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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte ERIC WEAVER, JOY CAMPBELL, LOUIS RUSSELL, MIQUEL MORETO PEDRAGOSA, ANNA PEREZ-BOSQUE, FRANCISCO JAVIER POLO POZO, and JOSEPH CRENSHAW ¹

Appeal 2014-001116
Application 12/992,913
Technology Center 1600

Before ERIC B. GRIMES, JACQUELINE T. HARLOW, and KRISTI L. R. SAWERT, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a method of reducing pulmonary inflammation, which have been rejected for obviousness and obviousness-type double patenting. We have jurisdiction under 35 U.S.C. § 6(b).

We affirm-in-part.

¹ Appellants identify the Real Party in Interest as The Lauridsen Group, Inc. (Appeal Br. 2.)

STATEMENT OF THE CASE

The Specification states that “a plasma composition comprising immunoglobulin including concentrated levels of IgG, when administered orally, reduces pulmonary inflammation, and induces a lowering of pro-inflammatory cytokines.” (Spec. 3:10–12.)

Claims 1–19 are on appeal. Claims 1 and 12 are illustrative and read as follows:

1. A method of reducing pulmonary inflammation in an animal comprising: administering to an animal having pulmonary inflammation an effective amount of a plasma fraction comprising at least 30% by weight IgG and 10% or less by weight IgA, wherein the plasma fraction is administered to provide a dose range from about 10 mg to 500 mg per kg body weight per day.
12. The method of claim 1 whereby the plasma fraction is administered intrapulmonarily.

The claims stand rejected as follows:

Claims 1–11, 15, and 16 under 35 U.S.C. § 103(a) as obvious based on Campbell² (Final Rej. 3³);

Claims 12–14 and 17–19 under 35 U.S.C. § 103(a) as obvious based on Campbell and Blumberg⁴ (Final Rej. 5–6);

Claims 1–11, 15, and 16, provisionally, for obviousness-type double patenting based on the claims of application 13/402,291 (Final Rej. 7); and

² Campbell et al., US 2005/0271674 A1, published Dec. 8, 2005.

³ Office Action mailed Jan. 25, 2013.

⁴ Blumberg et al., US 2004/0063912 A1, published Apr. 1, 2004.

Claims 12–14 and 17–19, provisionally, based on the claims of the '291 application and Blumberg (Final Rej. 8).

I

The Examiner has rejected claims 1–11, 15, and 16 as obvious based on Campbell. The Examiner finds that Campbell discloses oral administration of a plasma fraction meeting the requirements of claim 1 to treat respiratory diseases such as pneumonia. (Final Rej. 3.) The Examiner finds that Campbell does not disclose the dosages recited in claim 1 but suggests optimizing dosages for different patients. (*Id.* at 4.) The Examiner concludes that it would have been obvious to optimize the dosages administered by Campbell, because dosage is a result-effective variable. (*Id.*)

Appellants argue that Campbell is not enabling for the method of claim 1. (Appeal Br. 8–10.) Appellants also argue that the recited dosage range would not have been obvious based on Campbell. (*Id.* at 10–13.) Finally, with respect to claim 1, Appellants argue that the Specification's working example provides evidence of the criticality of the recited dosage range. (*Id.* at 13–14.)

We agree with the Examiner that Campbell supports a prima facie case of obviousness. Campbell discloses that “a plasma composition comprising immunoglobulin, when administered orally, regulates and lowers nonspecific immunity responses and induces a lowering and regulation of serum IgG levels and TNF- α levels relative to animals not orally fed immunoglobulin or plasma fractions.” (Campbell ¶ 9.) Campbell states that the “immunoglobulin concentrate powder has been found to contain approximately 35-50% IgG.” (*Id.* ¶ 28.)

Campbell does not disclose the amount of IgA in its composition but Appellants' Specification states that "[a] preferred method of manufacturing the plasma fraction of the application is set forth in U.S. Pat. App. Serial No. 10/470,982, the disclosure of which is incorporated herein by reference." (Spec. 7:13–15.) The '982 application was published as the Campbell reference. (Campbell, front page.) Thus, the evidence shows that the plasma fraction disclosed by Campbell meets the IgG and IgA requirements of claim 1.

Campbell discloses that its plasma fraction can be used for prevention and treatment of various diseases (*id.* ¶ 38), including avian influenza, sinusitis, and pneumonia (*id.* ¶ 39). Appellants' Specification states that diseases associated with pulmonary inflammation include "influenza or other infection caused by the influenza virus; pneumonia caused by virus or bacteria; sinusitis or other inflammation of the sinus cavities;" etc. (Spec. 10:26–28, 11–5.) Thus, Campbell suggests treating animals having pulmonary inflammation.

