

**Par Pharmaceuticals, Inc., Roxane
Laboratories, Inc., and Breckenridge
Pharmaceutical, Inc.,**
Petitioners

V.

Novartis AG,
Patent Owner

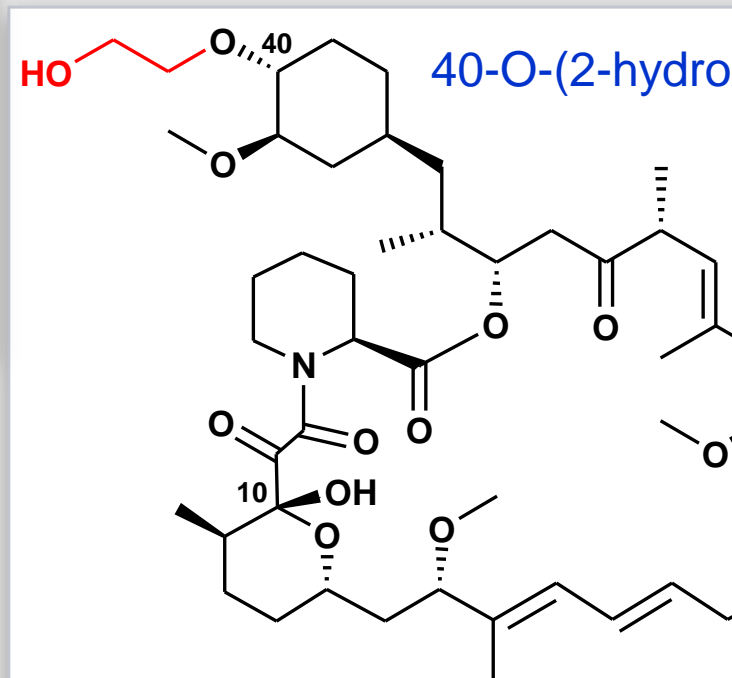
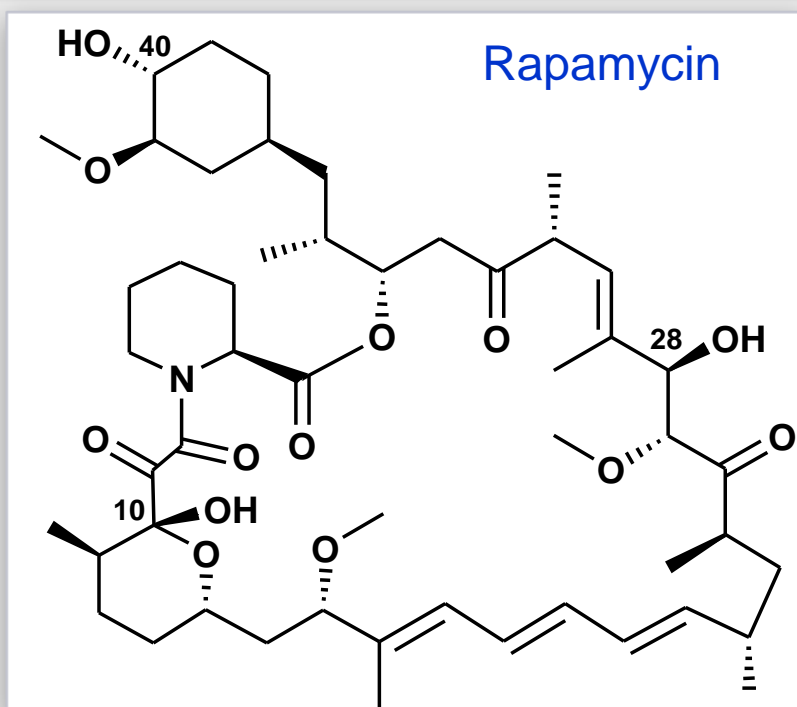
IPR2016-00084, IPR2016-01023, IPR2016-01102

U.S. Patent No. 5,665,772

Oral Argument

February 2, 2017

'772 Patent Claims Rapamycin Derivatives and Their Use as Immunosuppressants



Instituted Grounds

- Ground 1: Claims 1-3 and 10 are obvious in view of Morris, Duyne, Rossmann, Lemke, and Yalkowsky
 - Claims recite C40 rapamycin derivatives
- Ground 2: Claims 8 and 9 are obvious in view of Morris, Van Dyne, Rossmann, Lemke, Yalkowsky, and Hughes
 - Claims recite methods of immunosuppression and prevention of allograft rejection

I. Rapamycin Would Have Been A Lead Compound

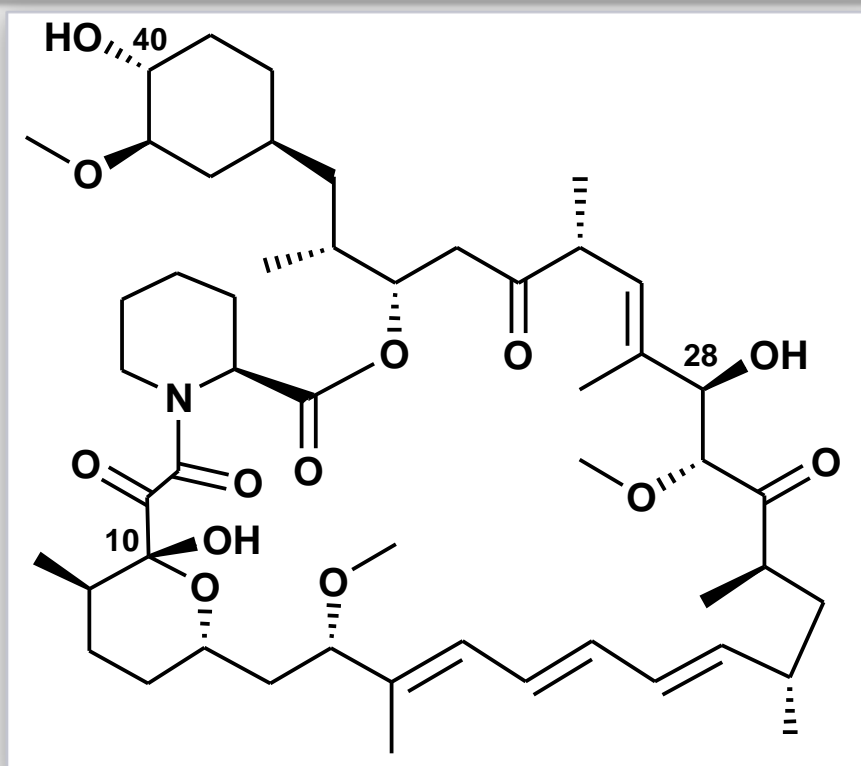
II. A POSA Would Have Been Motivated to Improve Solubility

III. A POSA Would Have Modified Rapamycin at the 3-Hydroxyl Using Known Techniques

IV. Purported Deficiencies Raised by Novartis

V. Secondary Considerations Do Not Outweigh the Primary Considerations

Rapamycin Would Have Been a Lead Compound



- Well-known drug with exciting and potent immunosuppressant activity
Pet. 6, 16-17, 26, 41-42; Jorgensen Decl. ¶¶ 72-74, 133; Morris (1992) a
- IND filed, “poised to accelerate,” “particularly intriguing” (Morris (1992)
Pet. 6, 16-17, 26, 41-42; Jorgensen De
- Hughes (1992) and Schiehser (1991) made derivatives with

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