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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte TOMMY L. CHAU, JOHN M. PINNEY,
JACK E. HENNINGFIELD, EDWARD J. CONE,
SAUL M. SHIFFMAN, and JOSEPH G. GITCHELL

Appeal 2019-006294
Application 14/172,604
Technology Center 1600

Before JEFFREY N. FREDMAN, ELIZABETH A. LAVIER, and
MICHAEL A. VALEK, *Administrative Patent Judges*.

VALEK, *Administrative Patent Judge*.

DECISION ON APPEAL

Appellant¹ submits this appeal under 35 U.S.C. § 134(a) involving claims to methods of making an orally administrable medicinal delivery system comprising a nicotine compound. We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE.

¹ We use the word “Appellant” to refer to “applicant” as defined in 37 C.F.R. § 1.42. Appellant identifies JSRNTI, LLC as the real party in interest. Appeal Br. 2.

STATEMENT OF THE CASE

Claims 43–62 are on appeal and can be found in the Claims Appendix of the Appeal Brief. Claim 43 is representative of the claims on appeal. It reads as follows:

43. A method of making an orally administrable medicinal delivery system, comprising:
- at least partially dissolving a nicotine compound in a bulk sweetener solution comprising a solvent and a first bulk sweetener;
 - subsequent to said at least partially dissolving, coating the nicotine compound and the first bulk sweetener on a saliva-soluble bulk sweetener powder comprising a second bulk sweetener to establish a coated powder premix; and
 - subsequent to establishing the coated powder premix, combining the coated powder premix with a chewing gum base and a buffer.

Appeal. Br. 25. The only other independent claim, claim 53, recites the same steps “to establish a coated powder premix,” which is then combined “with a lozenge base and a buffer.” *Id.* at 27.

Appellant seeks review of the following rejections:

- I. Claims 43–62 under 35 U.S.C. § 103 as obvious over Lindell;²
- II. Claims 43–62 for obviousness-type double patenting (“ODP”) over claims 13–20 of the ’654 patent³ in view of Lindell; and
- III. Claims 43–62 for ODP over claims 28–35 and 43–56 of

² WO 02/102357 A1, published Dec. 27, 2002 (“Lindell”).

³ US 6,893,654 B2, issued May 17, 2005 (“’654 patent”).

the '060 patent⁴ in view of Lindell.

Appeal Br. 5.

Analysis

I. 103 Rejection:

The issue for this rejection is whether the preponderance of the evidence supports Examiner's conclusion that the methods in claims 43–62 are obvious over Lindell.

Relying on Lindell Example 5, Examiner finds that Lindell discloses a nicotine gum comprising all of the ingredients in claim 43. *See* Final Act. 3–4. Examiner acknowledges that “Lindell does not teach that the gum base and buffer are added subsequent to the liquid and powder” ingredients. *Id.* at 4. However, Examiner concludes that:

[i]n making the formulation, one of ordinary skill in the art would have found it obvious to add the components in any order given that no order is specified (see p. 34, lines 5–15). Thus it would have been obvious to add the sorbitol nicotine and xylitol together first in order to dissolve the nicotine. Given the recited active steps are met, it is reasonably expected that the nicotine would be partially dissolved in the sorbitol and the sorbitol liquid would act as a paste, sticking to and coating the xylitol powder. Further, it would have been obvious to include the nicotine with coating components, which are only combined with the chewing gum base and buffer when the gum base and buffer are coated with the nicotine coating in a final step (see Lindell at p. 5, lines 21–24).

Ans. 4.

Appellant contends that Examiner's conclusion of obviousness is flawed because Lindell does not teach the steps recited “to establish a coated powder premix” in the independent claims. *See* Appeal Br. 5–17, 20. In

⁴ US 6,358,060 B2, issued Mar. 19, 2002 (“’060 patent”).

particular, Appellant urges that “Lindell teaches adding the liquid and solid powder mixture components directly to the softened gum base, not premixing liquid and solid components, such as nicotine, a solvent, and a first bulk sweetener” to form a solution that is then used to coat a second bulk sweetener powder to form the recited premix. *Id.* at 7. Appellant contends that “[r]ather than coat, Lindell grinds and mixes” its powder ingredients “to assure good distribution,” whereas the “nicotine [produced in Appellant’s process] is concentrated in the coating on the second bulk sweetener to establish the premix.” *Id.* at 8–9. According to Appellant, the claimed process results in a more soluble form of nicotine and “disperses the nicotine over a relatively large surface area, making the nicotine more available for delivery and absorption by a user’s oral mucosa to promote a high initial nicotine release rate.” *Id.* at 4 (citing Spec. 12:5–14; 28:14–19).

