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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/483,379	05/30/2012	Beth Shaz	1958427-00196	5461

45200 7590 11/27/2018

K&L Gates LLP-Orange County
1 Park Plaza
Twelfth Floor
IRVINE, CA 92614

EXAMINER
MCNEIL, STEPHANIE A N

ART UNIT	PAPER NUMBER
1653	

NOTIFICATION DATE	DELIVERY MODE
11/27/2018	ELECTRONIC

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte BETH SHAZ and CHRISTOPHER D. HILLYER

Appeal 2017-011723
Application 13/483,379[1]
Technology Center 1600

Before DONALD E. ADAMS, RICHARD M. LEBOVITZ, and MICHAEL J. FITZPATRICK, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL

This Appeal under 35 U.S.C. § 134(a) involves claims 1–21 (App. Br. 5).[2] Examiner entered rejections under 35 U.S.C. § 103(a). We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE.

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[1] Appellants identify "New York Blood Center, Inc." as the real party in interest (App. Br. 3).

[2] Appellants' Appeal Brief filed March 27, 2017.

STATEMENT OF THE CASE

Appellants' disclosure relates to "methods of producing uniform dose and volume pathogen-free blood components." (Spec. ¶ 5). Appellants' claim 1 is representative and reproduced below:

> 1. A method for preparing uniform dose blood component transfusion products, the method comprising the following steps in the recited order:
>
> a) leukoreducing 5-100 individual whole blood units from different donors of the same blood group and type to form leukoreduced blood components, wherein the leukoreduced blood components comprise red blood cells (RBCs), platelets, and plasma;
>
> b) pooling the leukoreduced blood components from the 5-100 individual blood units to form a pooled leukoreduced blood component;
>
> c) treating the pooled leukoreduced blood component to inactivate one or more pathogens;
>
> d) separating a pooled RBC component, a pooled platelet component, and a pooled plasma component from the pooled leukoreduced blood component;
>
> e) adding a storage solution to the pooled RBC component and dividing the pooled RBC component into uniform volume and dose RBC transfusion product units, wherein each uniform volume and dose RBC transfusion product unit contains a uniform number of RBCs or a uniform amount of hemoglobin;
>
> f) adding a storage solution to the pooled platelet component and dividing the pooled platelet component into uniform volume and dose platelet transfusion products units, wherein each uniform volume and dose platelet transfusion product unit contains a uniform number of platelets; and
>
> g) dividing the pooled plasma component into uniform volume and dose plasma transfusion product units.

(App. Br. 25.)

Grounds of rejection before this Panel for review:

Claims 1–5, 9–14, and 18–21 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Fujihara,[3] Hei,[4] Hess,[5] and Cardoso.[6]

Claims 6, 8, 15, and 17 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Fujihara, Hei, Hess, Cardoso, and Zhang.[7]

Claims 7 and 16 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Fujihara, Hei, Hess, Cardoso, and Beutler.[8]

Claim Interpretation:

Due to an Election of Species Requirement, Examiner limited the scope of: The "storage solution" set forth in Appellants' claims 2 and 11 to a storage solution that comprise at least phosphate and the method of inactivating one or more pathogen to at least irradiation (*see* Final Act.[9] 2;

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[3] Fujihara et al., *Prestorage leucofiltration prevents the accumulation of matrix metalloproteinase-9 in red cell concentrates stored in mannitol-adenine-phosphate medium*, 89 VoxSanguinis 114-15 (2005).
[4] Hei et al., US 2002/0192632 A1, published Dec. 19, 2002.
[5] Hess et al., US 6,447,987 B1, issued Sept. 10, 2002.
[6] Cardoso et al., *Mini-pool screening by nucleic acid testing for hepatitis B virus, hepatitis C virus, and HIV:preliminary results*, 38 TRANSFUSION 905–907 (1998).
[7] Zhang et al., *Cell Counter, Blood* in ENCYCLOPEDIA OF MEDICAL DEVICES AND INSTRUMENTATION, 81–90 (2nd ed., John G. Webster ed., John Wiley & Sons 2006).
[8] Beutler et al., *The definition of anemia: what is the lower limit of normal of the blood hemoglobin concentration?*, 107 BLOOD 147–50 (2005).
[9] Examiner's Final Office Action mailed November 3, 2016.

see also Examiner's February 22, 2013 Office Action; Appellants' Response to Restriction Requirement filed March 20, 2013; and Examiner's Non-Final Office Action mailed April 22, 2013). We limit the scope of our review to Appellants' elected invention. *Ex parte Ohsaka*, 2 USPQ2d 1460, 1461 (BPAI 1987).

