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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte ARGAW KIDANE and PADMANABH P. BHATT[1]

Appeal 2017-005149
Application 13/638,294
Technology Center 1600

Before DONALD E. ADAMS, ERIC B. GRIMES, and RYAN H. FLAX, *Administrative Patent Judges*.

FLAX, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision under 35 U.S.C. § 134(a) involving claims directed to a solid modified release formulation of mazindol. Claims 47–67 and 69–72 are on appeal as rejected under 35 U.S.C. § 112, second paragraph, and § 103, as well as for obviousness-type double patenting. We have jurisdiction under 35 U.S.C. § 6(b).

We affirm.

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[1] Appellants identify the Real Party in Interest as "Supernus Pharmaceuticals, Inc." Appeal Br. 3. Herein we reference the Specification of Sept. 28, 2012 ("Spec."); Final Office Action of Feb. 12, 2016 ("Final Action"); Appeal Brief of Aug. 10, 2016 ("Appeal Br."); Examiner's Answer of Dec. 16, 2016 ("Answer"); and Reply Brief of Feb. 14, 2017 ("Reply Br."). Oral argument was heard on November 1, 2018; the transcript of the hearing will be made a part of the record on appeal.

STATEMENT OF THE CASE

Independent claim 47 is representative and is reproduced below:

> 47. A solid modified release formulation of mazindol comprising mazindol as an active pharmaceutical ingredient, at least one release controlling polymer selected from pH-dependent polymers and pH-independent polymers, and at least one pharmaceutically acceptable excipient, wherein the total amount of water in the formulation is not more than 2% by weight of the formulation.

Appeal Br. 11 (Claims Appendix).

The following rejections are considered on appeal:

Claims 48 and 51–58 stand rejected under 35 U.S.C. § 112, second paragraph, as indefinite.[2] Final Action 3.

Claims 47–57, 61–67, 69, 70, and 72 stand rejected under 35 U.S.C. § 103(a) over Devane,[3] Konofal,[4] Maulding,[5] and Enose.[6] *Id.* at 5.

Claims 58–60 stand rejected under 35 U.S.C. § 103(a) over Devane, Konofal, Maulding, Enose, and Swanson.[7] *Id.* at 8–9.

Claim 71 stands rejected under 35 U.S.C. § 103(a) over Devane, Konofal, Maulding, Enose, and Hirsh.[8] *Id.* at 9–10.

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[2] We note, the Examiner's statement of rejection indicates "[c]laims 48, 51, and 52–57" stand rejected as indefinite; however, claim 58 is substantively discussed as rejected as indefinite and, so, we understand it to be included in the rejection. Final Action 3–4.

[3] US 2006/0240105 A1 (published Oct. 26, 2006) ("Devane").

[4] US 2009/0136593 A1 (published May 28, 2009) ("Konofal").

[5] H.V. Maulding et al., *Solvolysis of a Substituted Imidazoline, Mazindol*, 64(11) J. PHARMA. SCI. 1833–38 (1975) ("Maulding").

[6] US 2009/0042821 A1 (published Feb. 12, 2009) ("Enose").

[7] US 2008/0124393 A1 (published May 29, 2008) ("Swanson").

[8] US 2006/0024366 A1 (published Feb. 2, 2006) ("Hirsh").

Claims 47–67, 69–71, and 90 stand rejected for obviousness-type double patenting over U.S. Patent Application 13/841,898 and Devane and Hirsh. *Id.* at 14.[9]

DISCUSSION

"[T]he examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability. If that burden is met, the burden of coming forward with evidence or argument shifts to the applicant." *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992). We have considered Appellants' arguments made in the Appeal Brief and properly presented in the Reply Brief; arguments not so-presented in the Briefs are waived. *See* 37 C.F.R. § 41.37(c)(1)(iv) (2015); *see also Ex parte Borden*, 93 USPQ2d 1473, 1474 (BPAI 2010) (informative) ("Any bases for asserting error, whether factual or legal, that are not raised in the principal brief are waived.").