Campbell does not disclose the dosage range recited in claim 1. However, Campbell states that

[t]hose skilled in the medical arts will readily appreciate that the doses and schedules of the immunoglobulin will vary depending on the age, health, sex, size and weight of the patient rather than administration, etc. These parameters can be determined for each system by well-established procedures and analysis e.g., in phase I, II and III clinical trials.

(Campbell ¶ 30.) We agree with the Examiner that this guidance would have made it obvious to a person of ordinary skill in the medical arts to optimize the dosages of Campbell's plasma fraction based on known

parameters and using well-established procedures and analysis, such as those used in clinical trials.

In short, Campbell supports a prima facie case of obviousness with respect to claim 1. Appellants argue, however, that Campbell is not enabling, for the same reasons that the patent at issue was found to be nonenabling for the use of riluzole to treat ALS in *Impax Laboratories, Inc. v. Aventis Pharmaceuticals Inc.*, 545 F.3d 1312 (Fed. Cir. 2008). (Appeal Br. 8–9.)

We disagree. Campbell discloses the same plasma fraction composition recited in claim 1, suggests using that composition to treat animals having diseases associated with pulmonary inflammation, and expressly suggests optimizing the dosages based on specific parameters and well-known procedures. Thus, the facts of this appeal are very different from the facts (*see* Appeal Br. 8) of *Impax*.

Appellants also argue that Campbell is nonenabling because it lists a variety of diseases (Appeal Br. 8) but “provides no specific dosages for its immunoglobulins to treat any of the numerous types of diseases it lists” (*id.* at 10).

However, “a prior art printed publication cited by an examiner is presumptively enabling barring any showing to the contrary by a patent applicant.” *In re Antor Media Corp.*, 689 F.3d 1282, 1288 (Fed. Cir. 2012). Appellants’ argument that effective dosages would need to be established for any particular disease does not show that such experimentation would be undue, especially in view of Campbell’s disclosure that such optimization

depends on known parameters and can be done using well-established procedures.

Appellants argue that their “claimed invention is not the result of ‘routine optimization’ since the cited prior art provides no information that can be optimized.” (Appeal Br. 12.) Appellants argue that, because Campbell’s working experiments involved *ad libitum* access to the plasma fraction, “persons skilled in the art would have no ability to determine how much plasma fraction each animal received let alone an appropriate dosage range and frequency.” (*Id.*)

However, Campbell expressly states that “doses and schedules of the immunoglobulin will vary” depending on several parameters. (Campbell ¶ 30.) Campbell therefore recognized dosage and schedule as result-effective variables. The fact that Campbell did not expressly identify a range of potential dosages does not mean that dosage would not have been obvious to optimize, or that the dosages recited in claim 1 would have been nonobvious.

Finally, with respect to claim 1, Appellants argue that the Specification’s example demonstrates the criticality of the claimed range. (Appeal Br. 12–13.) However, the example states that “C57BL/6 Hsd mice were fed diets supplemented with 8% SDPP [spray-dried plasma protein] (SDPP group), 1.5% PF [plasma fraction] (immunoglobulin concentrate; PF group) or with milk proteins (Control group).” (Spec. 13:2–3.) Thus, as the Examiner has pointed out (Ans. 5–6), the example appears to involve the same *ad libitum* access to plasma fraction that is described in Campbell’s

examples. The example, in any event, does not describe administering any specific dosage of plasma fraction.

Claims 2–11, 15, and 16 have not been argued separately and therefore fall with claim 1. 37 C.F.R. § 41.37(c)(1)(iv).

II

The Examiner has rejected claims 12–14 and 17–19 as obvious based on Campbell and Blumberg. The Examiner finds that Campbell would have made obvious the method of claim 1 but does not teach intrapulmonary administration, as required by claims 12–14 and 17–19. (Final Rej. 6.) The Examiner finds that Blumberg discloses intrapulmonary administration of antibodies and concludes that pulmonary administration of Campbell’s antibody composition would have been obvious because Blumberg teaches that pulmonary administration has advantages over other forms of administration. (*Id.*)

Appellants argue that Campbell teaches the disadvantages of intravenous administration and teaches that oral administration has numerous advantages. (Appeal Br. 16.) Appellants conclude that “Campbell provides no basis or incentive for persons skilled in the art to administer immunoglobulins to animals by a non-oral route, and in fact discourages persons skilled in the art from employing a non-oral route of administration.” (*Id.* at 17.)

