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Paper 21
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMNEAL PHARMACEUTICALS, LLC,
Petitioner,

v.

ENDO PHARMACEUTICALS INC.,
Patent Owner.

Case IPR2014-00360
Patent 8,329,216 B2

Before TONI R. SCHEINER, FRANCISCO C. PRATS, and JACQUELINE WRIGHT BONILLA, *Administrative Patent Judges*.

BONILLA, *Administrative Patent Judge.*

DECISION
Petitioner's Request for Rehearing
37 C.F.R. § 42.71(d)

I. INTRODUCTION

Amneal Pharmaceuticals, LLC, ("Petitioner") filed a Petition requesting *inter partes* review of claims 1, 2, 6, 12-14, 17, 21-43, 45-51, and 54-82 of U.S. Patent No. 8,329,216 ("the '216 patent"). Paper 1 ("Pet."). Patent Owner, Endo Pharmaceuticals Inc., filed a Preliminary Response. Paper 7. We entered a Decision on July 25, 2014, instituting *inter partes* review of claims 1, 2, 6, 12-14, 17, 21-43, 45-51, and 54-71, but not claims 72-82, of the '216 patent. Paper 16 ("Decision") at 2, 21-22. Petitioner filed a Request for Reconsideration of our Decision not to review claims 72-82 as obvious over the Penwest Statement (Ex. 1009)[1] and Baichwal (Ex. 1010).[2] Paper 18 ("Req. Reh'g") at 1.

II. STANDARD OF REVIEW

When reconsidering 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 may be determined 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. *Star Fruits S.N.C. v. United States*, 393 F.3d 1277, 1281 (Fed. Cir. 2005); *Arnold P'ship v. Dudas*, 362 F.3d 1338, 1340 (Fed. Cir. 2004); *In re Gartside*, 203 F.3d 1305, 1315-16 (Fed. Cir. 2000). The party requesting rehearing has the burden of showing the decision should be modified. 37 C.F.R. § 42.71(d).

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[1] Penwest Pharms. Co., Registration Statement under The Securities Act of 1933 (Form S-1) (Dec. 17, 1997).

[2] Baichwal et al., U.S. Patent No. 5,128,143, "Sustained Release Excipient and Tablet Formulation," filed March 9, 1990; issued July 7, 1992.

III. ANALYSIS

Claims 72 and 77 of the '216 patent are independent, while claims 73-76 and 81 depend from claim 72, and claims 78-80 and 82 depend from claim 77. Both independent claims 72 and 77 recite, *inter alia*, that the claimed composition:

> (1) comprises "a controlled release matrix, comprising about 10% to about 75% (by total weight of the controlled release matrix) of a gelling agent which forms a gel upon exposure to gastrointestinal fluid"; and
>
> (2) "wherein upon placement of the composition in an in vitro dissolution test comprising USP paddle method at 50 rpm in 500 ml media having a pH of 1.2 to 6.8 at 37° C., about 15% to about 50%, by weight, of the oxymorphone or salt thereof is released from the composition after about 1 hour in the test" (i.e., "dissolution limitation" or "dissolution profile").

Ex. 1001, 33:14-26, 33:57-34:18.

In its Request, Petitioner contends that we "overlooked the disclosures in the Penwest Statement and Baichwal—and the sections of the Petition that pointed to those disclosures—that render obvious claims 72-82 of the '216 patent including the limitation that the controlled release matrix comprise about 10% to about 75% by weight of a gelling agent." Req. Reh'g 1-2. Petitioner points us to portions of its Petition explaining that "the Penwest Statement discloses that Penwest had developed a controlled release drug delivery system—the TIMERx drug system," which was "a hydrophilic matrix consisting primarily of two natural polysachharides, xanthum and locust bean gums, in the presence of dextrose." *Id.* at 2-3 (citing Pet. 42-43; Ex. 1009, 32, ¶2). In addition, the Penwest Statement disclosed that Penwest was "developing a controlled release formulation of

oxymorphone with that system." *Id*. at 2 (citing Pet. 42-43; Ex. 1009, 36, ¶6).

Petitioner further contends Baichwal discloses the dissolution limitations of claims 72-82 because "example formulations in Baichwal have dissolution profiles falling within the scope of the claims of the '216 patent." *Id.* at 3 (citing Pet. 46-47). In its Petition, however, Petitioner contends that "Baichwal discloses dissolution data for a number of active agents," citing to Table 2 in Baichwal. Pet. 46 (citing Ex. 1010, 13:1-20, Table 2). Notably, the Petition does not contend, nor explain how, Table 2, or elsewhere in Baichwal, describes any formulation, much less a composition comprising oxymorphone, having the recited dissolution profile in relation to an "active agent." Pet. 46-47. Instead, the Petition points to Examples 1-3 in the challenged '216 patent itself for the proposition that those examples, which "were formulated using locust bean gum and xanthan gum," have dissolution profiles falling within the scope of profiles recited in claims 72 and 77.

Petitioner notes that Baichwal describes "'a slow release pharmaceutical excipient comprising from about **20 to about 70 percent or more by weight of a hydrophilic material** comprising a heteropolysaccharide and a polysaccharide material capable of crosslinking the heteropolysaccharide in the presence of aqueous solutions.'" Req. Reh'g. 4 (emphasis in original) (citing Pet. 43; Ex. 1010, 4:16-21). According to Petitioner, "Baichwal's definition of gelling agent—quoted in the Petition—suggested a weight range of about 20 to about 70% by weight of a gelling agent." *Id*. Referring to certain cited Examples in Baichwal, Petitioner contends that an ordinary artisan "reading Baichwal, would have known how to adjust or vary the weight of the gelling agent from at least 20 to 70% by weight in the controlled release matrix to match a particular dissolution profile,

well within the range of 10% to 75% claimed in the '216 patent." *Id*. at 5 (citing Pet 44; Ex. 1010, Examples 1 and 54-57).

As stated in our Decision, "we are not persuaded that Petitioner adequately establishes that Maloney (*or any cited reference other Oshlack*) teaches or suggests, directly or inherently, the 'in vitro dissolution test comprising USP Paddle Method' oxymorphone release results recited in independent claims 72 and 77." Decision 21 (emphasis added). While we did not mention the Penwest Statement and Baichwal by name in that section of the Decision, we included the ground Petitioner discusses now in that analysis.

Even assuming Baichwal "suggested a weight range of about 20 to about 70% by weight of a gelling agent," and that an ordinary artisan reading the Penwest Statement and Baichwal "would have known how to adjust or vary the weight of the gelling agent . . . to match a particular dissolution profile," Petitioner does not explain convincingly how the cited references suggest, directly or impliedly, a composition having the "in vitro dissolution test comprising USP Paddle Method" oxymorphone release results recited in independent claims 72 and 77. Specifically, Petitioner does not explain with adequate specificity, in its Petition (or Request for Rehearing), *why* an ordinary artisan would have had reason to adjust or vary weight ranges of specific gelling agent components to achieve the recited dissolution limitation when making a composition comprising oxymorphone or its salt. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007) (stating that "analysis should be made explicit" when determining "whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue"); *see also* Dec. 9-12 (relating to Maloney).

Because the Petition did not provide a sufficient reason as to why one would have been motivated to create a composition comprising oxymorphone having the recited dissolution profile, we are not persuaded that we abused our discretion in concluding that Petitioner did not demonstrate that there is a reasonable likelihood that it would prevail on the ground that claims 72-82 would have been obvious over the Penwest Statement and Baichwal.

IV. DECISION ON REHEARING

Petitioner's sought-after relief is *denied*.

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