On this record, we are persuaded by Appellant’s arguments and determine Examiner’s rejection is not supported by the preponderance of the evidence. While it is true that Lindell discloses gums comprising two bulk sweeteners (i.e., sorbitol and xylitol), nicotine, chewing gum base, and a buffer (*see* Lindell 32 (Ex. 5)), it does not teach that those ingredients are combined according to the steps recited “to establish a coated powder premix” in Appellant’s independent claims. In particular, there is no disclosure of: 1) dissolving nicotine in a bulk sweetener solution comprising a first bulk sweetener and a solvent; and 2) using that nicotine solution to coat a saliva-soluble powder comprising a second bulk sweetener. Instead, Lindell suggests that the solid ingredients are first ground up and the resulting mixture is combined with the gum base concurrently with any liquid ingredients. *See* Lindell 34:5–15; *see also id.* at 24:28–30 (“Before

adding any solid component, except for the gum base, it is desirable to grind and size the solid component first, to ensure good distribution.”).

According to Examiner, “the only substantial difference between [Lindell] and the instant claims is the order of ingredient addition.” Ans. 7–8. We disagree. Claims 43 and 53 require the formation of a “coated powder premix.” The claims specify that this premix is established by performing a specific set of steps that requires first mixing a particular solid ingredient (nicotine) with a liquid (solvent/first bulk sweetener) and then coating that liquid onto a different solid ingredient (saliva-soluble powder). Thus, even if as Examiner found, it would have been obvious to add either Lindell’s solid or liquid ingredients first before combining them with the gum base, Examiner has not shown that the particular sequence of steps required to establish the recited “premix” would have been obvious.

In addition, Examiner has not articulated a sufficient rationale to explain why one of ordinary skill in the art would have been motivated to change the process taught in Lindell. Lindell Example 5 states that the mixing is performed according to a “conventional procedure.” Appellant submits the declaration of K. Warrant Clark, a chemist with “a detailed understanding as to the procedures used to make” chewing gum, who explains that “the conventional procedure at the time . . . did not involve the formation of a coated powder premix.” Declaration of K. Warren Clark dated Nov. 15, 2012 (“Clark Decl.”) ¶ 6, 29. Examiner has not identified any evidence to the contrary, nor otherwise articulated a reason why one of ordinary skill in the art would have found it obvious to deviate from the conventional procedures employed at the time by performing the recited steps “to establish a coated powder premix,” as claimed.

These facts also differ from the reasoning of *In re Burhans*, 154 F.2d 690 (CCPA 1946), relied upon in MPEP § 2144.04(IV)(C), where the MPEP summarizes *Burhans* as teaching the selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results. A necessary prerequisite for applying this reasoning is evidence that the process steps themselves were known and used in the cited prior art. As discussed above, the Examiner's rejection provides no evidence that the steps recited to "establish a coated powder premix" were taught in the prior art. Without a teaching of the steps in the prior art, there is no original order of steps for the artisan to rearrange into the claimed order of steps, and consequently nothing obvious about the claimed order of steps.

For these reasons, Examiner has not met the burden "of presenting a *prima facie* case of unpatentability" for claims 43 and 53. See *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992). Because Examiner's rejection of the dependent claims is premised on the same underlying findings as the independent claims, we reverse the rejection of those claims for the same reasons.

II. ODP Rejections

The issue for these rejections is whether the preponderance of the evidence supports Examiner's conclusion that the methods in claims 43–62 are obvious over the cited claims of the '654 and '060 patents each in view of Lindell and are therefore properly rejected for ODP.

Examiner groups the two ODP rejections together. Final Act. 6. For each rejection, Examiner finds that the present claims "are not patentably distinct from" the identified claims of the '654 and '060 patents "because a skilled artisan would have found it obvious to add bulk sweeteners as taught

by Lindell.” Final Act. 6. Moreover, Examiner determines that “Lindell suggests forming a coated powder premix,” relying on the “same reasons” Examiner offers for the obviousness rejection. *Id.*

Appellant argues that “neither the ’654 patent [claims] nor the ’060 patent [claims] discloses the order of ingredient addition or forming a coated powder premix.” Appeal Br. 23. Thus, Appellant urges that the claims of the ’654 patent and ’060 patent “do not overcome Lindell’s deficiencies, and the Examiner has not pointed to any teaching [in those claims] that overcomes the deficiencies.” *Id.*

We agree with Appellant for the reasons articulated above in our analysis of the obviousness rejection. In the Answer, Examiner states that the ’654 and ’060 patents “teach mixing a loading compound into the base material so that said loading compound remains releasable and rapidly transmucosally absorbable.” Ans. 8–9. While this may be so, the cited claims of those patents do not refer to a “coated powder premix,” nor has Examiner otherwise articulated how any of the claims of the ’654 and ’060 patents, alone or in combination with Lindell, teach the steps for establishing the coated powder premix in Appellant’s present claims. Accordingly, Examiner’s ODP rejections are not supported by the preponderance of the evidence.

CONCLUSION

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
43–62	103	Lindell		43–62
43–62		Nonstatutory Double Patenting: ’654 patent		43–62

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Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
43-62		Nonstatutory Double Patenting: '060 patent		43-62
Overall Outcome				43-62

REVERSED