

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMERIGEN PHARMACEUTICALS LIMITED,
Petitioner,

v.

SHIRE LLC,
Patent Owner.

Case IPR2015-02009
Patent RE42,096 E

Before TONI R. SCHEINER, LORA M. GREEN, and
SHERIDAN K. SNEDDEN, *Administrative Patent Judges*.

SCHEINER, *Administrative Patent Judge*.

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

Amerigen Pharmaceuticals Limited (“Amerigen” or “Petitioner”) filed a Petition (Paper 1, “Pet.”) requesting an *inter partes* review of claims 1–3, 5, 8, 9, 11, 18–21, 23, and 25 of U.S. Patent No. RE42,096 E (Ex. 1001, “the ’096 patent”). In our Decision on Institution (Paper 8, “Decision” or “Dec.”), we determined that Amerigen had established a reasonable likelihood of prevailing in its challenges with respect to claims 18–21, 23, and 25, but not with respect to claims 1–3, 5, 8, 9, and 11. Accordingly, we instituted *inter partes* review with respect to claims 18–21, 23, and 25, but declined to institute review with respect to claims 1–3, 5, 8, 9, and 11. See Paper 8.

On May 2, 2016, Amerigen filed a Request for Rehearing (Paper 11, “Reh’g Req.”) of our decision denying institution of an *inter partes* review for claims 1–3, 5, 8, 9, and 11.

We deny Amerigen’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 Amerigen’s arguments with these principles in mind.

ANALYSIS

Claims 1–3, 5, 8, 9, and 11 are directed, in relevant part, to a pharmaceutical composition providing delayed pulsed enteric release of one or more pharmaceutically active amphetamine salts, wherein the composition comprises an enteric release coating that “releases essentially all of said one or more pharmaceutically active amphetamine salts coated with said enteric coating within about 60 minutes after initiation of said delayed pulsed enteric release.”¹

Amerigen’s Petition set forth three challenges to claims 1–3, 5, 8, 9, and 11—one ground based on anticipation by Mehta,² and two obviousness challenges based, in part, on Mehta. *See* Pet. 2.

Asserted Anticipation of Claims 1–3, 5, 8, 9, and 11 by Mehta

In the Decision, we determined that Amerigen had not established that Mehta discloses, expressly or inherently,

a pharmaceutical composition comprising one or more
“pharmaceutically active amphetamine salts that are covered

¹ In the Decision, we construed the claim term “essentially all” to mean “less than 100%, and not less than 80%” (Dec. 16), and the claim term “enteric release coating” to refer to “a coating that will delay release of a drug until the drug has passed through the stomach and reaches the intestines” (*id.* at 15). Neither construction is disputed here.

² U.S. Patent No. 5,837,284, issued November 17, 1998, to Mehta et al. (“Mehta”) (Ex. 1003).

with an enteric release coating” that provides “a delayed pulsed enteric release,” “wherein said enteric release coating releases essentially all of said one or more pharmaceutically active amphetamine salts coated with said enteric coating within about 60 minutes after initiation of said delayed pulse[d] enteric release,” as required by claims 1–3, 5, 8, 9, and 11.

Dec. 24.

Amerigen contends that we erred in concluding that Mehta does not disclose a specific example embodying the “essentially all . . . within about 60 minutes” limitation (Reh’g Req. 2), because certain of Mehta’s disclosures, when read together, “expressly teach[] an embodiment having a delayed release that releases ‘less than 100%, and not less than 80%’ of the methylphenidate drug within about 60 minutes after initiation of the delayed pulsed enteric release” (*id.* at 6).

Mehta defines “delayed release” as follows:

“Delayed release,” . . . refers to a drug release profile which includes a period during which no more than about 10 percent of the drug in a particular dosage form is released, followed by a period of from about 0.5 hour to about 2.5 hours, preferably about 1.5 hours, more preferably about 1 hour, in which no less than about 70 percent, preferably no less than about 80 percent, and more preferably no less than about 90 percent, of the drug is released.

Ex. 1003, 6:8–16.

