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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte NACHIAPPAN CHIDAMBARAM and AQEEL FATMI

Appeal 2011-003789
Application 11/548,607
Technology Center 1600

Before DONALD E. ADAMS, DEMETRA J. MILLS, and
LORA M. GREEN, *Administrative Patent Judges*.

GREEN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the Examiner's rejection of claims 1-9, 11-13, 15-19, and 25-31 (App. Br. 2). We have jurisdiction under 35 U.S.C. § 6(b).

STATEMENT OF THE CASE

According to the Specification:

Valproic Acid, or 2-propylpentanoic acid, and its salts and derivatives are used to treat absence seizures, complex partial seizures, mania, migraine headache prophylaxis, and behavior dyscontrol. Once in the body, valproic acid and its salts and derivatives are converted to valproate ion, which is responsible for the therapeutic effect. Valproic acid and its salts and derivatives are also known to cause significant side effects including gastrointestinal discomfort (nausea, indigestion, vomiting, diarrhea, and abdominal pain) which can decrease patient compliance.

(Spec. 1.)

The Specification teaches further that “[s]ustained release forms of divalproex sodium, valproic acid and its salts and derivatives have been developed in an effort to minimize the gastrointestinal side effects associated with these compounds” (*id.* at 2).

Claim 1 is representative of the claims on appeal, and reads as follows:

1. An enteric valproic acid soft capsule comprising:
 - (a) a fill material comprising valproic acid, divalproex sodium, or a mixture thereof in a dosage from 125 to 500 mg; and
 - (b) a capsule shell having incorporated therein a film-forming water soluble polymer and an acid-insoluble polymer, wherein the valproic acid in a dosage of 500 mg is released following oral administration to a fasting individual to produce a C_{max} between approximately 37.6 and 72.5 µg valproic acid/ml with a T_{max} of between 1 and 4 hours or wherein the valproic acid is released following oral administration to a non-fasting individual to produce a C_{max} between 27.2 and 58.64 µg valproic acid/ml with a T_{max} of between 3 and 9 hours.

The following grounds of rejection are before us for review:

- I. Claims 1-8, 11, 12, 15-19, and 25-31 stand rejected under 35 U.S.C. § 103(a) as being rendered obvious by the combination of Hassan¹ Biraghi², and the PDR³ (Ans. 4).
- II. Claim 9 stands rejected under 35 U.S.C. § 103(a) as being rendered obvious by the combination of Hassan, Biraghi, and the PDR as further combined with Chen⁴ (Ans. 8).
- III. Claims 1-9, 11, 12, 15-19 stand rejected under 35 U.S.C. § 103(a) as being rendered obvious by the combination of Chen, Hassan, and the PDR (Ans. 10).
- IV. Claims 1-9, 11, 12, 15-19, and 25-31 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of USSN 10/529,984 as combined with Biraghi and the PDR (Ans. 12).

We affirm Rejections I and II. We vacate rejection III as cumulative to Rejections I and II. We also affirm Rejection IV.

¹ Hassan et al., WO 2004/030658 A1, published Apr. 15, 2004.

² Birgahi et al., *Comparison of the effectiveness of several formulations of sodium valproate: tablets, enteric-coated capsules, solutions and rectal capsules*, 3 ITAL. J. NEUROL. SCI. 197-200 (1982).

³ Physician's Desk Reference, 49th Edition, pp. 414-418 (May 30, 1995).

⁴ Chen et al., US 6,267,985 B1, issued Jul. 31, 2001.

ANALYSIS

As to Rejection I, the Examiner relies on Hassan for teaching the claimed enteric capsule, the shell having incorporated therein a film-forming water soluble polymer and an acid-insoluble polymer (Ans. 4-5). In addition, the Examiner finds that Hassan teaches that “[e]nteric dosages are desirable to protect the contents from gastric conditions or to protect the gastric tissue from an irritant (page 1, lines 14-16)” (*id.* at 4). The Examiner notes that Hassan does not “specify that the fill consists of valproic acid or divalproex sodium” (*id.* at 5).

