problem that a POSA would have tried to solve.

(f) The prior art fails to establish that a POSA would have reasonably expected everolimus to have increased water solubility, similar immunosuppressive activity as rapamycin, and/or its unique combination of immunosuppressive and anti-tumor properties.

(g) Compelling objective indicia of non-obviousness concerning both everolimus's immunosuppressive and anti-tumor properties further support a finding of non-obviousness.

(h) Concerning Ground 2, Hughes fails to provide a reasonable expectation that everolimus's methods of treatment would have been obvious.

(2) Petitioners' reliance on evidence that fails to comply with the Federal Rules of Evidence and/or 37 C.F.R. § 42, as set forth in Patent Owner's Motion to Exclude.

(3) Petitioners' improper attempts to raise new arguments and cite new evidence in their Reply (Paper 46) and accompanying declarations (Exhibits 1118 and 1119), that should have been included in the Petition.

(4) Petitioners' mischaracterization in their Reply (Paper 46) of many of the arguments set forth in Patent Owner's Response (Paper 27).

(5) Any other issues raised by Petitioners in a request for oral argument, motion to exclude, or any other paper filed by Petitioners before oral argument.

(6) Any other issues that the Board deems necessary.

Patent Owner requests the ability to use audio-visual equipment to display demonstrative exhibits, including the use of a projector and screen for PowerPoint display.

Dated: December 20, 2016

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