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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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*Ex parte* JEFFRY G. WEERS,  
THOMAS E. TARARA, and ANDREW CLARK

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Appeal 2015-004534  
Application 10/616,448  
Technology Center 1600

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Before DONALD E. ADAMS, RICHARD J. SMITH, and  
RYAN H. FLAX, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL<sup>1</sup>

This appeal under 35 U.S.C. § 134(a) involves claims 1, 5, 13, 29, 35–38, 40, and 47–50 (App. Br. 2). Examiner entered rejections under 35 U.S.C. § 103(a) and obviousness-type double patenting. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

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<sup>1</sup> Appellants identify “[t]he real party in interest [as] Novartis AG” (App. Br. 2).

STATEMENT OF THE CASE

The claims are directed to “methods for inhalation drug delivery . . . for pulmonary administration via dry powder inhalers” (Spec. 1: 10–12).

Claims 1, 29, and 47 are representative and reproduced below:

1. A method for the pulmonary administration of a dry powder composition from a passive dry powder inhaler to the respiratory tract of a patient, the method comprising:

providing a dry powder composition comprising particles comprising a lipid and an active agent, wherein the active agent comprises tobramycin, the particles having a particle size of 0.5 to 5 microns, a mass median aerodynamic diameter of from about 0.5 to about 5.0 microns, and the powder having a bulk density of less than 0.5 g/cm<sup>3</sup>;

loading the dry powder composition into a passive dry powder inhaler; and

administering the dry powder composition from the inhaler to the respiratory tract of a patient,

wherein the emitted dose is at least 80% and a lung deposition is at least 25% substantially independent of inhalation flow rate for flow rates across the range from 10-60 L/min.

(App. Br. 13.)

29. A method for the pulmonary administration of a dry powder composition from a passive dry powder inhaler to the respiratory tract of a patient, the method comprising:

providing a dry powder composition comprising hollow and porous particles comprising:

(i) a phospholipid matrix comprising a phospholipid selected from the group consisting of dipalmitoylphosphatidylcholine, distearoylphosphatidylcholine, diarachidoylphosphatidylcholine, dibehenoylphosphatidylcholine, diphosphatidyl glycerol, phosphatidylcholines, saturated phosphatidylethanolamines, saturated phosphatidylserines, saturated phosphatidylglycerols, and saturated phosphatidylinositols;

(ii) an active agent comprising tobramycin;

(iii) a particle size of 0.5 to 5 microns; and  
(iv) a mass median aerodynamic diameter of less than 5 microns;

loading the dry powder composition into a passive dry powder inhaler having a resistance in the range of 0.01 to 0.30 (cmH<sub>2</sub>O)<sup>1/2</sup>/LPM; and

administering the dry powder composition from the inhaler to the respiratory tract of a patient,

wherein a FPF<sub>4+F</sub> fine particle fraction emitted from the inhaler is at least 60% as determined by an Anderson Cascade Impaction or multi-stage liquid impinger, an emitted dose is at least 60% and a lung deposition is greater than 25% at different inhalation flow rates, an interpatient variation in lung deposition is less than 40%, and an inpatient variation in lung deposition does not exceed 6%.

(App. Br. 14.)

47. A method for inhalation of a dry powder drug with reduced variability in the lung dose comprising:

providing a dry powder drug composition comprising particles comprising a lipid and [] active agent, wherein the active agent comprises tobramycin, the composition having a particle size of 0.5-5 microns, a mass median aerodynamic diameter of less than 5 microns, and a bulk density of less than 0.5 g/cm<sup>3</sup>,

loading the composition into a passive dry powder inhaler; and

inhaling the drug composition from the inhaler resulting in lung deposition wherein a variability between patients is less than 40%, and a variability with a flow rate of 30 L/min as compared with a flow rate of 90 L/min is less than 20%.

(App. Br. 15.)

The claims stand rejected as follows:

Claims 1, 5, 13, 29, 35–38, 40, and 47–50 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Edwards<sup>2</sup> and Vaghefi.<sup>3</sup>

Claims 1, 5, 13, 29, 35–38, 40, and 47–50 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1–4, 6–15, 17–19, 21–24, 26–34, and 36–57 of Tarara<sup>4</sup> in combination with Andersson.<sup>5</sup>

*Obviousness:*

#### ISSUE

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

#### FACTUAL FINDINGS (FF)

FF 1. We adopt Examiner’s findings concerning the scope and content of the prior art (Final Rej. 3–11; Ans. 2–6) and reproduce the following for reference purposes.

FF 2. Edwards relates “to methods of delivery of a bioactive agent to the pulmonary system” (Edwards 3: 24–25; *see* Final Rej. 3–4).