The Examiner relies on Biraghi for teaching that valproic acid is not well tolerated by the stomach (*id.* at 5-6). Moreover, the Examiner finds that “a lower incidence of gastric intolerance occurred with an enteric-coated formulation of sodium valproate” (*id.* at 6). The Examiner relies on the PDR for teaching dosages, and for teaching that dosages of divalproex sodium are equivalent to valproic acid (*id.*).

The Examiner concludes that it would have been obvious to use valproic acid as the fill in the enteric capsule of Hassan as Biraghi teaches that valproic acid is not well tolerated by the stomach and Hassan teaches that enteric dosage forms are desirable to protect gastric tissue (*id.*).

As to the claimed C_{max} and T_{max}, the Examiner notes that Hassan teaches the same capsule shell, and, as set forth above, the prior art suggests filling the capsule with valproic acid or sodium valproate (*id.* at 7-8). The Examiner finds that as the prior art suggests the claimed composition, that composition would necessarily have the claimed C_{max} and T_{max} (*id.* at 8).

Appellants assert that Biraghi described the effectiveness of several formulations of sodium valproate, arguing that “[v]alproic acid and divalproex sodium are structurally different from sodium valproate and have different physical and chemical properties” (App. Br. 15). Appellants assert that there “is no disclosure or suggestion in Biraghi to substitute valproic acid or divalproex sodium for the sodium valproate and the Examiner has failed to show why one of ordinary skill in the art would make such a substitution” (*id.*).

Appellants’ arguments are not convincing. The Supreme Court has emphasized that “the [obviousness] analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *KSR Int’l v. Teleflex Inc.*, 550 U.S. 398. 418 (2007). “If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability. (*Id.*) Under the correct obviousness analysis, “any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed.” *Id.* at 420.

The Examiner cited Biraghi for teaching that valproic acid is not well tolerated by the stomach. As acknowledged by Appellants’ Specification, as well as the PDR, valproic acid and divalproex sodium are known in the art. Thus, it would have been well within the level of skill of the ordinary artisan to combine any known form of valproic acid, such as valproic acid itself or divalproix sodium, which, as acknowledged by the instant Specification and

reiterated by Biraghi, are known to cause gastrointestinal upset, with the enteric capsule of Hassan.

Appellants argue further that selecting valproic acid to fill the capsule of Hassan “does not automatically result in the pharmacokinetic profile specified in the claims” (App. Br. 11). According to Appellants, the “presence of excipients in the fill material and the specific materials used to prepare the capsule shell affect the rate of release of the drug from the dosage form and thus the resulting pharmacokinetic profile” (*id.*).

Appellants argue further that it was improper for the Examiner to use an inherency analysis, as while “every combination of known elements inherently has the properties it has, those properties are not necessarily known or predictable before the elements are actually combined” (*id.* at 16). Appellants rely on the T_{\max} data in Biraghi, Palva, and in the examples in the Specification to demonstrate the variability of the T_{\max} data for valproic acid products (*id.*). Appellants also argue that the “claimed compositions provide a pharmacokinetic profile that is unexpected in view of the art cited by the Examiner” (*id.* at 19).

Again, Appellants arguments have been carefully considered, but are not found to be convincing. The composition taught by the prior art references as combined by the Examiner meets all of the composition limitations required by claim 1. While the art is silent on what T_{\max} and C_{\max} that specific dosage form would have, we agree with the Examiner that is a property that would be possessed by that dosage form. Moreover, “[m]ere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention.” *In re Baxter-Travenol Labs.*,

952 F.2d 388, 392 (Fed. Cir. 1991); *see also, In re Woodruff*, 919 F.2d 1575, 1577-78 (Fed. Cir. 1990) (obviousness rejection affirmed where using claimed elements in the manner suggested by the prior art necessarily resulted in claim-recited effect).