Amerigen acknowledges that “Mehta’s explicit definition for delayed release is not directly tied to a specific embodiment.” *Id.* (citing Ex. 1003, 6:5–17; Pet. 21–22). Nevertheless, Amerigen contends that “Mehta’s definition of ‘delayed release’ presents a single-sentence melding the description of the duration of the release period and the description of the extent (*i.e.*, percentage) during the period of release,” and Amerigen, in the

Petition, “informed the Board of a delayed release taught in at least one embodiment in Mehta: the layered embodiment taught in columns 11 and 12 of the Mehta patent.” *Id.* (citing Pet. 4–5; Ex. 1003, 11:66–12:14). That embodiment of Mehta is as follows:

[T]he dosage form can comprise a single group of particles providing both a substantially immediate dose of a methylphenidate drug, and a delayed dose of methylphenidate drug. The particles comprise, in admixture with one or more binders, from about 2% to about 75% by weight of a methylphenidate drug for delayed release, and a coating comprising the pharmaceutically acceptable, substantially neutral copolymers described herein.

Ex. 1003, 11:66–12:14.

According to Amerigen, “[t]he use of ‘delayed release’ in this example invokes the definition from earlier in the patent and provides the crucial limitation to the embodiment as if it were explicit in that embodiment.” *Id.* at 5–6. Amerigen contends that, contrary to the Board’s conclusion, “Mehta expressly teaches an embodiment having a delayed release that releases ‘less than 100%, and not less than 80%’ of the methylphenidate drug within about 60 minutes after initiation of the delayed pulsed enteric release as required by Claim Nos. 1–3, 5, 8, 9, and 11.” *Id.* at 6 (citing Ex. 1003, 6:5–17).

Amerigen contends that “not recognizing this crucial embodiment taught in Mehta led the Board to treat this ‘essentially all . . . within about 60 minutes’ limitation as if it were neither expressly taught nor enabled” (*id.* at 7), and “led to further error as the Board engaged in an unnecessary, and therefore legally improper, inherency analysis of the ‘essentially all . . . within about 60 minutes’ limitation” (*id.*). Moreover, Amerigen contends that Mehta’s disclosures, both claimed and unclaimed, are presumed to be

enabled (Reh’g Req. 6), yet “[i]n its Preliminary Response, Patent Owner provided only attorney argument with no supporting testimony to address the presumption of enablement and Petitioner’s expert testimony” (*id.* at 8).

These arguments are not persuasive. First, Petitioner cites no authority for the proposition that a generic disclosure, such as that discussed above, is an express disclosure of every possible permutation of that generic disclosure. Second, even if we were to accept, for the sake of argument, that Mehta’s combined disclosures constitute an express disclosure of a composition capable of delayed release of “essentially all [of the drug] . . . within about 60 minutes,” non-instituted claims 1–3, 5, 8, 9, and 11 further require that the delayed release is enteric (i.e., the composition releases the second dose of the drug in the intestines, not the stomach).

As we noted in the Decision, however, Mehta does not use the word “enteric,” nor does Mehta discuss delivery of the delayed dose to the intestines. Dec. 28. Nevertheless, we considered the possibility that Mehta might inherently disclose a composition that releases into the intestine not less than 80% of the second dose of the drug within about 60 minutes of the delayed release. Accordingly, we turned to Mehta’s Examples 1–5, but determined that not one of the exemplified delayed release compositions achieved a release of “essentially all” of the drug from a delayed release coating within about 60 minutes—regardless of whether the delay was long enough to be considered enteric.³ *Id.* at 24. As we noted in the Decision,

³ As further noted in the Decision, the ’096 patent teaches that its composition comprises a pH-dependent or pH-independent enteric coating to ensure that the delayed dose of the drug is released in the intestines, rather than the stomach. The pH-independent enteric release coating “delays the release of the . . . drug for a specified time period (‘lag time’) until a

“the time observed for approximately 85% release of the drug ranged from 3 to 5 hours for compositions providing a 1 hour delay (less than Mehta’s suggested delay of 2 to 7 hours), and from 5 to 10 hours for compositions providing a delay of 2, 3, 4, or 5 hours.” *Id.* (citing Ex. 1003, 14:21–45 (Table 1)).

Consequently, we do not agree with Amerigen that “Mehta expressly teaches an embodiment having a delayed release that releases ‘less than 100%, and not less than 80%’ of the methylphenidate drug within about 60 minutes after initiation of the delayed pulsed enteric release as required by Claim Nos. 1–3, 5, 8, 9, and 11.” Reh’g Req. 6 (citing Ex. 1003, 6:5–17). Moreover, we adhere to our finding that Mehta does not inherently disclose such an embodiment.