FF 3. Edwards discloses that the bioactive agent may be an antibiotic and prefers the administration of “highly dispersible particles [that] includ[e] a bioactive agent and a phospholipid” (*see* Edwards 5: 61–65 and 11: 23–25; Final Rej. 4 and 5).

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<sup>2</sup> Edwards et al., US 6,858,199 B1, issued Feb. 22, 2005.

<sup>3</sup> Vaghefi, US 5,875,776, issued Mar. 2, 1999.

<sup>4</sup> Tarara et al., US 7,306,787 B2, issued Dec. 11, 2007.

<sup>5</sup> Andersson et al., US 5,934,273, issued Aug. 10, 1999.

FF 4. Edwards discloses that particles within the scope of Edward’s invention “have a mass median geometric diameter (MMGD) . . . greater than about 5  $\mu\text{m}$  and ranging to about 30  $\mu\text{m}$ ,” “a mass median aerodynamic diameter (MMAD) ranging from about 1  $\mu\text{m}$  to about 5  $\mu\text{m}$ ,” and “a tap density of less than about 0.4  $\text{g}/\text{cm}^3$ ” (*see* Edwards 3: 66–67, 4: 4–5 and 9: 9–13; *see* Final Rej. 6).

FF 5. Edwards and Appellants exemplify the same “the dry powder inhaler . . . disclosed i[n] U.S. Pat. No[.]. 4,995,385” for use in the administration of dry powder compositions comprising, *inter alia*, an antibiotic (*see* Edwards 5: 15–18; Spec. 11: 27–29; Final Rej. 4–5).

FF 6. Edwards discloses the administration of particles “in a single, breath-activated step,” wherein the “at least 50% of the particle mass enclosed in the receptacle is emitted from the inhaler during administration of the particles to a subject’s respiratory system” (Edwards 8: 1–8; Final Rej. 3–4).

FF 7. Edwards discloses that “[t]he methods of [Edwards’] invention can be optimized at flow rates of at least about 20 L/min to about 90 L/min” (Edwards 17: 8–10; *see* Final Rej. 4).

FF 8. Edwards discloses a lung deposition of 59% “over a range of inspiratory flow rates” (*see* Edwards 4: 43–45 and 50–59; Final Rej. 4).

FF 9. Edwards does not disclose the antibiotic tobramycin and Examiner relies on Vaghefi to disclose “dry powder inhalers . . . for administration of pharmaceuticals[, such as tobramycin,] to the lung . . . by inhalation” (Vaghefi 1: 4–8 and 12: 34; *see* Final Rej. 7–8).

#### ANALYSIS

Based on the combination of Edwards and Vaghefi, Examiner concludes that, at the time Appellants’ invention was made, it would have

been prima facie obvious to select tobramycin, as suggested by Vaghefi, for use as the active agent antibiotic in the method disclosed by Edwards (*see* Final Rej. 7–8).

Claim 1:

Particles within the scope of Edward’s invention “have a mass median geometric diameter (MMGD) . . . greater than about 5  $\mu\text{m}$  and ranging to about 30  $\mu\text{m}$ ” (FF 4). Examiner “interprets the term ‘about 5’ to read on values lower than 5  $\mu\text{m}$ ” (Ans. 2). Stated differently, Edward’s disclosure of particles having an MMGD of greater than *about* 5  $\mu\text{m}$  to about 30  $\mu\text{m}$  reads on a range that has a lower limit that encompasses some amount below and/or including 5  $\mu\text{m}$  and, thus, overlaps Appellants’ claimed range (*see* Ans. 3; *see generally* Edwards 1:65–2:1 (“Dry powder aerosols for inhalation therapy are generally produced with mean geometric diameters primarily in the range of less than 5  $\mu\text{m}$ ”). *See Modine Manufacturing Co. v. U.S. ITC*, 75 F.3d 1545, 1554 (Fed. Cir. 1996) (“Although it is rarely feasible to attach a precise limit to ‘about,’ the usage can usually be understood in light of the technology embodied in the invention.”). *See also, Iron Grip Barbell Co. v. USA Sports, Inc.*, 392 F.3d 1317, 1322 (Fed. Cir. 2004) (“where there is a range disclosed in the prior art, and the claimed invention falls within that range, there is a presumption of obviousness.”).

Therefore, we recognize, but are not persuaded by, Appellants’ contention that Edwards fails to disclose a method of administering a dry powder composition, comprising particles in a range that overlaps Appellants’ particle size of 0.5 to 5 microns (App. Br. 5–6; Reply Br. 4–5).

Edwards discloses a method of administering a dry powder composition, wherein the emitted dose is “at least 50%” (FF 6). As Examiner explains, “the phrase ‘at least 50%’ includes all values above 50% and that includes 80%” (Ans. 5). Therefore, we recognize, but are not persuaded by Appellants’ contention that Edwards fails to disclose an emitted dose of at least 80% (*see* App. Br. 7; Reply Br. 5–6).