I. INDEFINITENESS

For claims under examination, "'a claim is indefinite when it contains words or phrases whose meaning is unclear,'" i.e., "ambiguous, vague, incoherent, opaque, or otherwise unclear in describing and defining the claimed invention." *In re Packard*, 751 F.3d 1307, 1310–13 (Fed. Cir. 2014); *see also* MPEP § 2173.02(I) (Rev. 07.2015, Nov. 2015) (advising examiners that a rejection for indefiniteness is appropriate "after applying the broadest reasonable interpretation to the claim, if the metes and bounds of the claimed invention are not clear"). As explained in the MPEP

[9] U.S. Patent Application 13/841,898 was abandoned August 7, 2015. *See* Notice mailed March 3, 2016. Therefore, this rejection is dismissed.

§ 2173.05(e), a "lack of clarity could arise [for example] where a claim refers to 'said lever' or 'the lever,' where the claim contains no earlier recitation or limitation of a lever and where it would be unclear as to what element the limitation was making reference."

As noted by the Examiner, Appellants' briefing does not address this rejection. *See generally* Appeal Brief; *see also* Answer 6. "When the appellant fails to contest a ground of rejection to the Board, . . . the Board may treat any argument with respect to that ground of rejection as waived. In the event of such a waiver, the PTO may affirm the rejection of the group of claims that the examiner rejected on that ground without considering the merits of those rejections." *Hyatt v. Dudas*, 551 F.3d 1307, 1314 (Fed. Cir. 2008). Therefore, we affirm this rejection.

II. OBVIOUSNESS

"The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007). "In determining whether the subject matter of a patent claim is obvious, neither the particular motivation nor the avowed purpose of the patentee controls. What matters is the objective reach of the claim. If the claim extends to what is obvious, it is invalid under § 103." *Id.* at 419.

Findings of Fact ("FF")

Except as otherwise indicated below, we adopt the Examiner's findings of fact and rationale as set forth in the Final Action and Answer. The following findings of fact highlight certain evidence relevant to the issue of obviousness.

FF1. Devane discloses pharmaceutical formulations that are immediate release, delayed release, or controlled or extended release, or combinations of these types of release profiles. Devane ¶¶ 26–30.

FF2. Further to the preceding finding of fact, Devane discloses that the active ingredient for such pharmaceutical formulations can be the anorectic drug mazindol at a dosage of from about 0.1 to about 1,000 mg. Devane ¶¶ 59, 64.

FF3. Further to the preceding findings of fact, Devane discloses that the pharmaceutical formulation can be a solid, multilayered tablet, including an excipient, and that its modified release profile can be achieved via coating materials including a selection of pH dependent and pH independent polymers.[10] Devane ¶¶ 71–74.

FF4. Further to the preceding finding of fact, Devane does not disclose the water content of such a tablet. *See generally* Devane.

FF5. Konofal discloses the therapeutic use of mazindol to treat attention deficit/hyperactivity disorder and discloses formulating the mazindol as tablets and powders, including prolonged and delayed release formulations, and including excipients. Konofal Abstract, ¶¶ 1, 43, 69.

FF6. Konofal does not specify the water content of its tablet and/or powder formulations; however, a powder is understood to be a

[10] *Cf.* Appellants' claim 63 (pH-dependent polymers include hydroxypropyl methylcellulose acetate succinate and shellac) and claim 64 (pH-independent polymers include carboxymethylcellulose and celluose acetate).

fine, dry particulate formulation of a solid substance. *See* Oxford Dictionary, *powder*, https://en.oxforddictionaries.com/definition/ - powder, Nov. 5, 2018.

FF7. Enose discloses a pharmaceutical formulation, for example, a tablet or coated tablet or powder, where the water content is 6.5% or less, which range would include 2% and even none at all. Enose Abstract, ¶¶ 31–33.

FF8. Further to the preceding finding of fact, Enose discloses producing such a formulation by using excipients having low water content and manufactured using dry or non-aqueous formulation processes. Enose ¶ 34.

