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Paper No. 38
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COALITION FOR AFFORDABLE DRUGS VII, LLC,
Petitioner,

v.

POZEN INC.,
Patent Owner.

Case IPR2015-01718
Patent 8,945,621 b2

Before TONI R. SCHEINER, LORA M. GREEN, and JACQUELINE WRIGHT BONILLA, *Administrative Patent Judges.*

SCHEINER, *Administrative Patent Judge*.

DECISION
Denying Patent Owner's Request for Rehearing
37 C.F.R. § 42.71

On March 4, 2016, Patent Owner filed a Request for Rehearing (Paper 19, "Reh'g Req.") of our Decision instituting an *inter partes* review (Paper 17, "Decision" or "Dec.") of claims 1–16 of U.S. Patent No. 8,945,621 B2 (Ex. 1001, "the '621 patent"). Petitioner, with our authorization, filed an Opposition to Patent Owner's Request for Rehearing of the Decision to Institute. Paper 20.

We deny Patent Owner's Request for Rehearing for the reasons set forth below.

STANDARD OF REVIEW

When reconsidering a decision on institution, the Board reviews the decision for an abuse of discretion. *See* 37 C.F.R § 42.71(c). An abuse of discretion occurs 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. *See 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 burden of showing that a decision should be modified lies with the party challenging the decision." Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,768 (Aug. 14, 2012). In its request for rehearing, the dissatisfied party must, in relevant part, "specifically identify all matters the party believes the Board misapprehended or overlooked." 37 C.F.R. § 42.71(d); Office Patent Trial Practice Guide, 77 Fed. Reg. at 48,768. We address Patent Owner's arguments with these principles in mind.

ANALYSIS

The challenged claims are directed to a method of reducing the incidence of NSAID-associated gastric ulcers in patients taking low dose aspirin comprising administering esomeprazole and naproxen in a specified unit dose form. The final clause of each of independent method claims 1, 8, 15, and 16 reads as follows: "wherein administration of the unit dose form is more effective at reducing the incidence of the NSAID-associated ulcers in patients taking LDA than in patients not taking LDA who are administered the unit dose form." Ex. 1001, 27:16–20, 59–63, 28:36–39, 60–63.

In our Decision, we determined that Petitioner had established sufficiently for purposes of institution that one of ordinary skill in the art would have had a reason to administer the specific esomeprazole/naproxen unit dose form recited in the claims to patients taking low dose aspirin, based on the cited prior art. Dec. 11–12, 18. However, we agreed with Patent Owner that Petitioner had not established—either in the Petition, or the portions of Dr. Shargel's Declaration cited in the Petition—that the prior art relied on would have

> led the ordinary artisan to expect that administering the specific unit dose form of the challenged claims to patients taking an NSAID and LDA would be "more effective at reducing the incidence of the NSAID-associated ulcers in patients taking LDA than in patients ***not*** taking LDA who are administered the unit dose form," as required by each of the challenged claims.

Dec. 13 (citing Prelim. Resp. 12).

Nevertheless, in our Decision, we noted that the U.S. Court of Appeals for the Federal Circuit has stated that "[a] 'whereby' clause that merely states the result of the limitations in the claim adds nothing to the patentability or substance of the claim." Dec. 15–16 (citing *Texas*

Instruments, Inc. v. U.S. Int'l Trade Comm'n., 988 F.2d 1165, 1172 (Fed. Cir. 1993); *Minton v. National Ass'n of Securities Dealers, Inc.*, 336 F.3d 1373, 1381 (Fed. Cir. 2003)). We further noted "[a]lthough the challenged claims use the word 'wherein,' rather than the word 'whereby' as in the claims in *Texas Instruments* and *Minton*, the effect is the same if the clause merely states the result of the method steps and does not further inform the mechanics of the method or the structure of the dosage form administered." *Id.* at 16. Finally, we noted that the issue of the weight to be accorded to the final "wherein" clause of the challenged claims had not yet been addressed on the record. *Id.* at 16.

In its Request for Rehearing, Patent Owner contends that we "misinterpret[ed] the final 'wherein' clauses of independent claims 1, 8, 15, and 16." Reh'g Req. 4. Specifically, Patent Owner contends that "[t]he Examiner's statement of reasons for allowance focused on the unexpected result that patients taking LDA in combination with the claimed pharmaceutical composition demonstrated a lower incidence of gastric ulcers than patients taking the claimed pharmaceutical composition but not LDA." *Id.* at 8. Patent Owner contends that "the Examiner's addition of the final 'wherein' clause during prosecution to limit the claim scope to the unexpected result cited by the Examiner cannot be overlooked or disregarded." *Id.* at 10. According to Patent Owner, "this action by the Examiner must be considered by the Board as affording this clause patentable weight, and not doing so would be contrary to controlling Federal Circuit authority." *Id.* Patent Owner contends that Petitioner has "failed to establish that any of the cited references teach or suggest the final 'wherein' clause of independent claims 1, 8, 15, and 16," and, therefore, "has failed to

demonstrate a reasonable likelihood that it would prevail with respect to any of the claims challenged in the Petition." *Id.*

Nevertheless, we are not persuaded that we overlooked or misapprehended the Examiner's reliance on the final "wherein" clause in allowing the application that matured into the '621 patent. We also are not persuaded that the weight to be accorded the final "wherein" clause is as straightforward as Patent Owner proposes.

For example, Patent Owner cites *Hoffer v. Microsoft Corp.*, 405 F.3d 1326, 1329 (Fed. Cir. 2005) for the proposition that a "whereby" clause described in the specification and/or prosecution history as an integral part of the invention is limiting and must be accorded patentable weight. Reh'g Req. 9. *Hoffer* however, confirms that determining whether a "wherein" or "whereby" clause merely "states the result of the patented process . . . [or] states a condition that is material to patentability" is highly fact-specific. *Hoffer*, 405 F.3d at 1329. Indeed, in *Hoffer*, the court found a "whereby" clause to be limiting not simply, as Patent Owner argues, because "it was described in the specification and prosecution history as an 'integral part of the invention.'" Reh'g Req. 9. Rather, the court found the clause limiting because it required "a network of users at multiple remote user terminals who are 'collectively able to concurrently engage in interactive data messaging'" and because "[t]his capability is more than the intended result of a process step; *it is part of the process itself*." *Hoffer*, 405 F.3d at 1330 (emphasis added). As we indicated in our Decision, it was not clear from the record whether the final clause of the independent claims further informs the mechanics of the claimed method or the structure of the dosage form

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