Edwards discloses a lung deposition of 59% “over a range of inspiratory flow rates” and that flow rates “can be optimized at flow rates of at least about 20 L/min to about 90 L/min” (FF 7–8). In this regard, we note that Edwards exemplifies the use of the same inhaler as disclosed by Appellants and, therefore, provides a reasonable expectation that similar inhaler’s will provide for similar optimizable flow rates (FF 5). *In re Aller*, 220 F.2d 454, 456 (CCPA 1955) (“where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.”). Therefore, we are not persuaded by Appellants’ contention that Examiner “ignored the range from 10 to 25 L/min” (App. Br. 7; Reply Br. 6).

Edwards suggests a method of administering an active agent, such as an antibiotic (FF 5). Vaghefi discloses the administration, to the lung, of the antibiotic, tobramycin, by inhalation (FF 9). We recognize, but are not persuaded by, Appellants’ unsupported contention that the formulation of Vaghefi’s tobramycin antibiotic according to the methodology disclosed by Edwards would not “result in a formulation that meets the criteria required by [Appellants’] claim 1” (App. Br. 8). *In re Pearson*, 494 F.2d 1399, 1405 (CCPA 1974) (“Attorney’s argument in a brief cannot take the place of evidence.”). On this record, Appellants failed to provide persuasive

evidence or argument to support a conclusion that Vaghefi's tobramycin antibiotic could be formulated according to, and used in, the methods disclosed by Edwards.

Claims 29 and 47:

For the reasons set forth above, we are not persuaded by Appellants' contentions relating to particle size and tobramycin (*see* App. Br. 9–10). Appellants fail to specifically allege any further error in Examiner's rejection. To the contrary, with respect to claim 29, Appellants contend that Edwards and Vaghefi "do not disclose or suggest the other characteristics recited in claim 29 for reasons discussed above" (App. Br. 9). With respect to claim 47, Appellants contend that Edwards and Vaghefi "do not disclose or suggest the other characteristics recited in claim 47" (App. Br. 10). To the extent that Appellants' contention relates to subject matter discussed above, we are not persuaded for the reasons stated above. To the extent that Appellants' contention may relate to embodiments of claims 29 and 47 not addressed above, we note that "[a] statement which merely points out what a claim recites will not be considered an argument for separate patentability of the claim." 37 C.F.R. § 41.37(c)(1)(iv).

#### CONCLUSION OF LAW

The preponderance of evidence relied upon by Examiner supports a conclusion of obviousness. The rejection of claims 1, 29, and 47 under 35 U.S.C. § 103(a) as unpatentable over the combination of Edwards and Vaghefi is affirmed. Claims 5, 13, 35–38, 40, and 48–50 are not separately argued and fall with claim 1.

*Obviousness-type Double Patenting:*

ISSUE

Does the preponderance of evidence relied upon by Examiner support a conclusion of obviousness-type double patenting?

ANALYSIS

Appellants contend that neither Tarara's claims nor Anderson disclose tobramycin, which is required by Appellants' claimed invention (App. Br. 6). In response, Examiner asserts that Tarara's claim 40 relates, *inter alia*, to a method of delivering a therapeutic dose of a bioactive agent, which may be an antibiotic, to the pulmonary air passages in a single breath and an "ordinary artisan knows tobramycin is an antibiotic" (Ans. 6). The problem, however, is that, unlike the obviousness rejection discussed above, Examiner failed to establish an evidentiary basis on this record to support a conclusion that a person of ordinary skill in this art would have recognized, from Tarara's claims taken in combination with Anderson, that tobramycin is the type of antibiotic suitable for administration to the lungs by Tarara's claimed method.

In addition, as Appellants' explain, Examiner failed to establish that Tarara's claimed method taken in combination with Anderson, suggests "a lung deposition [that] is at least 25% substantially independent of inhalation flow rate for flow rates across the range from 10-60 L/min" (App. Br. 11). We recognize, but are not persuaded by, Examiner's unsupported assertion that "flow rate is just the inhalation rate of the particles and [is] variable from patient to patient depending on the device used to administer the powder but[, nonetheless, is] obvious to the ordinary artisan of inhaled

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particle therapeutics,” based on the combination of Tarara’s claimed method taken in combination with Anderson (Ans. 7).

#### CONCLUSION OF LAW

The preponderance of evidence relied upon by Examiner fails to support a conclusion of obviousness-type double patenting. The rejection of claims 1, 5, 13, 29, 35–38, 40, and 47–50 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1–4, 6–15, 17–19, 21–24, 26–34, and 36–57 of Tarara in combination with Andersson is reversed.

#### 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