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Paper No. 18
Entered: October 27, 2015

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX INC.,
Petitioner,

v.

MERCK SHARP & DOHME CORP.,
Patent Owner.

Case IPR2015-00419
Patent 5,691,336

Before LORA M. GREEN, ZHENYU YANG, and ROBERT A. POLLOCK, *Administrative Patent Judges*.

YANG, *Administrative Patent Judge*.

DECISION
Order Denying Petitioner's Request for Rehearing
37 C.F.R. § 42.71

INTRODUCTION

Apotex Inc. ("Petitioner") filed a Petition for an *inter partes* review of claims 1, 3–8, and 10–25 of U.S. Patent No. 5,691,336 ("the '336 patent," Ex. 1001). Paper 1 ("Pet."). The Board denied the Petition. Paper 14 ("Dec."). Petitioner filed a Request for Rehearing. Paper 15 ("Reh'g Req."). Petitioner also filed a Petition under 37 C.F.R. § 41.3, suggesting reconsideration by an expanded panel. Paper 16.

For the following reasons, we deny Petitioner's Request for Rehearing. The Acting Chief Administrative Judge declined to expand the panel.

STANDARD OF REVIEW

When rehearing a decision on institution, the Board reviews the decision for an abuse of discretion. 37 C.F.R. § 42.71(c). An abuse of discretion occurs when a decision was based on an erroneous conclusion of law or clearly erroneous factual findings, or a clear error of judgment. *In re Gartside*, 203 F.3d 1305, 1315–16 (Fed. Cir. 2000).

The party requesting rehearing bears the burden of showing the decision should be modified. 37 C.F.R. § 42.71(d). Specifically, a request for rehearing must identify all matters the party believes the Board misapprehended or overlooked. *Id.*

DISCUSSION

In our Decision denying the Petition, we determined that Petitioner has failed to sufficiently explain why, at the time of the '336 patent

invention, a skilled artisan would have chosen compound 96 of Dorn '699 to further develop its prodrug, which is the subject matter of the challenged claims. Dec. 12. In its Request, Petitioner argues that we erred in concluding that compound 96 is not a lead compound. Reh'g Req. 1. We are not persuaded.

Petitioner relies on *In re Dillon*, 919 F.2d 688 (Fed. Cir. 1990) (en banc). According to Petitioner, "[u]nder *Dillon*, structural similarity alone is sufficient to provide motivation to a person skilled in the art ("POSA") to modify a prior art compound." *Id.* at 7. *Dillon* did not hold so. Instead, *Dillon* held that "structural similarity between claimed and prior art subject matter, proved by combining references or otherwise, *where the prior art gives reason or motivation to make the claimed compositions*, creates a prima facie case of obviousness." *Dillon*, 919 F.2d at 692 (emphasis added). In other words, a patent challenger must provide "some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness," independent of the structural similarity. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007). Indeed, the Federal Circuit has repeatedly explained so. *See e.g.*, *Daiichi Sankyo Co., Ltd. v. Matrix Laboratories, Ltd.*, 619 F.3d 1346, 1352 (Fed. Cir. 2010) ("Proof of obviousness based on structural similarity requires . . . evidence that a medicinal chemist of ordinary skill would have been motivated to select and then to modify a prior art compound (e.g., a lead compound) to arrive at a claimed compound . . . ."). "Absent a reason or motivation based on such prior art evidence, mere structural similarity between a prior art compound

and the claimed compound does not inform the lead compound selection." *Otsuka Pharm. Co. v. Sandoz, Inc.*, 678 F.3d 1280, 1292 (Fed. Cir. 2012).

We recognize that the motivation to select and modify a lead compound need not be explicit in the art. *Daiichi*, 619 F.3d at 1352. Here, however, Petitioner does not offer any persuasive evidence or otherwise explain why a skilled artisan would have selected compound 96 of Dorn '699 for modification. As we pointed out in the Decision, Dorn '699 lists over 600 compounds by their chemical names but provides no activity data for any of them. Dec. 11. Under such circumstances, Petitioner's failure to articulate any reason why one of ordinary skill in the art would have selected compound 96 is fatal to its obviousness analysis.

Petitioner contends that our lead compound analysis conflicts with *Ex parte Dong*, Appeal No. 2011-010047 (P.T.A.B. Jan. 28, 2013), and *Ex parte Cao*, Appeal No. 2010-004081 (B.P.A.I. Sept. 19, 2011). *Id.* at 2–6. According to Petitioner, we must follow *Dong* and *Cao*, in which the panels affirmed obviousness rejections, even though the prior art taught numerous compounds and did not provide activity data. *Id.* We disagree. First, the Board did not designate either *Dong* or *Cao* as precedential. Thus, those opinions do not bind this panel. More importantly, obviousness, while a question of law, is based on underlying factual findings. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). And the facts in this case are distinguishable from those in *Dong* and *Cao*. For example, the reference in *Dong* did not only list the prior art compound among hundreds of others, it actually made the compound. *Dong*, 2013 WL 5375700, *3. In contrast, in this case, Dorn '699 prepared over 90 specific compounds in Examples 1–85

and 88–93. Ex. 1003, 60:58–102:1, 121:26–122:60. It also taught how to make nearly 500 other specific compounds in Examples 86 and 87. *Id.* at 102:2–121:25. Dorn '699, however, neither actually prepared compound 96, nor taught how to make it. Because of the different facts, the approach in *Dong* does not apply in this case.

In the Decision, we also denied the Petition on an independent basis. We contrasted a body of well-studied, potent tachykinin receptor antagonists with Dorn '699, which reported no biological or pharmacokinetic data. Dec. 9. Petitioner argues that we erred in stating that a skilled artisan would have pursued those more promising compounds. Reh'g Req. 12 (citing Dec. 9). We are not persuaded. Our determination is not, as Petitioner asserts, an "assumption," but a conclusion based on the evidence of record. Dec. 9 (citing Prelim. Resp. 16–18, which in turn, relies on Exs. 2001–05, 2007, 2008). Indeed, as Patent Owner pointed out in its Preliminary Response, by the time of the '336 patent invention, very potent, selective tachykinin receptor antagonists with desirable pharmacokinetic properties had been discovered. Prelim. Resp. 17 (citing Ex. 2007). Specifically, Patent Owner itself identified compound 7b, a "highly potent" tachykinin receptor antagonist, as a lead for further optimization. *Id.* at 18 (citing Ex. 2005).

Petitioner contends that those studies "do not disclose the numerous, specific human therapeutic applications disclosed in Dorn '699 . . . that would have motivated those skilled in the art to pursue development of Dorn's compounds." Reh'g Req. 12. We disagree. For example, prior art teaches that compounds modulating or blocking activity of tachykinin are suitable for treating human diseases, such as pain, inflammation, rheumatoid

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