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Paper No. 20
Filed: October 15, 2019

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 IPR2019-00136
Patent 5,847,170

Before TINA E. HULSE, CHRISTOPHER M. KAISER, and TIMOTHY G. MAJORS, *Administrative Patent Judges*.

MAJORS, *Administrative Patent Judge*.

DECISION
Denying Petitioner's Request on Rehearing
of Decision Denying Institution of *Inter Partes* Review
37 C.F.R. § 42.71(d)

I. INTRODUCTION

Neptune Generics, LLC ("Petitioner" or "Neptune") requests rehearing of our decision (Paper 15, "Decision" or "Dec.") denying institution of *inter partes* review of claims 1 and 2 of U.S. Patent No. 5,847,170 (Ex. 1001, "the '170 patent"). Paper 16 ("Request" or "Req.").[1] We deny the Request for the reasons explained below.

II. STANDARD OF REVIEW

In response to a request for rehearing, the panel reviews a decision whether to institute trial for an abuse of discretion. 37 C.F.R. § 42.71(c). An abuse of discretion may be found if there was an erroneous interpretation of law, a factual finding not supported by substantial evidence, or an unreasonable judgment in weighing relevant factors. 37 C.F.R. § 42.71(c); *Star Fruits S.N.C. v. U.S.*, 393 F.3d 1277, 1281 (Fed. Cir. 2005); *The Arnold Partnership v. Dudas*, 362 F.3d 1338, 1340 (Fed. Cir. 2004); *In re Gartside*, 203 F.3d 1305, 1315–16 (Fed. Cir. 2000). "The burden of showing a decision should be modified lies with the party challenging the decision." 37 C.F.R. § 42.71(d). Moreover, the rehearing request "must specifically identify all matters the [requesting] 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.*

III. ANALYSIS

As explained in the Decision, the Board denied institution of Petitioner's *inter partes* review challenge on a discretionary basis under

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[1] Petitioner also requested review of the Decision by the Precedential Opinion Panel ("POP"). Req. 1. The POP denied the request for POP review, and the original panel maintains authority over the present Request. Paper 19, 1–2.

35 U.S.C. § 325(d). *See generally*, Dec. 25–37. We determined that non-institution was appropriate based on, *inter alia*, comparisons of the art and arguments in the present Petition and an earlier petition challenging the same claims of the same patent, which petition was filed by Mylan (Ex. 2011) and for which the Board denied institution (Ex. 2020).

According to Petitioner, "the panel overlooked or misapprehended both the law of new chemical compound obviousness and the differences between Neptune's and Mylan's petitions." Req. 4. That is so, Petitioner contends, because the art and arguments in the Petition are not similar, "much less substantially similar," to the arguments presented by Mylan. *Id.* More specifically, Petitioner argues, the Board erred in its Decision in three ways: (1) in our comparison of Petitioner's lead compound versus the lead compounds advanced by Mylan; (2) in finding the Commerçon reference and related argument cumulative to art and arguments raised in the Mylan petition; and (3) in our assessment of the similarities between the Wong and Klein references. Req. 5–15.

We have considered Petitioner's arguments, but we do not agree that the Decision denying institution under § 325(d) was in error. We address in greater detail below.

Lead Compound

In the Decision, we agreed with Patent Owner that, although Petitioner's challenge urged a "different" lead compound (paclitaxel versus Kant's compound 20 or docetaxel), that distinction was superficial on the record before us. Dec. 28. As Patent Owner persuasively argued, "Neptune's and Mylan's lead compound analyses arrive at the same compound; paclitaxel having a C-10 methoxy group and a BOC sidechain, *i.e.*, Kant Compound 20." Prelim. Resp. 20–21. And, as we also pointed

out, Petitioner turned to Kant for substantially the same reasons Mylan did—to show that a methoxy substitution at the core molecule's C-10 position is capable of providing a more potent paclitaxel analog. Dec. 28; Ex. 2011, 6 (explaining that Kant teaches "compound 20, which displays the best tubulin binding properties of all analogues studied, the highest efficacy of the studied analogues having a docetaxel side chain, and higher efficacy than paclitaxel").[2]

The Board did not find persuasive Petitioner's argument that use of paclitaxel as the lead compound was sufficient to avoid discretionary denial on this record. Pet. 78; Paper 122–3. As we further explained,

> Kant relates to paclitaxel and its analogues. Ex. 1010, 1–2. And Kant describes the same advanced precursor (10-DAB-III) that is used for the synthesis of paclitaxel as being used to synthesize Kant's analogues with a C-10 substitution. *Id.* The Board [in *Mylan*], however, considered Kant and other evidence on these very points, when declining institution of trial for the Mylan Petition. Ex. 2020, 5, 7–8, 12.
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> Petitioner here urges that paclitaxel is a lead compound but, in much the same way as Kant, Petitioner's modification of the art begins with 10-DAB-III, adding a side chain (with a BOC-containing group) and substituting a methoxy group at C-10. Pet. 37–40. Plus, as Patent Owner points out, Petitioner uses Kant in substantially the same way as Mylan did to rationalize such modifications. Prelim. Resp. 21; *see, e.g.*, Pet. 42–43, 46–47 ("[M]ethylation of C-10 showed a desirable increase in activity when compared to similar BOC-containing paclitaxel analogs. Indeed, Kant Table II . . ."). That Mylan may have jumped ahead to Kant's compound 20, citing its favorable properties as a reason

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[2] Mylan's chosen terminology, sometimes describing Kant's Compound 20 as C-10 methoxy docetaxel (as the compound includes a BOC sidechain like docetaxel) does not materially change our analysis of these similarities and it is undisputed that Kant, in fact, describes its compounds as being *paclitaxel* analogues. Ex. 1010.

> for selecting and modifying it, while Petitioner gets to essentially the same compound in more than one step—with an arguably more thorough discussion on paclitaxel and the precursor used to make it and its analogues—does not, in our view, substantially or materially change the argument.

Dec. 30–31. The Board did not misapprehend or overlook Petitioner's arguments concerning lead compounds.[3] We addressed them, as noted above. Although Petitioner disagrees with our assessment of the similarities between the petitions on this issue, such disagreement does not persuasively demonstrate error that requires the Decision be changed.

In its Request, Petitioner contends the Board denied Mylan's petition because it rejected Kant compound 20 as a lead compound. Req. 5–7 ("the Mylan decision . . . held that a POSA would not select Compound 20 as the lead compound").[4] Petitioner argues, *inter alia*, that "[n]ot a single one of the reasons the Board raised in rejecting Compound 20 as the lead applies to paclitaxel . . . and nothing in the Decision found to the contrary." *Id.* (arguing "*Mylan* found that starting with Compound 20 as the lead

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[3] Petitioner requested, and was granted, the opportunity for additional pre-institution briefing to address Patent Owner's arguments in favor of § 325(d) discretionary denial. *See generally* Paper 13.

[4] It is also questionable whether Petitioner adequately addressed and developed *pre-institution* the arguments it is making now in its Request on this point. *See* 37 C.F.R. § 42.71(d). In the Request, Petitioner cites the Petition at pages 77–78, but those pages generically contend that "the Mylan petition relied upon completely different lead compounds." Pet. 77–78; Req. 5–6. Petitioner also cites to a footnote of the pre-institution Reply (Paper 13). Req. 6–7 (citing Reply 2 n.1). That footnote is also generic, stating that "the Board denied Mylan's petition, in significant part due to Mylan's failure to establish Kant 20 as a lead compound." Paper 13.

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