Accordingly, we are not persuaded that we erred in our determination that Amerigen had not established a reasonable likelihood of prevailing in its challenge of claims 1–3, 5, 8, 9, and 11 as anticipated by Mehta.

*Asserted Obviousness of Claims 1–3 and 5 over Mehta
and the Adderall PDF*

*Asserted Obviousness of Claims 8, 9, and 11 over
Mehta, the Adderall PDF, and Rosen*

With respect to its asserted obviousness grounds, Amerigen contends that it “provided expert testimony of enablement” of the “essentially all . . .

predetermined time” (Dec. 27–28 (citing Ex. 1001, 3:61–4:8, 13:43–44)). Where “the lag time period is only time-dependent, i.e., pH-independent[,]” the ’096 patent teaches that “[t]he lag time is preferably within 4 to 6 hours after oral administration of the delivery system.” *Id.* at 27 (citing Ex. 1001, 4:5–8).

within about 60 minutes” limitation (Reh’g Req. 8 (citing Ex. 1005,⁴ 471–472, 512–514)), but our “oversight of the crucial embodiment [discussed above] led the Board to not apply the presumption of enablement, which led to its erroneous finding of a lack of reasonable likelihood of success” (*id.* at 9).

This argument is not persuasive. We considered, for example, Dr. Elder’s testimony that one of ordinary skill in the art would expect “that the number of variables and number of experimental runs to optimize the coating for the amphetamine would present no unusual problems of technology or expense” because one “can use statistical experimental design to optimize a formulation within the 21 trials that Mehta discloses to design one for amphetamine salts” (Ex. 1005 ¶ 471), as well as Dr. Elder’s testimony that one would expect “that routine optimization of the coating using the parameters identified by Mehta would provide enough guidance for controlling the release timing” (*id.* ¶ 512). Nevertheless, we found the actual results reported by Mehta to be more compelling. As we stated in the Decision:

[N]one of Mehta’s delayed release formulations that could be considered to be enteric by virtue of their delay periods (i.e., those with delays of 4 or 5 hours) had release rates of “essentially all” of the drug anywhere near the required time period. Even if Mehta could be read to suggest that a delay of 4 or 5 hours followed by a release of essentially all of the delayed dose within 60 minutes would be desirable, we are not persuaded that Mehta’s disclosure that “the amount of drug released is influenced by: amount of coating, ratio of the two

⁴ Amerigen supported its challenges with the Declaration of Edmund J. Elder, Jr., Ph.D., R.Ph., executed September 30, 2015 (“Elder Declaration”) (Ex. 1005).

polymers, amount of talc, and curing time” is adequate guidance for one of ordinary skill in the art to achieve such a dosage form. In general, Mehta demonstrates that longer delays are accompanied by longer release times, with formulations that could be considered to provide enteric release (i.e., a release after a 4 or 5 hour [delay]) having 85% release times of 8 or more hours.

Dec. 33–34 (citing Ex. 1003, Table 1).

Finally, Amerigen contends that we inconsistently “found claims 18, 19–21, 23 and 25 to have a reasonable likelihood of success even without having acknowledged the embodiment incorporating the delayed release definition.” Reh’g Req. 9.

This argument is not persuasive. As we explained in the Decision, claims 18–21, 23, and 25 (to the extent claim 25 depends from claims 18–20) stand on a different footing than claims 1–3, 5, 8, 9, and 11 because claims 18–21, 23, and 25 “do not require release of ‘essentially all’ of the pharmaceutically active amphetamine salts coated with the enteric coating within about 60 minutes after initiation of a delayed pulsed enteric release” (Dec. 34), nor do they “require a particular percentage of the drug to be released within 60 minutes” (*id.* at 35).

Accordingly, we are not persuaded that we erred in our determination that Amerigen had not established a reasonable likelihood of prevailing in its obviousness challenges of claims 1–3, 5, 8, 9, and 11.

CONCLUSION

We have considered Petitioner Amerigen’s request for rehearing, but are not persuaded that we abused our discretion in declining to institute an *inter partes* review with respect to claims 1–3, 5, 8, 9, and 11.

ORDER

It is

ORDERED that Petitioner's request for rehearing of the Decision denying institution of an *inter partes* review of claims 1–3, 5, 8, 9, and 11 of U.S. Patent No. RE42,096 E is *denied*.

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