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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte HIDEKI ICHIKAWA, YOSHINOBU FUKUMORI, SATORU ABE, and YUSUKE MASUE[1]

Appeal 2019-001525
Application 13/701,619
Technology Center 1600

Before ERIC B. GRIMES, RICHARD M. LEBOVITZ, and DEBORAH KATZ, *Administrative Patent Judges.*

GRIMES, *Administrative Patent Judge.*

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134(a) involving claims to a coated particle, which have been rejected as obvious. We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE.

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[1] Appellant identifies the real parties in interest as Kobe Gakuin Educational Foundation and Nippon Soda Co., Ltd. Appeal Br. 3. We use the word "Appellant" to refer to "applicant" as defined in 37 C.F.R. § 1.42(a).

STATEMENT OF THE CASE

"[T]he present inventors found that by dry-coating a nuclear particle with hydroxyalkyl cellulose and a binder, a coating particle suitable for gastric soluble solid preparation, enteric soluble solid preparation, sustained-release solid preparation, bitterness-inhibiting solid preparation, and the like [is] obtained." Spec. ¶ 6. "The coating particle of the present invention has high coating ratio, is easy to control an elution rate of medical agents, and has excellent fluidity." Spec. ¶ 9. "The hydroxyalkyl cellulose used in the present invention has a volume average particle size of preferably from 0.1 to 20 μm." Spec. ¶ 27.

"A dry coating method is preferred." Spec. ¶ 37. "The dry-coating method is a method of mixing a nuclear particle with hydroxyalkyl cellulose, a binder and other coating base such as an elution controlling base and silica . . . and stirring those, thereby adhesion-coating the surface of the nuclear particle with the powder for a coating layer." Spec. ¶ 38. "The coating particles obtained by the dry-coating have excellent fluidity and sustained releasability." Spec. ¶ 40.

Claims 1–3 and 8–15 are on appeal. Claim 1, reproduced below, is illustrative:

> 1. A coating particle comprising a nuclear particle covered with a coating layer, wherein the coating layer is a layer comprising hydroxyalkyl cellulose particles and a binder; and the nuclear particle has a volume average particle size of from 50 to 500 μm and the hydroxyalkyl cellulose particle has a volume average particle size of from 0.1 to 20 μm.

OPINION

Obviousness

Claims 1–3 and 8–15 stand rejected under 35 U.S.C. § 103 as obvious based on Yanai,[2] Akiyama,[3] Itoh,[4] and Sonoda.[5] Non-Final Action[6] 4. The Examiner finds that Yanai teaches a "controlled release composition contain[ing] a core comprising an active that is coated with a coating layer that comprises a polymer, polyethylene glycol and silica." *Id.* The Examiner finds that "Yanai expressly teaches examples of polymers that exhibit delayed dissolution type water solubility and the examples given are hydroxyethylcelluloses, which are hydroxyalkyl celluloses." Non-Final Action 4–5. The Examiner finds that "Yanai teaches that an example of a polymer that can be used in the coating is HPC-H. This hydroxypropyl cellulose necessarily has a particle size of 6.27 micrometers as evidenced by the [instant] specification." Non-Final Action 5 (citation omitted). As support, the Examiner cites the Specification's description of HPC-H as "hydroxypropyl cellulose having a volume average particles size of 6.27 μm." Spec. 12:22–23.

The Examiner finds that Yanai does not teach a dry coating preparation method, but finds that Sonoda "teaches the preparation of a

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[2] Yanai et al., US 2006/0177506 A1 (Aug. 10, 2006).
[3] Akiyama et al., US 2006/0013868 A1 (Jan. 19, 2006).
[4] Itoh et al., US 5,194,464 (Mar. 16, 1993).
[5] Sonoda et al., *Improvement of Dissolution Property of Poorly Water-Soluble Drug by Using Dry Coating Method with Starches as Core-particles*, J. Soc. Powder Technol., Japan, 46:338–346 (2009).
[6] Office Action mailed Jan. 16, 2018.

coating particle in which a nuclear particle of starch is dry-coated with hydroxyalkyl cellulose and a binder." *Id*. at 7.[7]

The Examiner concludes that it would have been obvious for a person of ordinary skill in the art making the coated tablet of Yanai to "use the preparation method of Sonoda in order to have the improved dissolution properties as taught by Sonoda." Non-Final Action 8.