As to Appellants assertion on unexpected results, “it is well settled that unexpected results must be established by factual evidence. Mere argument . . . does not suffice.” *In re De Blauwe*, 736 F.2d 699, 705 (Fed. Cir. 1984). In addition, “when unexpected results are used as evidence of nonobviousness, the results must be shown to be unexpected compared with the closest prior art.” *In re Baxter-Travenol Labs.*, 952 F.2d 388, 392 (Fed. Cir. 1991). A showing of unexpected results must also be commensurate in scope with the breadth of the claims. *In re Grasselli*, 713 F.2d 731, 743 (Fed. Cir. 1983). We have considered the examples provided in the Specification and Biraghi, but the Specification does explain why the obtained T_{\max} and C_{\max} are unexpected, nor have Appellants provided any evidence as to why the obtained T_{\max} and C_{\max} are unexpected.

As to the rejection of claim 9 over Hassan, Biraghi, PDR, and Chen, Appellants essentially reiterate their arguments made with respect to claim 1 (App. Br. 17). Appellants then argue for the first time in the Reply Brief that there “is no disclosure or suggestion in Chen to select corn oil from among the 60 vegetable oils listed in Table 1” of Chen (Reply Br. 9). Thus, Appellants assert that the Examiner is using impermissible hindsight (*id.*). Appellants also argue that the “Examiner has still failed to show how one combines and/or modifies the references to prepare compositions having the claimed pharmacokinetic profile” (*id.*).

Appellants' arguments are not convincing for the reasons set forth with respect to claim 1. With respect to the arguments set forth for the first time in the reply brief, absent a showing of good cause, the Board is not required to address arguments in the Reply Brief could have been presented in the principal Brief. *Ex parte Borden*, 93 USPQ2d 1473, 1474 (BPAI 2010) ("informative").

As to Rejection IV, the Examiner's statement of the provisional obviousness-type double patenting rejection over copending Application No. 10529984 is set forth at pages 12-14 Answer. As we agree with the Examiner's findings and conclusions, we adopt them as our own.

Appellants argue that Biraghi and the PDR cannot be used as the basis of a double patenting rejection, as they are not published patent applications or issued patents (App. Br. 18). Specifically, according to Appellants, the "Examiner cannot provide the missing elements of the claims in a double patenting rejection by relying on secondary references not commonly owned, particularly secondary **non-patent** references" (Reply Br. 12). Appellants also reiterate the arguments made with respect to claim 1 in the obviousness rejection (App. Br. 18.).

Appellants point to no authority to support their assertion that non-patent references cannot be used to support an obviousness-type double patenting rejection over a copending application.

Moreover, the purpose of an obviousness-type double patenting rejection "is to prevent the extension of the term of a patent, even where an express statutory basis for the rejection is missing, by prohibiting the issuance of the claims in a second patent not patentably distinct from the

claims of the first patent.” *In re Longi*, 759 F.2d 887, 892 (Fed. Cir. 1985). Thus, the inquiry is directed “to whether the claimed invention in the application for the second patent would have been obvious from the subject matter of the claims in the first patent, in light of the prior art.” *Id.* at 893. While the additional prior art references relied upon the rejection being reviewed by the *Longi* court were patents, there is nothing in the opinion that states that references relied upon to demonstrate the state of the prior art need be patents, much less commonly owned. We thus affirm the provisional obviousness-type double patenting rejection.

SUMMARY

We affirm the following rejections:

Claims 1-8, 11, 12, 15-19, and 25-31 under 35 U.S.C. § 103(a) as being rendered obvious by the combination of Hassan, Biraghi, and the PDR; and

Claim 9 stands rejected under 35 U.S.C. § 103(a) as being rendered obvious by the combination of Hassan, Biraghi, and the PDR as further combined with Chen; as well as the provisional rejection of

Claims 1-9, 11, 12, 15-19, and 25-31 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of USSN 10/529,984 as combined with Biraghi and the PDR.

We vacate the rejection of claims 1-9, 11, 12, 15-19 under 35 U.S.C. § 103(a) as being rendered obvious by the combination of Chen, Hassan, and the PDR as being cumulative to the obviousness rejections based on Hassan.

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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)(2006).

AFFIRMED

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