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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte PATRICIA ALLISON TEWES RICHARDS

Appeal 2020-000025
Application 15/785,769
Technology Center 1600

Before DONALD E. ADAMS, ERIC B. GRIMES, and JEFFREY N. FREDMAN, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL

Pursuant to 35 U.S.C. § 134(a), Appellant[1] appeals[2] from Examiner's decision to reject claims 1–5 and 7–12. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM the obviousness-type double patenting rejections.

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[1] We use the word "Appellant" to refer to "applicant" as defined in 37 C.F.R. § 1.42. Appellant identifies the real party in interest as "SEBELA INTERNATIONAL LIMITED" (Appellant's April 1, 2019 Appeal Brief (Appeal Br.) 1).

[2] This Appeal is related to Appeal 2012-004394 (Application 15/408,924). Decision reversing the rejections under 35 U.S.C. § 103(a) entered October 21, 2013 (*see* Appeal Br. 2).

STATEMENT OF THE CASE

Appellant's disclosure "relates to a method for treating a patient suffering from a thermoregulatory dysfunction, especially hot flashes and flushes associated with hormonal changes due to naturally occurring menopause (whether male or female) or due to chemically or surgically induced menopause" (Spec. ¶ 3). Appellant's only independent claim, claim 1, is reproduced below:

> 1. A method for treating a patient suffering from a thermoregulatory dysfunction comprising:
>
> administering to said patient a compound selected from paroxetine, paroxetine mesylate, paroxetine hydrochloride, paroxetine hydrochloride anhydrous, paroxetine hydrochloride hemihydrate, and paroxetine hydrochloride monohydrate; said compound being in an amount, based on the paroxetine moiety, which is at least about 0.1 mg/day up to 9.5 mg/day.

(Appeal Br. A-1.)

Grounds of rejection before this Panel for review:

Claims 1–5 and 7–12 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Stearns '00[3] and Jenkins.[4]

Claims 1–5 and 7–12 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Stearns '05.[5]

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[3] V. Stearns, et al., *A pilot trial assessing the efficacy of paroxetine hydrochloride (Paxil®) in controlling hot flashes in breast cancer survivors*, 11 ANNALS OF ONCOLOGY 17–22 (2000).
[4] Jenkins, US 6,369,051 B1, issued April 9, 2002.
[5] V. Stearns, et al., *Paroxetine Is an Effective Treatment for Hot Flashes: Results from a Prospective Randomized Clinical Trial*, 23(28) J. CLIN. ONCOL. 6919-6930 (2005).

Claims 1–5 and 7–12 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1–5 of Richards '663.[6]

Claims 1–5 and 7–12 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1–12 of Richards '251.[7]

Claims 1–5 and 7–12 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1–5 of Richards '576.[8]

Claims 1–5 and 7–12 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1–14 of Richards '237.[9]

Obviousness:

ISSUE

Does the preponderance of evidence relied upon by Examiner support a conclusion of obviousness?

FACTUAL FINDINGS (FF)

FF 1. Stearns '00 discloses a method of treating hot flashes associated with dysfunction of thermoregulation comprising administering the selective serotonin-reuptake inhibitor (SSRI) paroxetine hydrochloride at a dosage of 10 mg daily for one week, followed by four weeks of paroxetine

[6] Richards, US 8,658,663 B2, issued Feb. 25, 2014.
[7] Richards, US 8,946,251 B2, issued Feb. 3, 2015.
[8] Richards, US 8,859,576 B2, issued Oct. 14, 2014.
[9] Richards, US 9,393,237 B2, issued July 19, 2016.

hydrochloride at a dosage of 20 mg daily (*see* Stearns '00 17: Summary; *id.* at 18: right column, ll. 28–32; *see also* Final Act.[10] 4).

FF 2. Stearns '00 discloses:

> Adverse effects were minimal and included mostly somnolence (Table 2). Two patients discontinued drug therapy due to excessive somnolence following three days, and seventeen days, respectively, of drug therapy. One patient discontinued the drug following twenty-three days of therapy due to anxiety. Two patients decreased their paroxetine dose to 10 mg due to somnolence encountered on the higher dose.

(Stearns '00 19: right column, ll. 17–24; *see* Ans.[11] 4 (Examiner finds that Stearns '00 discloses "that [a] lower dose of paroxetine ha[s] fewer side effects").)

FF 3. Stearns '00 discloses that its

> This pilot trial cannot answer questions related to the optimal dose of treatment. For example, many of the study participants noted an almost immediate reduction in the frequency and severity of their hot flashes. It is therefore possible that a dose of paroxetine 10 mg daily might be sufficient in alleviating hot flashes. Also, it is possible that women who did not respond to the standard antidepressant dose of 20 mg might benefit from an increased paroxetine dose. The pilot study was not sufficiently powered to detect differences in benefit between various subgroups, such as women who suffered long *versus* short duration of hot flashes, younger or older women.

(Stearns '00 21: left column, ll. 31–43; see generally Ans. 7).

FF 4. Examiner finds that Stearns '00 does not disclose the administration of paroxetine hydrochloride at a concentration below 10 mg/day (Final Act. 4).

