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**UNITED STATES PATENT AND TRADEMARK OFFICE**

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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PAR PHARMACEUTICAL, INC.,

Petitioner,

v.

NOVARTIS AG,

Patent Owner.

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Case IPR2016-00084

Patent No. 5,665,772

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**PATENT OWNER NOVARTIS'S REQUEST  
FOR REHEARING UNDER 37 C.F.R. § 42.71(c) AND (d)**

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**I. INTRODUCTION AND  
STATEMENT OF RELIEF REQUESTED**

Pursuant to 37 C.F.R. § 42.71(c) and (d), Patent Owner Novartis AG (“Novartis”) respectfully requests reconsideration of the Board’s April 29, 2016 decision instituting *inter partes* review of the challenged claims of U.S. Patent No. 5,665,772 (“the ’772 patent”), Paper 8 (“Dec.”), on Grounds 1 and 2 set forth in the Petition of Par Pharmaceutical, Inc. (“Par”), Paper 2 (“Pet.”).

Novartis requests rehearing because the Board overlooked or misapprehended the arguments presented at pages 22–23 and 26 of Novartis’s Preliminary Response, Paper 7 (“Prelim. Resp.”) regarding Lemke (Ex. 1008), and at pages 23–26 regarding Yalkowsky (Ex. 1007), either of which provides an independent basis to deny institution. The Board’s decision to institute this review does not specifically reference Novartis’s arguments regarding the Lemke and Yalkowsky references, or cite any of pages 22–26 of the Preliminary Response. The decision identifies only some of Novartis’s arguments and states that it has “considered these and other arguments raised by Novartis” (Dec. 15), but not that it considered all of Novartis’s preliminary response arguments.

At pages 22–23 and 26 of its Preliminary Response, Novartis explained that the chemical difference between everolimus and rapamycin at C40 does

not involve the *addition of* any of the water-solubilizing groups upon which Par based its challenge. Par's argument with respect to Lemke is thus based on a fundamental scientific error that is fatal to its case. At pages 23–26 of its Preliminary Response, Novartis explained that Yalkowsky's teachings about the internal entropy of flexible chains, upon which Par relies, apply only to chains of more than five atoms—*not* shorter chains like everolimus' C40 substituent. Thus, Par's suggestion to rely on Yalkowsky is contradicted by the reference itself. Novartis should not be put to the burden and expense of defending a case that Par has no reasonable likelihood of winning. *See* 35 U.S.C. § 314(a).

## **II. BASIS FOR RELIEF REQUESTED**

### **A. Background**

As the Board's decision explains, Par alleges that one of ordinary skill in the art, as of October 9, 1992, would have selected rapamycin as a lead compound, and would have had a motivation to increase its water solubility. Dec. 10–11. In particular, Par alleges that the person of ordinary skill would have chemically modified rapamycin at C40 by introducing a flexible substituent (based only on the teachings of Yalkowsky (Ex. 1007)), that adds an alcohol, amine or carboxylic acid functional group (based only on the teachings of Lemke (Ex. 1008)). Dec. 11–12 (citing Pet. 44–47).

**B. The Board’s Decision Overlooked  
Novartis’s Arguments On Lemke**

In instituting trial on Grounds 1 and 2, the Board overlooked the argument presented at pages 22–23 and 26 of Novartis’s Preliminary Response. There, Novartis explained that Par mischaracterizes the chemical difference between rapamycin and everolimus to justify relying on Lemke. Prelim. Resp. 22–23.

In particular, Novartis explained that Par cites Lemke for the proposition that it would have been obvious to consider the *addition of* water-solubilizing substituents to rapamycin. *Id.* (citing Pet. 33–34). According to Par, Table 16-1 of Lemke (Ex. 1008 at 116, reproduced at Pet. 24; *see also infra* n.2) discloses the favorable water-solubilizing effects of *adding* hydroxyl, amino, and carboxylate groups. Prelim. Resp. 22 (citing Pet. 33–34; Ex. 1003 at ¶ 84). However in focusing on the portions of Lemke’s Table 16-1 relevant to alcohol (hydroxyl), amino and carboxylate groups, Par failed to address the evidence in Table 16-1 that is actually relevant to the challenged claims—the entry pertaining to ether groups.

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