Appellant argues that "almost all coating processes disclosed in . . . Yanai use a 'coating solution.' These coating processes are categorized as 'wet-coating processes.'" Appeal Br. 9. Appellant argues that, "[i]n a film obtained through a wet-coating process using a coating solution, it is not reasonable to expect that the raw material (having a particle size) remains because the raw material has been dissolved in a solvent." Appeal Br. 9–10. Thus, Appellant argues that "paragraph [0147] of Yanai merely discloses '[s]pecific examples of the polymer exhibiting delayed-dissolution type water solubility.' However, this does not mean that the polymer is still in the form of a particle when in a coating layer." Appeal. Br. 9.

With regard to Yanai's disclosure of compression molding, Appellant argues that compression molding might be categorized as a "dry-coating process" but "the coating layer is formed by compressing raw materials. Therefore, it is expected that there would be no remaining polymer particles of the raw materials in a compression molded coating." Appeal Br. 10.

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[7] The Examiner cites Akiyama for teaching coated particles having a specific amount of hydroxypropyl cellulose, and Itoh as teaching polyethylene glycol (PEG) with a particular particle size as a binder, as recited in some dependent claims. Non-Final Action 6–7. Akiyama's and Itoh's teachings are not germane to the prima facie case with respect to independent claim 1.

Appellant concludes, "each of the coatings in Yanai has an absence of particles – even if the starting material was in the form of particles, these particles do not survive the coating process." Appeal Br. 10.

We agree with Appellant that the evidence cited by the Examiner does not support a case of obviousness. Yanai discloses a controlled release composition for oral administration, wherein a core containing a physiologically active substance is coated with a coating layer containing a polymer. Yanai Abstract. Yanai discloses that the polymer in the coating "is not particularly limited, as long as it can form a film structure having the function of controlling release of the physiologically active substance contained in the core." Yanai ¶ 145. Yanai states that its composition "is prepared by coating the core . . . with an aqueous dispersion or non-aqueous solution of the coating polymer . . . and drying." Yanai ¶ 174. "Alternatively, the composition is also prepared by compression molding the coating polymer on the periphery of the core to form a coating layer, for example, using the same conventional methods in the art of preparation technology as in the preparation of a multilayer tablet or a core-containing tablet." Yanai ¶ 174.

To meet the claim limitation of a "hydroxyalkyl cellulose particle has a volume average particle size of from 0.1 to 20 μm," the Examiner finds that "Yanai teaches that an example of a polymer that can be used in the coating is HPC-H. This hydroxypropyl cellulose necessarily has a particle size of 6.27 micrometers." Ans. 5 (citation omitted). As evidence, the Examiner cites the Specification's statement that HPC-H is a "hydroxypropyl cellulose having a volume average particles size of 6.27 μm." Spec. 12:22–23.

Thus, the Examiner appears to rely upon the doctrine of inherency to conclude that the final product of Yanai will necessarily contain unaltered particles of the hydroxyalkyl cellulose source material, such as HPC-H. However,

> [i]nherency . . . may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient [Citations omitted.] If, however, the disclosure is sufficient to show that the natural result flowing from the operation as taught would result in the performance of the questioned function, it seems to be well settled that the disclosure should be regarded as sufficient.

In re Oelrich, 666 F.2d 578, 581 (CCPA 1981) (quoting *Hansgirg v. Kemmer*, 102 F.2d 212, 214 (CCPA 1939)) (bracketed material in original).

Here, the Examiner has not pointed to evidence or provided sound technical reasoning to show that the final product of Yanai will necessarily contain hydroxyalkyl cellulose particles having a volume average particle size of 0.1 to 20 μm. As Appellant has pointed out, Yanai discloses two processes for applying a coating layer: using a coating solution or compression molding using the same conventional methods used to make core-containing or multilayer tablets. *See* Yanai ¶ 174.