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[10] Examiner's June 25, 2018 Final Office Action.
[11] Examiner's July 29, 2019 Answer.

FF 5. Jenkins' "invention relates to methods of using substituted indole compounds in the combination with a . . . (SSRI) for the treatment [of, *inter alia*,] . . . hot flush" (Jenkins 1:6–10; *see generally* Final Act. 4).

FF 6. Jenkins discloses that its

> invention includes acceptable salt forms of the substituted indoles formed from the addition reaction with either inorganic or organic acids . . . [and] [a]dditionally . . . includes quaternary ammonium salts of the compounds herein. . . . It is understood that the dosage, regimen and mode of administration of these compounds will vary according to the extent of the malady and the individual being treated and will be subject to the judgement [sic] of the medical practitioner involved. It is preferred that the administration of one or more of the SSRIs and substituted indole compounds herein begin at a low dose and be increased until the desired effects are achieved.
>
> Effective administration of these compounds may be given at an effective dose of from about 0.1 mg/day to about 500 mg/day.

(Jenkins 15:49–59; *see id*. at 16:48–49 (Jenkins discloses that "[t]he SSRI compounds . . . may be administered in regimens and at dosages known in the art"); *id.* at 17: 1–4 (Jenkins discloses that "[t]he joint administration of the two groups of compounds in . . . [its] methods will be determined by a medical professional based upon the condition of the recipient and the malady for which the prophylaxis or treatment is provided"); *id.* at 17: 21–24 (Jenkins discloses that "[w]hen optimum dosages for the indole compounds and the SSRI of these formulations have been determined, it may [be] preferable to incorporate both into a single formulation for ease of administration"); *see generally* Final Act. 4; Ans. 4.)

FF 7. Jenkins discloses that "SSRI agents useful with the present methods of treatment include . . . paroxetine . . . or a pharmaceutically acceptable salt thereof" (Jenkins 7:44–47; *see id.* at 16:48–60 (Jenkins discloses that "[t]he

SSRI compounds of [its] methods may be administered in regimens and at dosages known in the art" and, specifically discloses that "[p]aroxetine hydrochloride . . . has a recommended daily dosage of from 20 to 50 mg"); *see* Final Act. 4).

FF 8. Stearns '05 "report[s] results of a prospective, double-blind, randomized cross-over clinical trial designed to evaluate the efficacy of two doses of paroxetine [hydrochloride] versus placebo" (Stearns '05 6920: left column, ll. 17–20; *see also id.* at right column, ll. 16–18; *see generally* Final Act. 7).

FF 9. Stearns '05 discloses that an "objective [of its study] was to compare the effectiveness of the standard starting dose of paroxetine for depression and other psychiatric illnesses (20 mg) and low-dose (10 mg) for the treatment of hot flashes" (Stearns '05 6920: left column, ll. 22–26).

FF 10. Stearns '05 reports that the "[e]fficacy was similar between the two doses, but women were less likely to discontinue low-dose paroxetine" treatment (*id*. at 6919: Abstract; *see generally* Final Act. 7).

FF 11. Examiner finds that Stearns '05 does not disclose the administration of paroxetine hydrochloride at a concentration below 10 mg/day (Final Act. 7).

ANALYSIS

The rejection over the combination of Stearns '00 and Jenkins:

Based on the combination of Stearns '00 and Jenkins, Examiner concludes that, at the time Appellant's invention was made, it would have been prima facie obvious "to administer paroxetine in an amount of up to 9.0 mg/day, not more than 8.5 mg/day, or not more than 8.0 mg/day to treat hot flashes because Jenkins teaches that paroxetine can be administered at an

effective dose of from 0.1 mg/day to about 500 mg/day" (Final Act. 4). In this regard, Examiner finds that

> one of ordinary skill in the art would have been motivated to determine the effective amounts of paroxetine such as not more than about 9.5 mg/day, not more than about 9.0 mg/day, not more than 8.5 mg/day, or not more than 8.0 mg/day as in instant claims, with [a] reasonable expectation of success of treating hot flashes, since the optimization of effective amounts of known agents to be administered, is considered well in the competence level of an ordinary skilled artisan in pharmaceutical science, involving merely routine skill in the art.

(*Id.* at 4–5; *see also* Ans. 4–6.) We are not persuaded.

Although Stearns '00 discloses the use of a daily paroxetine dose of 10 mg, or more, for the treatment of hot flashes, Stearns '00 makes clear that its "pilot trial cannot answer questions related to the optimal dose of treatment" (FF 3; *see also* FF 1–2). In addition, Examiner recognizes that Stearns '00 does not "disclose the administration of paroxetine hydrochloride at a concentration below 10 mg/day" (FF 4). Examiner, therefore, relies on Jenkins to make up for this deficiency in Stearns '00 (*see e.g.,* FF 5–7). We are, however, not persuaded that Jenkins makes up for the deficiency in Stearns '00.

