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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEPTUNE GENERICS, LLC

PETITIONER

V.

AVENTIS PHARMA S.A.

PATENT OWNER

CASE NO.: IP2019-00136
PATENT NO. 5,847,170
FILED: MARCH 26, 1996
ISSUED: DECEMBER 8, 1998
INVENTORS: HERVÉ BOUCHARD,
JEAN-DOMINIQUE BOURZAT, ALAIN COMMERÇON

TITLE: TAXOIDS, THEIR PREPARATION, AND PHARMACEUTICAL COMPOSITIONS CONTAINING THEM

PETITIONER'S REQUEST FOR REHEARING
UNDER 37 C.F.R. § 42.71(d)(1)

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I. STATEMENT OF PRECISE RELIEF REQUESTED

Petitioner Neptune Generics, LLC ("Neptune"), requests rehearing, pursuant to 37 C.F.R. § 42.71(d)(1), of the Board's Decision denying institution of review for challenged claims 1-2 of U.S. Patent No. 5,847,170 ("the '170 patent"). (Paper 15, "Decision" or "Dec."). Petitioner is simultaneously requesting a Precedential Opinion Panel by contacting the appropriate e-mail address, as instructed in the relevant Standard Operating Procedure. The proper application of 325(d) to a new chemical compound obviousness analysis is of such extraordinary and recurring importance to the PTAB and its participants that a precedential panel is necessary to supply uniform guidance for future cases. The panel denied institution because the prior art or arguments in Neptune's petition were purportedly "substantially similar" to those presented in a previous petition in *Mylan Laboratories Limited v. Aventis Pharma S.A.*, IPR2016-00627 (filed Feb. 17, 2016). *See* Dec. at 25-35. This finding distorts both 325(d) and the law of obviousness.

The panel found "substantial similarity" even though Neptune presented: (**1**) a ***different lead compound*** (paclitaxel) and ***different reasons*** for selecting the lead compound than Mylan's lead compounds (Kant Compound 20 or docetaxel); (**2**) a ***different primary reference*** for selection of paclitaxel as the lead compound and for promising areas for substitutions of that lead compound (*Commerçon*) than Mylan used to select and modify its different lead compounds (*Kant*); (**3**) ***different***

primary references for substitution at the C-7 position (*Commerçon* and *Wong*) than Mylan used for C-7 substitution (*Klein*); and (**4**) a ***different primary reference*** for substitution at the C-10 position (*Commerçon*) than Mylan used (*Kant*), as well as ***different arguments*** for applying *Kant*—the only Neptune primary reference that overlaps with a Mylan primary reference—as an additional basis to substitute paclitaxel's C-10 position (*Kant's* paclitaxel data as a control) than Mylan used when it applied *Kant* as its sole reference to modify its different lead compound (*Kant* contains no data as a control that supports modifying the C-7 position of Compound 20 or docetaxel); and (**5**) a ***different expert declarant*** presenting a different lead compound and different primary references.

Neptune respectfully submits that the panel overlooked or misapprehended the law governing new chemical compound obviousness, the plain and material factual differences between the art and arguments in the Neptune and Mylan petitions, and misapprehended or misapplied recent 325(d) decisions to reach an unreasonable judgment in weighing the relevant factors. Section 325(d) simply does not (and cannot) support discretionary denial of an obviousness challenge to a new chemical compound where the lead compound, and two of the three primary references presented in support of modifying it—***have never been presented to or considered by the Patent Office***—particularly where the Office rejected the prior petition because the lead compounds selected had no evidentiary support and were

based entirely on hindsight. Neptune argued the challenged claims are obvious when a POSA starts with paclitaxel, and modifies it based on *Commerçon*, *Kant* and *Wong*. Mylan's petition did not select paclitaxel as a lead compound—and it ***did not even cite*** *Commerçon* or *Wong*. A discretionary denial under these circumstances makes a mockery of both 325(d) and the law governing obviousness of new chemical compounds.

For these reasons, as discussed in detail below, Neptune respectfully requests rehearing of the panel's decision declining to institute review.

II. LEGAL STANDARD FOR REHEARING

A rehearing request "must specifically identify 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.* Institution decisions are reviewed on rehearing for an abuse of discretion. *See* 37 C.F.R. § 42.71(c). "An abuse of discretion may be indicated if a decision is based on an erroneous interpretation of law, if a factual finding is not supported by substantial evidence, or if the decision represents an unreasonable judgment in weighing relevant factors." *Google LLC v. Cywee Group Ltd.*, IPR2018-01257, Paper No. 12 at 2 (Jan. 30, 2019) (citing *Star Fruits S.N.C. v. U.S.*, 393 F. 3d 1277, 1281 (Fed. Cir. 2005).

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