FF9. The Specification describes optimizing the stability of mazindol in a formulation by preferably compressing "a dry powder blend." Spec. ¶ 66; *compare supra* FF5.

FF10. The Specification does not provide evidence that mazindol formulations having no more than 2% water content are more stable than any other specific water content formulations. *See* Spec. ¶ 107 (Example 14), Figure 12; *cf.* Kidane Declaration ¶ 13 (stating "[d]uring the same period, conventionally prepared mazindol formulations having greater water content (i.e., between 3 and 5%) fared far worse (about 17% hydrolysis)," citing what is stated to be "Figure 12 of the application (reproduced below).")[11].

[11] Argaw Kidane Declaration Under 37 C.F.R. § 1.132, dated Aug. 26, 2015 ("Kidane Declaration"). As discussed below, the Kidane Declaration does not reproduce the Specification's Figure 12, as it indicates.

Analysis

The Examiner determined claims 47–57, 61–67, 69–70, and 72 would have been obvious over the combination of Devane, Konofal, Maulding, and Enose, and that claims 58–60 would have been obvious over this same prior art combination also adding Swanson, and further that claim 71 would have been obvious over this same combination also adding Hirsh. *See generally* Final Action and Answer.

Appellants argue all claims together. Therefore, we address the claims and their rejections similarly. We have concluded claim 47 is representative and all claims fall therewith.

Appellants argue that no cited prior art provides a rationale (motivation) for formulating mazindol in a solid dosage form having no more than 2% water, as claimed. Appeal Br. 4. Appellants do not dispute "that minimizing or eliminating water from a solid formulation *of a drug known to hydrolyze in 'solid' form* was a solution known in the art." *Id.* However, Appellants argue that the Examiner makes too great a leap in assuming that the hydrolysis of mazindol in an aqueous solution, as disclosed in Maulding, would have motivated the skilled artisan to reduce the water content of solid formulations of mazindol to 2% or less. *Id.* Appellants argue Maulding's disclosure of the hydrolysis of mazindol in aqueous solution would not extend to solid formulations. *Id.* at 5.

While Appellants' contention that Maulding would not have necessarily motivated the skilled artisan to reduce the water content of a mazindol solid formulation is reasonable, the evidence on appeal does not support that any reduction in water content of prior art solid mazindol

formulations would have been required. As noted in the findings of fact above, the prior art combination taught and suggested a solid formulation of mazindol as claimed, a polymer as claimed, and an excipient as claimed. FF1–FF4. Further, the prior art combination also taught and suggested that a solid formulation of mazindol would be a dry formulation. FF5–FF6. Moreover, the prior art combination also taught and suggested that forming such low-water-content, solid formulations was well within the ability of the skilled artisan. FF7–FF8. There is no persuasive evidence on this appeal record that prior art mazindol formulations would have more than 2% water content. FF9–FF10. The cited prior art suggests they would not.

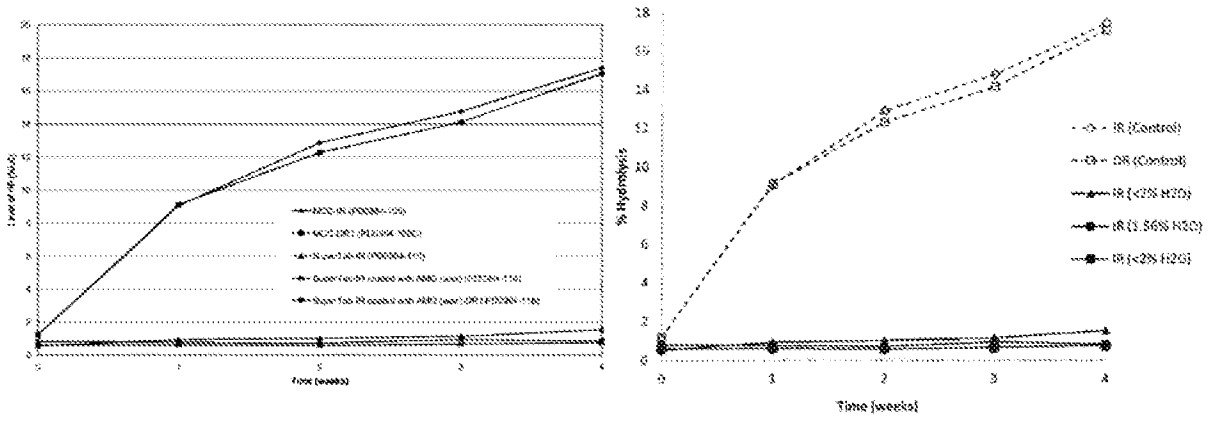
"Where . . . the claimed and prior art products are identical or substantially identical . . . the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. . . . [The] fairness [of the burden-shifting] is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products." *In re Best*, 562 F.2d 1252, 1255 (CCPA 1977). Here, the prior art combination teaches and suggests a solid mazindol formulation that is at least substantially identical to the claimed solid modified release mazindol formulation. Appellants have not shown that the prior art formulations are different from the claimed formulation.

