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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte CHRISTOPHER D. BREDER[1]

Appeal 2021-002289
Application 15/615,423
Technology Center 1600

Before RICHARD M. LEBOVITZ, JOHN G. NEW, and DAVID COTTA, *Administrative Patent Judges*.

NEW, *Administrative Patent Judge*.

DECISION ON APPEAL

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[1] We use the term "Appellant" to refer to the "applicant" as defined in 37 C.F.R. § 1.142. Appellant identifies Supernus Pharmaceuticals, Inc. as the real party-in-interest. App. Br. 2. Oral argument in this appeal was heard on September 27, 2021, and a transcript of the hearing ("Trans.") will be made part of the record.

SUMMARY

Appellant files this appeal under 35 U.S.C. § 134(a) from the Examiner's Final Rejection of claims 1–8. Specifically, claims 1–7 stand rejected as unpatentable under 35 U.S.C. § 103(a) as being obvious over the combination of Heiligenstein (WO 99/15177, April 1, 1999) ("Heiligenstein") and DelPrete (US 2008/0014252 A1, January 17, 2008) ("DelPrete").

Dependent claim 8 stands rejected as unpatentable under 35 U.S.C. § 103(a) as being obvious over the combination of Heiligenstein, DelPrete, and A.C. Altamura et al., *Age, Therapeutic "Milieu" and Clinical Outcome in Depressive Patients Treated with Viloxazine: A Study with Plasma Levels*, 10 PROG. NEURO-PSYCHOPHARMACOL. & BIOL. PSYCH. 67–75 (1986) ("Altamura").

We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE.

REPRESENTATIVE CLAIM

Independent claim 1 is representative of the claims on appeal and recites:

> 1. A method of antagonizing 5-HT7 and 5-HT1B receptor activity in a patient suffering from ADHD, consisting of administering to the patient in need thereof a therapeutically effective amount of viloxazine, wherein the administration antagonizes both receptors.

App. Br. 13.

ISSUE AND ANALYSIS

We do not agree with, and decline to adopt, the Examiner's findings, reasoning, and conclusion that the claims are obvious over the combined teachings and suggestions of the cited prior art.

1. Claims 1–8

Issue

Appellant argues that the Examiner erred because a person of ordinary skill in the art would have had no motivation to replace reboxetine in Heiligenstein's method with viloxazine, as taught by DelPrete, nor would there have been a reasonable expectation of success in treating ADHD with viloxazine. App. Br. 8.

The Examiner's findings and conclusion

The Examiner finds that Heiligenstein teaches methods of treating ADHD by administering the norepinephrine reuptake inhibitor reboxetine in an effective dose of 1–100 mg per day. Final Act. 4. The Examiner notes that the limitations of the claims on appeal reciting antagonizing 5-HT7 and 5-HT1B receptor activity, and improved adverse effect profile, are mechanisms of action that will necessarily occur when the same drug is administered to a subject, and are therefore inherent properties of reboxetine.

Id. (citing *In re Spada*, 911 F.2d 705, 709 (Fed. Cir. 1990); MPEP § 2112.01 (9th ed. Rev. 10.2019, rev. June 2020)).

The Examiner acknowledges that Heiligenstein neither teaches nor suggests viloxazine. Final Act. 5. However, the Examiner finds that DelPrete teaches that both reboxetine and viloxazine are well-known norepinephrine reuptake inhibitors. *Id.* (citing DelPrete ¶ 18).