As Appellant explains, notwithstanding Examiner's assertion to the contrary, a "skilled artisan reading Jenkins would not understand Jenkins to teach or suggest that every dose of every SSRI within the range of 0.1 mg/day to 500 mg/day is useful against every condition mentioned in Jenkins" (Appeal Br. 7; *see* FF 6; *see generally* Reply Br. 1–4; *cf.* Final Act. 4–5). To the contrary, Jenkins discloses that "[t]he SSRI compounds of [its] methods may be administered in regimens and at dosages known in the art"

and, specifically discloses that "[p]aroxetine hydrochloride . . . has a recommended daily dosage of from 20 to 50 mg" (FF 7; *see also* Appeal Br. 7).

Thus, although the combination of Stearns '00 and Jenkins may provide a reasonable expectation that a lower dose of paroxetine, i.e. paroxetine hydrochloride, would have fewer side effects, the combination of Stearns '00 and Jenkins provides no expectation that a dose below 10 mg/day would exhibit a therapeutic effect in the treatment of a patient suffering from a thermoregulatory dysfunction as required by Appellant's claimed invention (*see* Appeal Br. 7–9). In sum, Examiner failed to establish an evidentiary basis to support a conclusion that a person of ordinary skill in this art, at the time of Appellant's claimed invention, would have reasonably expected a dose of less than 10 mg/day of paroxetine, i.e., paroxetine hydrochloride, would be effective in treating a patient suffering from a thermoregulatory dysfunction as is required by Appellant's claimed invention.

The rejection over Stearns '05:

Based on Stearns '05, Examiner concludes that, at the time Appellant's invention was made, it would have been prima facie obvious "to administer paroxetine in an amount of up to 9.5 mg/day, not more than about 9.0 mg/day, not more than 8.5 mg/day, or not more than 8.0 mg/day to treat hot flashes because Stearns et al. teach that lower dose of paroxetine have fewer side effects" (Final Act. 7–8; *see also* Ans. 12). In this regard, Examiner finds that "one of ordinary skill in the art would have been motivated to administer lower doses of paroxetine with reasonable

expectation of success of treating hot flashes with fewer side effects" (*id*. 8). We are not persuaded.

Examiner recognizes that Stearns '05 does not disclose the administration of paroxetine hydrochloride at a concentration below 10 mg/day (FF 11; *see also* Appeal Br. 10). Thus, Examiner failed to establish an evidentiary basis on this record to support a conclusion that a person of ordinary skill in this art, at the time of Appellant's claimed invention, would have reasonably expected a dose of less than 10 mg/day of paroxetine, i.e., paroxetine hydrochloride, would be effective in treating a patient suffering from a thermoregulatory dysfunction as is required by Appellant's claimed invention (*see* Appeal Br. 10; *see also* Reply Br. 4–5).

CONCLUSION

The preponderance of evidence relied upon by Examiner fails to support a conclusion of obviousness.

The rejection of claims 1–5 and 7–12 under 35 U.S.C. § 103(a) as unpatentable over the combination of Stearns '00 and Jenkins is reversed.

The rejection of claims 1–5 and 7–12 under 35 U.S.C. § 103(a) as unpatentable over Stearns '05 is reversed.

Obviousness-type Double Patenting:

ANALYSIS

Appellant's claim 1, reproduced above, is representative.

On this record, Appellant does not contest the rejections of claim 1 under the judicially created doctrine of obviousness-type double patenting. Appellant also did not file a terminal disclaimer to moot these rejections (*see* Final Act. 12 (Examiner acknowledges Appellant's "remarks that 'a

Terminal Disclaimer over each cited patent is being simultaneously filed'," but "did not find any Terminal Disclaimers" on this record, and suggested that Appellant "file the Terminal Disclaimers")).

"If a ground of rejection stated by the examiner is not addressed in the appellant's brief, appellant has waived any challenge to that ground of rejection and the Board may summarily sustain it." MPEP § 1205.02 (9th Ed., Rev. 08.2017 (Jan. 2018)).

Accordingly, the obviousness-type double patenting rejections are summarily affirmed.

CONCLUSION

The rejection of claim 1 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1–5 of Richards '663 is affirmed. Claims 2–5 and 7–12 are not separately argued and fall with claim 1.

The rejection of claim 1 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1–12 of Richards '251 is affirmed. Claims 2–5 and 7–12 are not separately argued and fall with claim 1.

The rejection of claim 1 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1–5 of Richards '576 is affirmed. Claims 2–5 and 7–12 are not separately argued and fall with claim 1.

The rejection of claim 1 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1–14 of Richards '237 is affirmed. Claims 2–5 and 7–12 are not separately argued and fall with claim 1.

DECISION SUMMARY

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
1–5, 7–12	103(a)	Stearns '00, Jenkins		1–5, 7–12
1–5, 7–12	103(a)	Stearns '05		1–5, 7–12
1–5, 7–12		Nonstatutory Double Patenting, Richards '663	1–5, 7–12	
1–5, 7–12		Nonstatutory Double Patenting, Richards '251	1–5, 7–12	
1–5, 7–12		Nonstatutory Double Patenting, Richards '576	1–5, 7–12	
1–5, 7–12		Nonstatutory Double Patenting, Richards '237	1–5, 7–12	
Overall Outcome			1–5, 7–12	

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).

AFFIRMED