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mylan_docketing@cardinal-ip.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte IAN SMITH

Appeal 2014-009992
Application 13/380,083
Technology Center 3700

Before JILL D. HILL, LISA M. GUIJT, and ERIC C. JESCHKE
Administrative Patent Judges.

HILL, *Administrative Patent Judge.*

DECISION ON APPEAL

STATEMENT OF THE CASE

Ian Smith (“Appellant”) appeals under 35 U.S.C. § 134(a) from the Examiner’s decision to reject claims 1 and 4–21.¹ We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE.

¹ Claims 2 and 3 are cancelled. Appeal Br. 18 (Claims App.).

CLAIMED SUBJECT MATTER

Sole independent claim 1, reproduced below, represents the claimed subject matter, with the key disputed limitation italicized.

1. A dose unit for a dry powder inhaler comprising:
 - a dose carrier (15; 515, 524) including a plurality of pockets (17; 517) each adapted to contain a dose of medication powder suitable for inhalation, said pockets being sequentially arranged such that the content of the pockets (17; 517) can be sequentially exposed to a flow of air (Fa) for successive inhalations and
 - a plurality of medication powder doses (X; X1, X2) arranged in said pockets (17; 517) of the dose carrier (15),
wherein the doses are regularly distributed in the pockets according to a sequence of identical groups, *each group including at least one blank pocket (B) containing an excipient powder without pharmaceutically active ingredient and one pocket containing a dose of medication powder (X; X1, X2).*

REJECTIONS²

I. Claims 1 and 6–21 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Anderson (US 2005/0154491 A1; pub. July 14, 2005), Nilsson (US 2006/0120969 A1; pub. June 8, 2006), and Genosar (US 2010/0139655 A1; pub. June 10, 2010).

II. Claims 4 and 5 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Anderson, Genosar, Nilsson, and Houzego (WO 2005/002564 A1; pub. Jan. 13, 2005).

² The Examiner rejected claim 5 under 35 U.S.C. § 112, second paragraph. Final Act. 2. In the Advisory Action, the Examiner withdraws this rejection. Adv. Act. 1.

ANALYSIS

Rejection I

Regarding claim 1, the Examiner finds that Anderson discloses the limitations thereof, but does not disclose that each group of its “sequence of identical groups” includes at least one blank pocket containing an excipient powder without a pharmaceutically active ingredient. Final Act 3–4. The Examiner finds, however, that Genosar discloses an inhaler with a magazine of drug containing volumes that *may* comprise a different drug or drug combination. *Id.* at 4. According to the Examiner, one of the drugs of Genosar could be an excipient, because the term “drug” is defined as “a substance used as a medication or in the preparation of a medication,” which includes excipients. *Id.*

The technical dictionary definitions of “drug” and “excipient” provided by Appellant are more consistent with the usage of these terms in Genosar. *See* Appeal Br. 4 (citing Gerhard Nahler, *Dictionary of Pharmaceutical Medicine*, 2d Edition, p. 56 (2009)). In addition, Genosar expressly defines the term “drug” as a pharmaceutically active ingredient, which is necessarily present in its pockets with or without added excipient. Appeal Br. 11. Appellant explains that an excipient can be a vehicle for a drug, but that the term excipient is understood by those skilled in the art to be excluded from the term “drug.” *Id.* at 12. Regarding the meaning of the term “drug,” Appellant has the better argument. The general dictionary relied upon by the Examiner (Ans. 5) is not consistent with the technical dictionary or the use of the term “drug” in Genosar, which distinguishes drugs, vaccines, and therapeutic agents from excipients.

Given the above reasonable definition of the term “drug,” Appellant contends that Genosar does not disclose that its magazine contains an excipient powder without pharmaceutically active ingredient because each of the magazines includes a drug, vaccine, or therapeutic agent. Appeal Br. 11 (citing Genosar ¶ 17). We agree with Appellant.

The Examiner then finds that “[f]urther evidence of the use of excipient and blank medication volumes is taught by Nilsson,” which discloses an inhaler with insulin dose containers representing empty, low, medium, and high doses, “so that the size of the insulin dose is selected by a user before each administration.” Final Act. 4 (citing Nilsson ¶ 36). The Examiner concludes that it would have been obvious that Nilsson’s “empty dose container” is “empty of active insulin, but *could* contain excipient powder” that acts as a carrier for the GLP-1. *Id.* at 5 (emphasis added).

Appellant argues that Nilsson discloses administering GLP-1 with insulin or with an *empty* dose container, and that there is no disclosure of the empty dose containers containing an excipient powder. Appeal Br. 12, 13 (citing Nilsson ¶¶ 36, 61, 63).

In response, the Examiner agrees that Nilsson provides “no explicit teaching of ‘individually sealed enclosures containing only excipient.’” Ans. 7. The Examiner contends again, however, that when only one of Nilsson’s drugs is administered, the empty pocket could include an inert substance, such as an excipient. *Id.* at 7–8.

Appellant has the better argument. Nilsson fails to explicitly disclose that the empty dose container may contain excipients, as acknowledged by the Examiner. *See* Ans. 7. Indeed, the dose container is referred to as “empty,” which indicates that it contains nothing. *See* Nilsson ¶ 36. The

Examiner speculates that the empty pocket could contain excipient, but obviousness cannot be established using factual findings that are based on speculation.

For these reasons, we do not sustain the rejection of claim 1. Claims 6–21 depend directly or indirectly from claim 1, and we therefore do not sustain the rejection thereof.

Rejection II

Rejection II additionally pertains to claims that depend from independent claim 1. The Examiner does not rely on Houzego in any manner that would cure the deficiencies of Anderson, Genosar, and Nilsson, and we, therefore, do not sustain Rejection II for the reasons set forth above regarding Rejection I.

DECISION

We REVERSE the Examiner’s rejection of claims 1 and 6–21 under 35 U.S.C. § 103(a) as unpatentable over Anderson, Nilsson, and Genosar.

We REVERSE the Examiner’s rejection of claims 4 and 5 under 35 U.S.C. § 103(a) as unpatentable over Anderson, Genosar, Nilsson, and Houzego.

REVERSED