

Filed On Behalf Of: Novartis AG

By: Nicholas N. Kallas
NKallas@fchs.com
ZortressAfinitorIPR@fchs.com
(212) 218-2100

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 5,665,772

**PATENT OWNER'S IDENTIFICATION OF PORTIONS
OF PETITIONERS' REPLY THAT EXCEED THE
PROPER SCOPE OF REPLY OR RAISE NEW ARGUMENTS**

¹ The Board on October 27, 2016 joined Breckenridge's IPR2016-01023 and Roxane's IPR2016-01103 with Par's IPR2016-00084 challenging claims 1-3 and 8-10 of the '772 patent.

Pursuant to the Board’s email of January 6, 2017, Novartis submits the following numbered list setting forth the portions of Petitioners’ Reply (Paper 46) that exceed the proper scope of reply or raise new arguments, along with a one-sentence statement of the basis for the objection.

1. Page 3, line 20 – page 4, line 3, and page 4, lines 13-15. Petitioners assert a new basis for selecting rapamycin as a lead compound (“potency”) that could and should have been raised as part of their *prima facie* case, but was not included in the Petition.

2. Page 4, lines 10-12 and 17-20 (*see also* page 1, lines 17-20). Petitioners assert a new basis for selecting rapamycin as a lead compound (“researchers regularly selected rapamycin”) that relies on evidence (exhibits cited in Ex. 2093 ¶¶ 63-83) that could and should have been raised as part of their *prima facie* case, but were not included in the Petition.

3. Page 6, lines 3-16. Petitioners rely on new evidence (Ex. 1034 at 116; Ex. 1118 ¶¶ 25-26) to assert that it was known in the art that rapamycin’s solubility led to formulation problems, when this argument and evidence could and should have been raised as part of their *prima facie* case, but were not included in the Petition.

4. Page 6, lines 5-16. Petitioners rely on new evidence (Ex. 1034; Ex. 1118 ¶¶ 26, 32-35) to assert a motivation to chemically modify rapamycin, when

this evidence could and should have been raised as part of their *prima facie* case, but was not included in the Petition.

5. Page 10, lines 10-12 and 14-17. To the extent Petitioners are arguing that (i) Lemke (Ex. 1008) discusses internal entropy and/or (ii) Yalkowsky (Ex. 1007) discusses polar groups and hydrophilicity, these arguments could and should have been raised as part of their *prima facie* case, but were not included in the Petition.

6. Page 12, line 1 – page 14, line 9, and page 15, line 13 – page 16, line 1. Petitioners attempt to explain how Yalkowsky is relevant to the instant case, including why everolimus qualifies as a long-chain derivative of rapamycin with more than 6 atoms in the chain, when such arguments and evidence could and should have been raised as part of their *prima facie* case, but were not included in the Petition, and when Petitioners' declarant, Dr. Jorgensen, refused to answer questions at his August 9, 2016 deposition about the length of everolimus's side chain (*see* Novartis's Patent Owner Response, Paper 27 at 22 and 22 n.4).

7. Page 16, lines 1-9. Petitioners attempt to explain the relationship between ideal solubility and real systems, and rely on new evidence (Ex. 1118 ¶¶ 13, 92-102 and exhibits cited therein including Ex. 1117), when such arguments and evidence could and should have been raised as part of their *prima facie* case, but were not included in the Petition.

8. Pages 17-18, footnote 6. Petitioners rely on new evidence (Ex. 1119 ¶¶ 32-36, 43, 101-106 and exhibits and evidence cited therein) and make a new argument that everolimus's antitumor activity would have been reasonably expected as of October 1992, when this evidence and argument that could and should have been raised as part of their *prima facie* case, but were not included in the Petition.

9. Page 19, lines 10-13. Petitioners assert a new basis to assert that everolimus would have been expected to “retain[] immunosuppressant activity” that relies on evidence (Ex.1118 ¶¶103-108, and exhibits cited therein, and exhibits cited in Ex. 2092 ¶ 63) that could and should have been raised as part of their *prima facie* case, but was not included in the Petition.

Respectfully submitted,

Dated: January 12, 2017

/Nicholas N. Kallas/
Nicholas N. Kallas
Registration No. 31,530
Lead Counsel for Patent Owner
FITZPATRICK, CELLA, HARPER
& SCINTO
1290 Avenue of the Americas
New York, NY 10104-3800
Tel. 212-218-2100

CERTIFICATE OF SERVICE

I certify that a copy of the foregoing Patent Owner's Identification of Portions of Petitioners' Reply that Exceed the Proper Scope of Reply or Raise New Arguments was served on January 12, 2017 by causing it to be sent by email to counsel for Petitioners at the following email addresses:

Daniel G. Brown (dan.brown@lw.com)

Robert Steinberg (bob.steinberg@lw.com)

Brenda L. Danek (Brenda.danek@lw.com)

Jonathan M. Strang (jonathan.strang@lw.com)

Matthew L. Fedowitz (mfedowitz@merchantgould.com)

B. Jefferson Boggs (jboggs@merchantgould.com)

Daniel R. Evans (devans@merchantgould.com)

Keith A. Zullo (kzullo@goodwinlaw.com)

Marta Delsignore (mdelsignore@goodwinprocter.com)

Dated: January 12, 2017

/Nicholas N. Kallas/

Nicholas N. Kallas

Registration No. 31,530

Lead Counsel for Patent Owner

FITZPATRICK, CELLA, HARPER
& SCINTO

1290 Avenue of the Americas

New York, NY 10104-3800

Tel. 212-218-2100