We agree with Appellants that the Examiner has not shown that a person of ordinary skill in the art would have considered it obvious to modify Campbell’s method to include intrapulmonary administration. Campbell focuses exclusively on oral administration of its composition, and

does not suggest other modes of administration as alternatives. For example, Campbell states that “oral administration of plasma protein can induce a change in serum immunoglobulin and TNF- α as well as other nonspecific immunity responses.” (Campbell ¶ 10.)

Campbell teaches that oral administration “greatly simplifies the administration of immunomodulating compositions . . . as these compositions . . . can now be simply added to feedstuff or even water to modulate vaccination, to modulate disease challenge, or to treat animals with immune dysfunction disease states.” (*Id.*, see also ¶¶ 41–45 (discussing further advantages of oral administration).)

Blumberg discloses “includ[ing] a neonatal Fc receptor (FcRn) binding partner by their administration to central airways of the lung. Such therapeutics include therapeutic and diagnostic IgG antibodies.” (Blumberg ¶ 2.) Blumberg discloses that the FcRn binding partner can be a non-specific IgG (*id.* ¶ 35), or it can be any of a variety of therapeutic or diagnostic antibodies (*id.* ¶ 47). Blumberg states that the “methods and compositions are useful for any indication for which the therapeutic is itself useful in the detection, treatment or prevention of a disease, disorder, or other condition of a subject.” (*Id.* ¶ 2)

We do not agree, however, with the Examiner’s conclusion that Blumberg’s disclosure would have made obvious intrapulmonary administration of Campbell’s composition. Neither of the cited references discloses pulmonary administration of a plasma fraction, as in Campbell, as compared to purified antibodies, as in Blumberg. Blumberg discloses that

pulmonary administration is non-invasive (*id.* ¶ 12) but that does not represent an advantage over Campbell’s oral administration.

The Examiner also points to Blumberg’s statement that its method is especially useful for infants and neonates. (Ans. 6, citing Blumberg ¶ 17.) The context of this statement in Blumberg, however, is that its methods “do not require breath holding, deeper-than-normal inhalation, or special timing.” (Blumberg ¶ 17.) The Examiner has not persuasively explained why pulmonary administration would have advantages over oral administration with infants or neonates.

In summary, the Examiner has not shown that the cited references would have provided a reason to modify Campbell’s method to include Blumberg’s pulmonary administration. We therefore reverse the rejection of claims 12–14 and 17–19 based on Campbell and Blumberg.

III

The Examiner has provisionally rejected claims 1–11, 15, and 16 for obviousness-type double patenting based on the claims of application 13/402,291 (Final Rej. 7).

The Examiner finds that the claims of the ’291 application “recite treating respiratory diseases in animals by orally administering immunoglobulin concentrate derived from blood plasma, with specific conditions including pneumonia and *Pasturella* infection being recited.” (*Id.* at 7–8.) The Examiner finds that the ’291 application identifies the application that became the Campbell publication as a preferred source for practicing its methods, which states that it is routine to determine effective dosages for disease treatment. (*Id.*) We agree with the Examiner’s findings

and conclusion that the copending claims are directed to inventions that are not patentably distinct.

Appellants argue that the '291 application is a continuation of the application that was published as the Campbell reference and therefore “has the same disclosure as the cited Campbell et al. reference. As such, and for the same reasons described in detail above, the '291 application is also not enabling for the invention of claims 1-11, 15 and 16 of the instant application.” (Appeal Br. 18.)

This argument is unpersuasive for the reasons discussed above in regard to the rejection under § 103(a) based on Campbell. The provisional rejection of claims 1–11, 15, and 16 based on the '291 application is affirmed.

The Examiner has provisionally rejected claims 12–14 and 17–19 based on the claims of the '291 application and Blumberg (Final Rej. 8). The Examiner relies on Blumberg for its teaching of pulmonary administration and concludes that claims 12–14 and 17–19 are not patentably distinct from claims of the '291 application, which do not recite pulmonary administration. (*Id.*)

However, for the reasons discussed above with regard to the § 103(a) rejection based on Campbell and Blumberg, we conclude that the references do not provide sufficient reason to modify Campbell to include the pulmonary administration taught by Blumberg. We therefore reverse the provisional rejection of claims 12–14 and 17–19.

SUMMARY

We affirm the rejection of claims 1–11, 15, and 16 under 35 U.S.C. § 103(a) based on Campbell. We also affirm the provisional rejection of claims 1–11, 15, and 16 for obviousness-type double patenting based on the claims of the '291 application.

We reverse the rejection of claims 12–14 and 17–19 under 35 U.S.C. § 103(a) based on Campbell and Blumberg. We also reverse the provisional rejection of claims 12–14 and 17–19 based on the claims of the '291 application and Blumberg.

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-IN-PART