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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):
mylan_docketing@cardinal-ip.com

McCOLLUM, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a system for inducing bronchodilation or providing relief of bronchospasm. The Examiner has rejected the claims as obvious. We have jurisdiction under 35 U.S.C. § 6(b).

We affirm.

STATEMENT OF THE CASE

Claims 1–14 are on appeal (App. Br. 16). Claims 1, 3, 4, and 5 are representative and read as follows:

1 Appellants identify the real party in interest as Dey Pharma, L.P. (App. Br. 1).
1. A system for inducing bronchodilation or providing relief of bronchospasm in an individual suffering from chronic obstructive pulmonary disease, said system comprising:
   (a) one or more single dispensing containers; and
   (b) an aqueous inhalation solution comprising a therapeutically effective amount of albuterol and a therapeutically effective amount of about 0.001 mg to about 1.0 mg of ipratropium bromide;
   wherein the aqueous inhalation solution is prefilled in each of the one or more dispensing containers as a premixed, premeasured, single unit dose of about 0.1 ml to about 0.5 ml, the aqueous inhalation solution administered without dilution to the individual from a nebulizer chamber such that the mist is removed from the nebulizer chamber in less than 12 minutes when said aqueous inhalation solution is introduced into a high performance nebulizer.

3. The system of claim 1, wherein said amount of albuterol ranges from about 2.0 mg to about 3.0 mg.

4. The system of claim 1, wherein the albuterol is albuterol base, and said amount of albuterol base is about 2.5 mg and the amount of ipratropium is about 0.5 mg.

5. The system of claim 1, wherein the inhalation solution in each of the one or more containers is sterile.

Claim 14 is also independent and is set forth in the Claims Appendix to Appellants’ Appeal Brief (id. at 18–19).

Claims 1–14 stand rejected under 35 U.S.C. § 103(a) as obvious over:
(1) COMBIVENT® in view of Asmus³ and Coates⁴ (Ans. 2); and

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(2) Chest\(^5\) in view of Asmus \textit{id. at} 4).

In the first rejection, the Examiner relies on COMBIVENT for disclosing “Respules [that] contain 2.5 ml of a preservative-free solution containing 2.5 mg of salbutamol (albuterol) and 500 micrograms of ipratropium bromide”; that this “formulation is indicated for the treatment of reversible bronchospasm associated with obstructive airway diseases”; and that the “solution in the containers may be administered from a nebulizer or positive pressure ventilator” \textit{id. at} 2. In the second rejection, the Examiner relies on Chest for disclosing “a study in which 0.5 mg of ipratropium bromide (IB) and 3 mg albuterol sulfate (ALB) were administered using a small volume nebulizer . . . in patients with moderate to severe chronic obstructive pulmonary disease” and that the “medication was delivered in 2.5 ml of solution” \textit{id. at} 4–5). However, the Examiner finds that neither COMBIVENT nor Chest “disclose[s] smaller volumes of solution comprising these two ingredients” or “explicitly state[s] that the solution contained in the vial is sterile” \textit{id. at} 3 & 5).

In both rejections, the Examiner relies on Asmus for disclosing “2.5 mg of albuterol in a total volume of 0.5 mL in a multidose dropper vial” and a “[s]terilized single unit do[se] of various bronchodilators” \textit{id.}. In particular, the Examiner finds that Asmus discloses that “sterile-filled single dose products are about one half of the nebulized bronchodilator solutions manufactured in the United States” \textit{id.}.

The Examiner concludes:

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to place a smaller, concentrated volume of albuterol, 0.5 ml, and ipratropium bromide in a container because such concentrated albuterol solutions are known in the art and to maintain the ratio of albuterol and ipratropium bromide of the COMBIVENT® respules [or of Chest], the same amount of ipratropium should also be included in the more concentrated solution. The recitation of the delivery time for the solution in the system in the claim and that the solution is administered from the dispensing container is intended use language that does not further limit the product of the claims. The recitation of “premixed, premeasured, single unit dose” is also the intended use of the composition and the claims are being interpreted as not excluding subsequent dilution of the volumes in the containers.

(Id.)

ANALYSIS

For both rejections, we incorporate the Examiner’s findings of fact and conclusions of law (Ans. 2–5), as summarized above. We conclude that the Examiner has set forth a prima facie case that the systems of claims 1, 3–5, and 14 would have been obvious.

Appellants argue, however, that the applied references do not “Teach a Concentrated Aqueous Inhalation Solution having Albuterol and Ipratropium Bromide in a Premixed, Premeasured Single Unit Dose of about 0.1 ml to about 0.5 ml that is Delivered Directly to an Individual Without Dilution as Recited in Claim 1” (App. Br. 6 & 12 (emphasis omitted)). In particular,

Appellant[s] respectfully suggest that “premixed, premeasured, single unit dose” and “administered without dilution” as recited in Appellant[s]’ invention is not intended use language. These
limitations, which are part of the body of Appellant[s’] claims and not recited in the preamble, provide that the aqueous solution of the system claims will be directly administered to the individual and that such aqueous solutions will not be diluted in any way.

(Id. at 7–8; see also id. at 13.) We are not persuaded.

Consistent with our prior opinion in related U.S. Application No. 11/037,574 (Appeal 2010-005705), we are interpreting system claim 1 to be directed to a product (Prior Opinion 7). “It is well settled that the recitation of a new intended use for an old product does not make a claim to that old product patentable.” In re Schreiber, 128 F.3d 1473, 1477 (Fed. Cir. 1997). We conclude that this is true whether an intended use recitation is recited in the preamble or, as in the present case, in a wherein clause. See Griffin v. Bertina, 283 F.3d 1029, 1034 (Fed. Cir. 2002).

In addition, Appellants do not adequately explain how either of the relied upon features define more that the intended use of the product. Specifically, Appellants do not adequately explain why the product suggested by COMBIVENT or Chest in view of Asmus would not be capable of being administered without dilution to an individual.

Appellants also argue that the “issue here is not a new use of an otherwise old or obvious compound, but, rather, whether the subject-matter of the claimed system possesses an unexpected use of such compositions—i.e., direct administration of the claimed composition without dilution to an individual for the treatment of COPD” (Reply Br. 7). We are not persuaded.

Appellants provide attorney argument stating that “the ability for the claimed composition to treat chronic obstructive pulmonary disease (‘COPD’) in an individual was unexpected in the art prior to the time of
However, Appellants have not provided sufficient evidence to support this position.

With respect to the first rejection, Appellants additionally argue that “Coates teaches away from volumes of about 0.1 ml to about 0.5 ml as recited in Appellant[s'] claims as well as concentrated aqueous solutions intended for direct delivery without dilution” (id. at 8). We are not persuaded.

Coates discloses:

[A]erosolized output can be increased for a given dose of drug by minimizing the concentrating effects of nebulization, and by increasing the charge volume, which dilutes the concentration of the initial dose, although it will prolong nebulization time. For most devices, 4 mL is ideal, since drug output for volumes \( \leq 3 \) m\( \text{L} \) are lower and much more device-dependent. (Coates 418 (footnotes omitted).) In view of this disclosure, Appellants argue that Coates “indicates any undiluted solutions are diluted upon delivery to the patient” (Reply Br. 6). However, as discussed above, product claim 1 merely requires an aqueous inhalation solution that is capable of being administered to an individual without dilution. Appellants do not adequately explain why the suggested concentrated solution would not be capable of being administered without dilution.

For the same reasons, Appellants traverse the rejections of claim 14 (App. Br. 10–11 & 15–16). However, we are not persuaded by these arguments for the reasons discussed above.

Appellants additionally argue that none of the applied references disclose the amounts recited in claims 3 and 4 (id. at 10 & 14). However, as noted by the Examiner (Ans. 3), Asmus specifically discloses 2.5 mg of
albuterol in 0.5 ml (Asmus S55, Table II). In addition, COMBIVENT and Chest each disclose 0.5 mg (500 mcg) of ipratropium bromide (COMBIVENT 2; Chest 1514). Appellants do not adequately explain why the combination of COMBIVENT or Chest with Asmus fails to suggest the additional features of claims 3 and 4.

Moreover, Appellants argue that none of the applied references disclose the features of claim 5 (App. Br. 10 & 15). However, as noted by the Examiner (Ans. 3), Asmus discloses a sterile solution (Asmus S55, Table II). Appellants have not adequately explained why it would not have been obvious to include a sterile solution.

CONCLUSION

The evidence supports the Examiner’s conclusion that the applied references suggest the systems of claims 1, 3–5, and 14. We therefore affirm both obviousness rejections of these claims. For each rejection, claims 2 and 6–13 have not been argued separately and therefore fall with claim 1. 37 C.F.R. § 41.37(c)(1)(iv).

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