By contrast, Appellant's Specification states that a dry-coating method is preferred, and describes that method as "mixing a nuclear particle with hydroxyalkyl cellulose, a binder and other coating base . . . and stirring," preferably while heating. Spec. ¶ 38. Such a process is described in the example cited by the Examiner. Spec. ¶¶ 43–45. Thus, the fact that Appellant's Specification describes HPC-H particles of a certain size does not mean that Yanai's process would necessarily produce coating particles

of HPC-H of the same size. Thus, the Examiner's apparent reliance on inherency to meet the size limitation of the hydroxyalkyl cellulose particles recited in the claims is not supported by the cited evidence.

The Examiner also reasons that Sonoda teaches a dry-coating method, and it would have been obvious to "use the preparation method of Sonoda in order to have the improved dissolution properties as taught by Sonoda." Non-Final Action 8.

Appellant argues that Yanai and Sonoda "disclose disparate formulation technologies." Appeal Br. 11. Specifically, "[i]n Yanai, the polymer contained in the coating layer is selected from those that can form a film structure having the function of controlling release" of an active substance, while "Sonoda teaches a dry coating in which a coating film is *not* formed and the active substance is *attached* to the core particles." *Id*. Appellant argues that these different product structures reflect the different purposes of the compositions: "Yanai aims to achieve 'slow-release.' On the other hand, Sonoda aims to improve the dissolution property of poorly water-soluble drug. That is, Sonoda aims to achieve 'fast-release.'" *Id*. at 12.

The Examiner responds that "just because Sonoda aims to make the release of the active ingredient fast whereas Yanai teaches a controlled release composition does not mean that the teachings of the references cannot be combined." Ans. 8. The Examiner reasons that the improved dissolution properties taught by Sonoda "mean greater control over the release of the active ingredient and greater control for the formulator over the dissolution time and place in the gastrointestinal tract." *Id*. at 9. The

Examiner also reasons that "[g]reater control over the release of the drug is the common goal of both Yanai and Sonoda and a highly desirable and sought after goal for the ordinarily skilled artisan formulator in this field of endeavor." *Id*.

We are not persuaded that the Examiner's reasoning supports a prima facie case of obviousness. "Obviousness requires more than a mere showing that the prior art includes separate references covering each separate limitation in a claim under examination." *Unigene Labs., Inc. v. Apotex, Inc.*, 655 F.3d 1352, 1360 (Fed. Cir. 2011). "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 elements in the normal course of research and development to yield the claimed invention." *Id.*

Sonoda discloses dry-coating a starch core particle with a mixture containing flurbiprofen (drug). Sonoda Abstract. Yanai, by contrast, states that its coating layer "does not contain a physiologically active substance." Yanai ¶ 144. Thus, modifying the drug-free film coating disclosed by Yanai with the drug-containing coating disclosed by Sonoda would contradict the express teaching of Yanai.

Yanai states that the disclosed "core containing the physiologically active substance is coated with a coating layer containing a polymer, thus the maximum blood concentration of the physiologically active substance can be significantly lowered as compared with a rapid release preparation, and thereafter, sustained drug release over a long time can be realized." Yanai ¶ 5. Thus, the intended purpose of the coating layer disclosed by Yanai is to achieve sustained drug release over a long time.

In contrast, Sonoda discloses that the purpose of its composition is to *increase* dissolution of the active agent. Sonoda Abstract. Modifying the controlled release coating layer disclosed by Yanai with the rapid release coating layer disclosed by Sonoda thus would defeat Yanai's intended purpose of providing sustained drug release over a long time.

In summary, the Examiner has not persuasively shown that a skilled artisan would have had a reason to use Sonoda's dry-coating method to make the sustained release composition of Yanai. We conclude that the rejection of claims 1–3 and 8–15 under 35 U.S.C. § 103(a) based on Yanai, Akiyama, Itoh, and Sonoda is not supported by a preponderance of the evidence, and we therefore reverse it.

DECISION SUMMARY

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
1–3, 8–15	103	Yanai, Akiyama, Itoh, Sonoda		1–3, 8–15

REVERSED