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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte SAUJANYA GOSANGARI,
JUSTIN HUGHEY, TATYANA DYAKONOV,
GEORGE VAMVAKAS, and AQEEL A. FATMI,

Appeal 2019-006486
Application 14/877,208
Technology Center 1600

Before DONALD E. ADAMS, JEFFREY N. FREDMAN, and ELIZABETH A. LAVIER, *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, 9, 11, 19, 21, 28, 30, 32, 33, 43, 48, 49, 58, 81, and 84. We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE.

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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 "Patheon Softgels Inc.," which "is wholly owned by Thermo Fisher Scientific Inc." (Appellant's March 13, 2019 Appeal Brief (Appeal Br.) 3).

[2] This Appeal is related to co-pending Appeal 2019-006426, Application 14/679,233 (*see generally* Appeal Br. 4).

STATEMENT OF THE CASE

Appellant's disclosure relates to "abuse deterrent controlled release oral pharmaceutical compositions and methods for making the same. In particular, an abuse deterrent controlled release oral pharmaceutical composition comprising a soft capsule and an abuse deterrent controlled release matrix comprising an active pharmaceutical ingredient are described" (Spec. 1: 15–18). Appellant's independent claims 1 and 58 are reproduced below:

1. An abuse deterrent oral pharmaceutical composition comprising a soft gelatin capsule shell encapsulating a tamper resistant, homogenous viscous, yet flowable matrix consisting essentially of:

(a) about 50% to about 70% by mass olive oil, soybean oil, or a combination thereof;

(b) about 3% to about 10% by mass ethylcellulose;

[(c)] about 2% to about 30% by mass hydroxypropyl methylcellulose;

[(d)] about 4% to about 11 % by mass polyethylene glycol having a molecular weight of about 200 to about 8000;

[(e)] about 1 % to about 35% by mass of one or more active pharmaceutical ingredients that is dissolved in the flowable matrix; and

[(f)] optionally one or more antioxidants.

(Claims App.[3] 2.)

58. A tamper resistant oral pharmaceutical composition comprising a soft gelatin capsule shell encapsulating a tamper

[3] Appellant's corrected Claims Appendix included with Appellant's April 1, 2019 Response to Defective Brief. Appellant's Response to Defective Brief is not paginated, therefore all reference to page numbers refer to this document as if it were numbered consecutively starting with the first page.

resistant, homogenous viscous, yet flowable matrix consisting essentially of:

(a) about 50% to about 70% by mass soybean oil;

(b) about 2% to about 7% by mass ethylcellulose;

(c) about 2% to about 15% by mass hydroxypropylmethylcellulose;

(d) about 4% to about 11 % by mass polyethylene glycol 400; and

(e) about 10.5% by mass of hydrocodone or oxycodone; and optionally

(f) about 0.25% by mass BHT; and

(g) about 0.1 % by mass BHA.

(*Id.* at 6.)

Grounds of rejection before this Panel for review:

Claims 1, 9, 11, 30, 32, 33, 48, 49, 81, and 84 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Rariy[4] and Cohen.[5]

Claims 19, 21, 28, 43, and 58 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Rariy, Cohen, and Holm.[6]

Obviousness:

ISSUE

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

[4] Rariy et al., US 2011/0142943 A1, published June 16, 2011.
[5] Cohen et al., US 4,795,642, issued Jan. 3, 1989.
[6] Holm et al., US 2007/0122482 A1, published May 31, 2007.

FACTUAL FINDINGS (FF)

FF 1. Rariy relates to "pharmaceutical compositions, specifically compositions that are designed to reduce the potential for improper administration of drugs, such as those subject to abuse and methods of making thereof" (Rariy ¶ 2; *see* Ans.[7] 4).

FF 2. Examiner finds that Rariy discloses that its pharmaceutical compositions comprise "drug containing multiparticulates or drug particles encapsulated into hard or soft shell capsules" (Ans. 5; *see* Rariy ¶¶ 16, 54–60, 64, 71–81 and 93; *see also* Rariy 15: col. 1, ll. 5–11 and col. 2, ll. 1–3).

FF 3. Rariy discloses that its "drug containing multiparticulates . . . [may be] blended with extragranular material and filled into hard shell capsules," wherein "the extragranular material is a natural or synthetic gel forming excipient, added to form a gel or viscous environment around the particles when exposed to an aqueous environment" (Rariy ¶ 94; *see* Ans. 5 (Examiner finds that Rariy "teaches examples of suitable 'extragranular material, is a natural or synthetic gel forming excipient, added to form a gel or viscous environment around the particles when exposed to an aqueous environment'," which "reads on a homogenous viscous yet flowable semisolid")).

FF 4. Examiner finds that Rariy "fails to specify soybean oil, the amounts of each agent, the pharmaceutical ingredient percent mass to the matrix percent mass ratio, or the shell comprising gelatin, glycerol, and water" (Ans. 5).

[7] Examiner's August 6, 2019 Answer.

FF 5. Cohen discloses "[a] controlled-release pharmaceutical unit dosage form . . . comprising a gelatin capsule enclosing a solid matrix formed by the cation-assisted gelation of a liquid fill incorporating vegetable gum and a pharmaceutically-active compound, as well as methods for the preparation thereof" (Cohen, Abstract; *see* Ans. 5).

FF 6. Examiner finds that the combination of Rariy and Cohen fails "to specify the [use of] ethyl cellulose having a viscosity of 3 cP to about 20 cP, methylcellulose having a viscosity of about 500 to about 10,000, Ethocel 20 cP, or Methocel A4M" and relies on Holm to make up for this deficiency in the combination of Rariy and Cohen (Ans. 7).

ANALYSIS

The rejection over the combination of Rariy and Cohen:

Based on the combination of Rariy and Cohen, Examiner concludes that, at the time Appellant's invention was made, it would have been prima facie obvious

> to use soybean oils, the amounts of the pharmaceutical ingredient and matrix components in the ratios, and the shell comprising gelatin, glycerol, and water. The motivation comes from the teaching of Rariy . . . that the tamper-resistant pharmaceutical composition having controlled release can comprise a vegetable oil, carnauba wax, beeswax, gelatin, and glycerol. Cohen . . . teaches fill components of a gelatin-encapsulated controlled-release composition may comprise vegetable oils such as soybean oil and are coated with a soft gelatin shell comprising gelatin, glycerin, and water. Therefore, the skilled artisan would have had reasonable expectation of successfully achieving similar efficacy and results with the soft shell encapsulated controlled release formulation. Further, it would have been obvious to one having ordinary skill in the art before the effective filing date to modify the amounts and ratios, since it has been held that where the general conditions

> of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

(Ans. 6 (citing *In re Aller*, 220 F.2d 454, 456 (CCPA 1955).) We are not persuaded.

As Appellant explains, "Examiner provides no reasonable rationale that would suggest modifying the solid multiparticulates of Rariy into a flowable abuse deterrent matrix that is encapsulated in a softgel with any reasonable expectation of success" (Appeal Br. 13). Similarly, Appellant explains that "Cohen's gelled fill comprising gums (gelled by cations) is not analogous to Appellants' matrix composition because it is a gel (not a flowable viscous liquid)" (*id.*). In this regard, Appellant explains that its "claim terms 'homogenous' and 'dissolved' both indicate that the matrix fill is uniform and the . . . [active pharmaceutical ingredient] is dissolved within the matrix, i.e., that there are not particles. The presence of particles would not be a homogenous compositions" (Reply Br.[8] 5). We agree.

"[E]xaminer bears the initial burden, on review of the prior art or on any other ground, of presenting a prima facie case of unpatentability." *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992).

> Obviousness requires more than a mere showing that the prior art includes separate references covering each separate limitation in a claim under examination. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418, 127 S.Ct. 1727, 167 L.Ed.2d 705 (2007). Rather, obviousness requires the additional showing that a person of ordinary skill at the time of the invention would have selected and combined those prior art

[8] Appellant's August 29, 2019 Reply Brief.

> elements in the normal course of research and development to yield the claimed invention. *Id*. at 421, 127 S.Ct. 1727.

Unigene Laboratories, Inc. v. Apotex, Inc., 655 F.3d 1352, 1360 (Fed. Cir. 2011). Further, "rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006).

On this record, Examiner has, at best, established that pharmaceutical compositions may be formulated using Appellant's claimed ingredients (*see* Ans. 4–6; *see generally* FF 1–5). Examiner, however, failed to establish an evidentiary basis on this record to support a conclusion that the combination of Rariy and Cohen would have directed a person of ordinary skill in this art to a composition comprising a soft gelatin capsule shell encapsulating a tamper resistant, homogenous viscous, yet flowable matrix, consisting essentially of the ingredients required by Appellant's claimed invention (*see*, *e.g.*, Appeal Br. 17 ("Examiner has not shown that Rariy and Cohen specifically guide a person of ordinary skill to the general composition of the flowable matrix composition specified by Appellant[]")).

The "flowable" limitation, on this record, is particularly problematic. Although Examiner states that this is "recognized in the pharmaceutical art" (*see* Non-Final Act.[9] 2), Examiner has not established and evidentiary basis on this record to support a conclusion that the prior art soft gelatin capsules are actually "flowable". Stated differently, Examiner failed to establish an evidentiary basis on this record that rebuts Appellant's contention that a gel is "not a flowable viscous liquid" (Appeal Br. 13).

[9] Examiner's December 18, 2018 Non-Final Office Action.

The rejection over the combination of Rariy, Cohen, and Holm:

Based on the combination of Rariy and Cohen, Examiner concludes that, at the time Appellant's invention was made, it would have been prima facie obvious to formulate the pharmaceutical compositions of Rariy and Cohen with "methylcellulose polymers such as Methocel A4M and ethylcellulose such as Ethocel ® (ethylcellulose 20 cps)," because Holm discloses that they "are useful as fillers, diluents and/or binders and controlled release in modified release pharmaceutical composition[s]" (Ans. 7). We are not persuaded.

As Appellant explains, Holm fails to make up for the deficiency in the combination of Rariy and Cohen discussed above (*see* Appeal Br. 18).

CONCLUSION

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

The rejection of claims 1, 9, 11, 30, 32, 33, 48, 49, 81, and 84 under 35 U.S.C. § 103(a) as unpatentable over the combination of Rariy and Cohen is reversed.

The rejection of claims 19, 21, 28, 43, and 58 under 35 U.S.C. § 103(a) as unpatentable over the combination of Rariy, Cohen, and Holm is reversed.

DECISION SUMMARY

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
1, 9, 11, 30, 32, 33, 48, 49, 81, 84	103	Rariy, Cohen		1, 9, 11, 30, 32, 33, 48, 49, 81, 84
19, 21, 28, 43, 58	103	Rariy, Cohen, Holm		19, 21, 28, 43, 58
Overall Outcome				1, 9, 11, 19, 21, 28, 30, 32, 33, 43, 48, 49, 58, 81, 84

REVERSED