The Examiner concludes, therefore, that it would have been *prima facie* obvious to a person of ordinary skill in the art to substitute the norepinephrine reuptake inhibitor, viloxazine, as taught by DelPrete, with the norepinephrine reuptake inhibitor, reboxetine, in the method of treating ADHD, as taught by Heiligenstein. Final Act. 5–6. The Examiner also concludes that a person of ordinary skill in the art would have been motivated to substitute viloxazine for reboxetine because both are well-known norepinephrine reuptake inhibitors, as taught by DelPrete, and are therefore functional equivalents. *Id.* at 6. Therefore, reasons the Examiner, a skilled artisan would have had a reasonable expectation of success in treating ADHD in a patient in need thereof by administering viloxazine. *Id.*

Analysis

We are not persuaded that the Examiner has established a *prima facie* case of obviousness. The Examiner bears the initial burden of establishing a *prima facie* case of obviousness. *In re Deuel*, 51 F.3d 1552, 1557 (Fed. Cir. 1995). "Only if this burden is met does the burden of coming forward with rebuttal argument or evidence shift to the applicant." *Id.*

Heiligenstein teaches the administration of reboxetine for ADHD. Heiligenstein, 2. Heiligenstein teaches:

> Reboxetine is a safe drug, and its use in ADHD, in both adults and children, is a superior treatment for that disorder because of its improved safety. The compound is particularly selective, having few if any physiological effects besides those on norepinephrine processing, and therefore is free of side effects and unwanted activities. Further, it is effective at relatively low doses, as discussed below, and may safely and effectively be administered once per day. Thus, difficulties created by the multiple dosing of patients, who are children and disorganized adults, are completely avoided.

Id. Heiligenstein is silent with respect to viloxazine.

DelPrete is directed to topical compositions for the transdermal delivery of active agents and, specifically a composition comprising an adrenergic drug and an active agent in a transdermal delivery vehicle. DelPrete ¶ 2. The compositions of DelPrete are intended "for the topical treatment and prevention of ailments, including muscle pain and muscle cramps." *Id.* at ¶ 10.

DelPrete additionally teaches that "the compositions may also contain one or more active agents in addition to the transdermal vehicle and adrenergic drug." DelPrete ¶ 18. DelPrete teaches a long list of such optional additional active agents, including "Norepinephrine Reuptake Inhibitor[s] (NRI) or (NARI): Atomoxetine, Reboxetine, Viloxazine, Maprotiline…." *Id.* DelPrete is silent with respect to ADHD.

DelPrete thus teaches that reboxetine and viloxazine are norepinephrine reuptake inhibitors. That is the sole nexus between the teachings of DelPrete and Heiligenstein.

We are not persuaded that DelPrete's teaching that the norepinephrine reuptake inhibitors viloxazine and reboxetine may be used as optional additional active agents in a topical composition for the treatment of

muscle pain and muscle cramps provides sufficient motivation for a person of ordinary skill in the art to substitute viloxazine for reboxetine in the treatment of ADHD. This is particularly true given the teachings of Heiligenstein, quoted *supra*, concerning the high selectivity on norepinephrine processing and the efficacy of reboxetine in the treatment of ADHD. Furthermore, the testimony of Appellant's declarant, Dr. Andrew Cutler, additionally supports this contention:

> Considering viloxazine's different clinical and preclinical profile versus alomoxetine and reboxetine, I am convinced that viloxazine is not just an NRI [norepinephrine reuptake inhibitor] and that in addition, serotonin receptor binding is important for its efficacy and relatively favorable safety and tolerability profile.

Cutler Decl. ¶ 9.

Simply put, we conclude that DelPrete's teaching that both reboxetine and viloxazine are norepinephrine reuptake inhibitors that can be used as optional ingredients in a topical composition for the treatment of muscle ache and cramp is insufficient reason to motivate a person of ordinary skill in the art to substitute viloxazine for the highly selective reboxetine for the treatment of ADHD, with a reasonable expectation of success. We consequently reverse the Examiner's rejection of claims 1–7.

Furthermore, because claim 8 depends from claim 1, we reverse the Examiner's rejection of claim 8 for the same reasons.

CONCLUSION

The rejection of claims 1–8 as unpatentable under 35 U.S.C. § 103 is reversed.

REVERSED

Claim(s) Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
1–7	103	Heiligenstein, DelPrete		1–7
8	103	Heiligenstein, DelPrete, Altamura		8
Overall Outcome				**1–8**