Appellants have submitted the Kidane Declaration as support for the contentions that Maulding would not have motivated the skilled artisan to lower a mazindol formulation water content and that Appellants have shown unexpected results, where greater mazindol stability is achieved with a 2% water content formulation as compared to a higher water content

formulation. While we may agree with the former contention, as discussed above, we cannot conclude that the latter is supported by evidence.

The Kidane Declaration includes a paragraph (13) concluding that a mere 1–3% water-content reduction to 2% or less resulted in unexpected improvements in mazindol stability. As evidence, the Kidane Declaration purports to reproduce Figure 12 from the Specification; however, it is apparent that the declaration has not faithfully done so because the figure produced therein is different from the Specification's Figure 12. To illustrate, we reproduce, side-by-side, Figure 12 from the Specification (below at left) and the figure the Kidane Declaration represents to the Board as being Figure 12 from the Specification (below at right):

Figure 12. Stability profile of Mazindol IR and DR tablets, 1.5mg: various formulations.



Without even delving into details, it is apparent that the two graphs above are not the same (the formatting is not consistent, the legends are not consistent, the axes are not consistent, etc.). Whether they might convey the same information cannot be determined on the record on appeal.

Even considering Figure 12 from the Specification we conclude it cannot be interpreted as supporting Appellants' or their Declarant's contentions on unexpected results because the figure cannot be interpreted. The samples listed in the legend of Figure 12's graph are not identified in the Specification so that one can know their components or compare the claimed invention to the closest prior art. The "SuperTab-IR (PD0364-100)" appears to be the composition of Example 10 (Spec. ¶ 102) and the "SuperTab-IR coated with AMG (wax) (PD0364-114)" appears to be the composition of Example 12 (Spec. ¶ 105 (Table 11)). However, none of the other compositions appear to correspond to exemplified compositions.[12]

Thus, we are unpersuaded by Appellants' arguments directed to any differences between the claimed invention and the prior art, the water content of the prior art, or unexpected results. We find no other direct support in the Specification, or otherwise on the appeal record, that prior art solid formulations of mazindol, such as those disclosed by Devan and Konofal, would have had greater than 2% water content. The fact that such prior art formulations were taught as being formulated from a dry powder, like embodiments described in the Specification as within the scope of the invention, suggests that they would not. *See, e.g.*, FF6, FF9.

[12] Although the Specification does disclose a composition referred to as "PD0364-105" (Spec. ¶ 101 (Table 8), it is described as a delayed release composition (*id.*), while Figure 12 refers to composition "PD0364-105" as an "IR," or immediate release, composition. Thus, it is not clear whether the composition shown in Figure 12 is the one described in Table 8 of the Specification.

For the reasons above, we conclude the Examiner has established a prima facie case that the claims would have been obvious over the cited prior art combination(s). We are unpersuaded by Appellants' arguments to the contrary.

SUMMARY

The indefiniteness rejection is affirmed.

The obviousness rejections are each affirmed.

The provisional double patenting rejection is dismissed.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED