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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte TOBIAS GESSLER, THOMAS SCHMEHL, WERNER SEEGER, and ROBERT VOSWINCKEL

Appeal 2019-006217
Application 15/279,939
Technology Center 1600

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

VALEK, *Administrative Patent Judge.*

DECISION ON APPEAL

Appellant[1] submits this appeal under 35 U.S.C. § 134(a) involving claims to methods for delivering iloprost using an inhaler within a period of less than 2 minutes, which have been rejected for obviousness. We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE Examiner's rejection of claims 22–26 and 34–38, but enter a New Ground of Rejection pursuant to 37 C.F.R. § 41.50(b) rejecting claims 22 and 23 under 35 U.S.C. § 102.

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[1] We use the word "Appellant" to refer to "applicant" as defined in 37 C.F.R. § 1.42(a). Appellant identifies Vectura GmbH as the real party in interest. Appeal Br. 1.

STATEMENT OF THE CASE

"Iloprost is used in the therapy of pulmonary arterial hypertension" and other conditions and may be administered by inhalation. Spec. 1–2. The Specification explains that inhalable iloprost, marketed under the name Ventavis®, has previously been administered using various nebulizer devices over periods ranging from 4–10 minutes, depending on the dose and device. *Id.* at 2–3. "However, a shorter time of administration through an increased aerosol delivery rate has been considered unfeasible in the past" because of the "expectation of serious adverse events." *Id.* According to the Specification, "the inventors have found that pulmonary administration of iloprost as an aerosol bolus according to the invention is technically and clinically feasible, and is actually well-tolerated by patients." *Id.* at 8.

Claims 22–26 and 34–38 are on appeal and can be found in the Claims Appendix of the Appeal Brief. Claim 22 reads as follows:

> 22. A method for delivering an active ingredient selected from iloprost and salts thereof, to a patient in need thereof comprising the pulmonary administration of a pharmaceutical composition to the patient, wherein an amount of the composition administered comprises an effective single dose from 1.5 μg to 5.0 μg of the active ingredient and is provided using an inhaler configured to provide the dose in aerosolised form for bolus inhalation within a period of less than 2 minutes.

Appeal Br. 18 (Claims App'x).

Appellant seeks review of the following rejections:

I. Claims 22–25 under 35 U.S.C. § 103 as obvious over Gessler;[2]

[2] T. Gessler et al., *Ultrasonic Versus Jet Nebulization of Iloprost in Severe Pulmonary Hypertension*, 17 Eur. Respir. J. 14–19 (2001) ("Gessler").

II. Claim 26 under 35 U.S.C. § 103 as obvious over Gessler and Van Dyke[3] as evidenced by FDA[4]; and

III. Claims 22–26[5] and 34–38 under 35 U.S.C. § 103 as obvious over Van Dyke and Omron[6] as evidenced by FDA.

Appeal Br. 7.

Analysis

Examiner's three obviousness rejections turn on common issues concerning Appellant's argument that Gessler teaches away from the claimed methods. Our analysis below applies to all three rejections.

Examiner finds that both Gessler and Van Dyke teach the administration of inhalable iloprost and that Gessler teaches administration in an inhaler configured to administer the dose in a 2 minute period. *See* Non-Final Act. 4–7. Examiner further determines that Omron teaches a vibrating mesh nebulizer capable of administering the iloprost solution taught in Van Dyke in less than 2 minutes. *Id.* at 8. Examiner determines it would have been obvious "to use the mesh nebulizer taught by Omron because of its convenient and effective treatment [for] patients." *Id.* at 9.

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[3] Robert E. Van Dyke et al., *Delivery of Iloprost Inhalation Solution with the HaloLite, Prodose, and I-neb Adaptive Aerosol Delivery Systems: An In Vitro Study*, 52 Respiratory Care 184–190 (2007) ("Van Dyke").
[4] Ventavis® Prescribing Information, available at http://www.drugs.com/pro/ventavis.html ("FDA").
[5] Both Appellant and Examiner list claims 27 and 28 in the third obviousness rejection. *See* Appeal Br.7; Ans. 7. However, those claims were withdrawn and are not before us here.
[6] Omron Healthcare, Omron Instruction Manual MicroAir® Vibrating Mesh Nebulizer Model NE-U22V (2007) ("Omron").

Appellant argues that Examiner's rejections should be reversed because Gessler teaches away from inhalation periods of less than 2 minutes. Appeal Br. 8–11, 16. In particular, Appellant relies on the following passage from Gessler:

> Based on the data of the physical characterization, the inhalation time for delivery of an equivalent iloprost dose at the mouthpiece (2.8 µg) was reduced from 12 min with the jet nebulizer system to 2 min with the ultrasonic nebulizer, when retaining the same concentration of the iloprost solution (10 $\mu g \cdot mL^{-1}$). In preliminary catheter investigations, *however, some increase in systemic side effects was observed when administering the total iloprost dose of 2.8 µg via the inhalation route for such a short time period*. Therefore, we reduced the iloprost concentration from 10 $\mu g \cdot mL^{-1}$ to 5 $\mu g \cdot mL^{-1}$ when employing the ultrasonic nebulizer, and consequently doubled the inhalation time to 4 min with this device. This inhalation protocol was generally well tolerated.

Gessler, 17 (emphasis added). According to Appellant, "Gessler's explicit disclosure that a 2-minute inhalation period resulted in increased systemic side effects would have discouraged a person having ordinary skill in the art from pursuing the instantly claimed method." Appeal Br. 10. Thus, urges Appellant, Gessler evidences a teaching away from the recited methods that overcomes any prima facie showing of obviousness. *Id.* at 8 (citing MPEP § 2144.05(III)).

Examiner determines that Appellant's argument is not persuasive because "side effects are not a showing that there is no therapeutic effect." Ans. 9. According to Examiner, "[t]he rate of administration affects the side effect but not the therapeutic benefit." *Id.*

The issue before us is whether Gessler indeed evidences a teaching away from the methods recited in Appellant's claims such that Examiner's

obviousness rejections are not supported by the preponderance of the evidence.

On this record, we determine that Appellant has the better position. Specifically, Gessler teaches that reducing the inhalation period for a 2.8 μg dose of iloprost from twelve to two minutes resulted in increased systemic side effects. Gessler, 17. Gessler expressly attributes this increase in side effects to inhalation of the total dose in "such a short time period." *Id.* Thus, we agree with Appellant, that one of skill in the art reading Gessler would be discouraged from using an inhaler to deliver a dose "within a period of less than 2 minutes," as recited in Appellant's claims here. *See Meiresonne v. Google, Inc.*, 849 F.3d 1379, 1382 (Fed. Cir. 2017) ("A reference teaches away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken in the claim.") (internal quotations omitted).

Examiner suggests that there is no teaching away because "side effects are not a showing that there is no therapeutic effect." Ans. 9. We disagree. The relevant inquiry is not whether Gessler teaches that its dose provides a therapeutic effect, but instead whether Gessler "criticize[s], discredit[s], or otherwise discourage[s] investigation into the invention claimed." *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1327 (Fed. Cir. 2009). In this case, Gessler teaches that the increased side effects the authors observed resulted when the inhalation period was reduced to two minutes and that those side effects were serious enough to necessitate modification of the inhalation protocol by reducing the concentration of the iloprost solution and increasing the inhalation period to

four minutes. Gessler, 17. In light of this teaching, Examiner has not shown that it would have been obvious to administer the iloprost solution taught in Gessler and Van Dyke "within a period of less than two minutes," as claimed, much less that a skilled artisan would have reasonably expected to succeed in doing so without increasing systemic side effects.

For these reasons, we determine that Examiner's obviousness rejections are not supported by the preponderance of the evidence and therefore reverse.

NEW GROUND OF REJECTION

While we reverse Examiner's obviousness rejections, we enter a new ground rejecting claims 22 and 23 under 35 U.S.C. § 102 as anticipated by Gessler.

As discussed above, Gessler discloses the pulmonary administration of 2.8 μg of iloprost to a patient in need over a two minute period using an ultrasonic nebulizer device. Gessler, 17. A dose approaching 2.8 μg would necessarily have been delivered for inhalation prior to the end of that two minute period. For example, assuming a constant inhalation rate, approximately 2.1 μg of iloprost would have been delivered in the first 90 seconds of Gessler's two minute inhalation period. As such, Gessler describes the administration of "an effective single dose from 1.5 μg to 5.0 μg" of iloprost to a patient "using an inhaler configured to provide the dose in aerosolised form for bolus inhalation within a period of less than 2 minutes," as recited in claim 22.[7] Appeal Br. 18 (Claims App'x). In

[7] Gessler does not recite the term "bolus inhalation." However, it discloses a method in which a patient inhaled an amount of iloprost within the recited effective dose range in a period of less than 2 minutes. Gessler, 17. Thus, it

addition, Gessler discloses that the concentration of the iloprost solution administered in the two minute period was "10 μg·mL^{-1}," (Gessler, 17) which reads on the range, i.e., "strength of 10 μg/mL or more," recited in dependent claim 23.

Gessler's disclosure of the administration of a dose within the claimed range in a period of less than two minutes anticipates claims 22 and 23, notwithstanding the teaching away noted above. "Teaching away is not relevant to an anticipation analysis; it is only a component of an obviousness analysis." *Krippelz v. Ford Motor Co.*, 667 F.3d 1261, 1269 (Fed. Cir. 2012). Thus, while Gessler observes increased side effects associated with the inhalation of a 2.8 μg dose over a two minute period, it nevertheless discloses the administration of a dose within the recited ranges in a period of less than two minutes. In view of these findings, we enter a new ground of rejection of claims 22 and 23 under 35 U.S.C. § 102 as anticipated by Gessler.[8]

CONCLUSION

We reverse Examiner's obviousness rejections in full, but enter a new ground of rejection under 35 U.S.C. § 102 for claims 22 and 23.

In summary:

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inherently discloses the "bolus inhalation" limitation of claim 22.

[8] We leave it to Examiner upon continued examination to determine whether Gessler anticipates any of Appellant's other claims. However, we note that Gessler does not disclose, and therefore does not appear to anticipate, the higher dosage/concentration recited in claim 25 or a vibrating mesh nebulizer as recited in claims 34–38.

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed	New Ground
22–25	103	Gessler		22–25	
26	103	Gessler, Van Dyke, FDA		26	
22–26, 34–38	103	Van Dyke, Omron, FDA		22–26, 34–38	
22, 23	102	Gessler			22, 23
Overall Outcome				22–26, 34–38	22, 23

FINALITY AND RESPONSE

This decision contains a new ground of rejection pursuant to 37 C.F.R. § 41.50(b). 37 C.F.R. § 41.50(b) provides "[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review."

37 C.F.R. § 41.50(b) also provides that the Appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:

> (1) *Reopen prosecution*. Submit an appropriate amendment of the claims so rejected or new evidence relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the proceeding will be remanded to the examiner. . . .
>
> (2) *Request rehearing*. Request that the proceeding be reheard under § 41.52 by the Board upon the same record. . . .

REVERSED; 37 C.F.R. 41.50(b)