Paper No. ___
Filed: September 22, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MYLAN LABORATORIES LIMITED,
Petitioner,
v.
AVENTIS PHARMA S.A.,
Patent Owner.

_____

Case IPR2016-00627
Patent 5,847,170

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PETITIONER MYLAN LABORATORIES LIMITED'S REQUEST FOR REHEARING PURSUANT TO 37 C.F.R. § 42.71

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I. PRECISE RELIEF REQUESTED

Mylan Laboratories Limited ("Petitioner") respectfully requests that the Board reconsider its decision (Paper 10) denying *inter partes* review.

II. BASIS FOR REHEARING

A. Legal Standard for Rehearing

Pursuant to 37 C.F.R. § 42.71(d), a party may request rehearing of an institution decision by "specifically identify[ing] all matters the party believes the Board misapprehended or overlooked, and the place where each matter was previously addressed in a motion, an opposition, or a reply." *Id.* The Board reviews the prior decision for abuse of discretion, 37 C.F.R. § 42.71(c), such as an erroneous interpretation of law, a factual finding that is not supported by substantial evidence, or an unreasonable judgment in weighing relevant factors. IPR 2013-00369, Paper 39 at 2-3.

B. Summary of the Petition

The Petition shows in Ground 1 that a combination of Kant (Ex. 1005) and Klein (Ex. 1006) renders obvious the compound of claim 1, based on (i) the selection of 10-methoxy docetaxel (Compound 20) as a lead compound from Kant, (ii) Klein's teaching that methylation of both docetaxel and paclitaxel analogues at the C-7 hydroxyl results in potent anti-cancer compounds, and (iii) the simpler synthetic pathway that was known to result from simultaneously methylating both

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the C-7 and C-10 hydroxyls when making taxanes from the readily available synthetic precursor 10-DAB. Pet. at 31-35.

In Ground 2, (i) Colin (Ex. 1007) provides docetaxel as a lead compound, (ii) Klein teaches that functionalization of both the C-7 and C-10 hydroxyls (*e.g.*, methylation of the C-7 hydroxyl and acetylation of the C-10 hydroxyl) provides potent anti-cancer compounds, (iii) Klein demonstrates that reduction of the C-9 carbonyl to form 9-dihydro analogues is not responsible for the increased potency observed with functionalization of the C-7 and C-10 hydroxyls as the C-9 reduction diminished potency somewhat; and (iv) Kant teaches methylation is more potent than acetylation at the C-10 hydroxyl. Pet. at 38-39, 41, 43-44.

Following either route, the wide availability of the synthetic taxane precursor 10-DAB provided further motivation for methylating at both the C-10 and C-7 hydroxyls simultaneously, rather than a more laborious selective modification process of one, or sequential modification of one and then the other. Pet. at 39-41, 44, 47. Both Grounds also rely on synthetic simplicity to support retention of the C-9 carbonyl present in docetaxel and paclitaxel as an obvious choice for making a potent anti-cancer compound. Pet. at 34-35, 43-45. Both Grounds show dependent claim 2 (pharmaceutical composition) as obvious. Pet. at 35-38, 46-47.

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III. Kant Compound 20 as a Lead Compound

The Petition, with supporting evidence, shows in Ground 1 that a skilled artisan would reasonably select Compound 20 of Kant "as an anti-tumor compound" because of its "superior combination of tubulin binding ability and potency." Pet. at 31. The Decision misapprehends the legal standards, and misunderstands or overlooks key arguments and evidence.

A. Erroneous Legal Standards

The evaluation of Kant Compound 20 as a lead compound misapprehends the proper legal test by: (1) requiring Kant itself teach or suggest modifications to Compound 20; (2) conflating "lead compound" with the ideal synthetic precursor; (3) requiring proof Compound 20 was more potent than docetaxel and Compound 22; and (4) labeling a *Graham* factor 3 analysis as improper hindsight.

1. Requiring Motivation to Modify to Justify Lead Selection

The Decision rejects Compound 20 as a lead compound, reasoning that Kant does not teach or suggest modifications of Compound 20. Dec. at 12 ("Kant does not teach or suggest additional structural modifications to Compound 20 or docetaxel, which cuts against the notion of selecting Kant Compound 20 as a lead compound for further modification of this docetaxel analogue."); *id.* at 13 ("Kant also does not teach or suggest the possibility of simultaneous substitution of both the C-7 and C-10 positions…"). This holding contradicts Federal Circuit precedent

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