We are not persuaded by Examiner's interpretation of "the phrase 'transfusion products' . . . to include any sample which is capable of being administered to a subject *regardless of the outcome of said administration*" (Final Act. 2 (emphasis added); *see also* Ans.[10] 2; *cf.* App. Br. 22–23; Reply Br.[11] 2–3). To the contrary, we agree with Appellants' reasoning that "[t]o conclude that a term for a medicinal product being made for intravenous or intra-arterial administration encompasses anything that *is capable of administration* <u>*regardless of the outcome of said administration*</u> . . . is contrary to plain and accepted meaning and inconsistent with [Appellants'] [S]pecification" (Reply Br. 2; *see also* App. Br. 22 ("to one of ordinary skill in the art, a transfusion product comprises blood or a blood component that by its collection and processing can be expected to be safe and effective when used for transfusion")).

In addition, the evidence of record establishes that Examiner's interpretation of the term "transfusion products" is inconsistent with how those of ordinary skill in this art interpret the term (*see e.g.,* Hess 2:8–11 ("packed RBCs stored in the medium were not directly infusible but required the removal of the supernatant with a washing step prior to transfusion due to the presence of ammonium in the additive solution"); *id.* at ll. 17–19 ("the

[10] Examiner's Answer mailed July 19, 2017.
[11] Appellants' Reply Brief filed September 18, 2017.

resulting RBC units contained about 1 percent glycerol and thus, are not safe for transfusion in humans in massive amounts"); *id.* at ll. 24–26 ("such stored RBC suspensions were not acceptable for direct infusion due to their high content of potassium and ammonia and their low volume fraction of RBCs")).

Obviousness:

ISSUE

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

FACTUAL FINDINGS (FF)

FF 1. Fujihara discloses collecting whole blood from donors, dividing each donor's collected blood into two aliquots of equal volume, and filtering one aliquot from each donor (Fujihara 114; *see* Final Act. 4).

FF 2. Fujihara discloses preparing red cell concentrates (RCC) in mannitol-adenine-phosphate (MAP) medium from leukoreduced whole blood (Fujihara 114; *see* Final Act. 3 (Fujihara discloses "leukoreducing [] blood through a filter, before separating red blood cell concentrates from the whole leukoreduced blood")).

FF 3. Examiner finds that "removing the red blood cells from [] whole leukoreduced blood would result in a plasma/platelet fraction that is not whole blood" (Final Act. 3).

FF 4. Fujihara discloses gamma irradiating RCC in MAP medium prepared from non-leukoreduced whole blood collected from donors (Fujihara 114; *see* Final Act. 4).

FF 5. Examiner finds that Fujihara does not disclose pooling samples from 5–100 individual whole blood units from different donors of the same blood group and type to form leukoreduced blood components, "separating and storing the platelet and plasma fractions" or that "irradiation . . . and solvent/detergent treatment . . . can be used to inactivate pathogens" (Final Act. 3).

FF 6. Hei "relates to methods and devices for the removal of substances from blood products and particularly to methods and devices for the removal of psoralens and psoralen photoproducts from plasma that contains platelets without significantly affecting platelet function" (Hei ¶ 1).

FF 7. Examiner finds that Hei discloses counting "the number of red blood cells [and platelets] in a sample," "separating [] platelets and plasma from whole blood and transferring selected volumes of the samples into bags" and concentrating platelets (Final Act. 3–4).

FF 8. Hess "relates to methods and materials associated with the storage of whole blood and red blood cells (RBC)" (Hess 1:23–25).

FF 9. Hess "provide[s] an additive solution for storage of human RBC's which is physiologically safe and suitable for direct infusion into humans in massive amounts" (Hess 2:49–52).

FF 10. Hess discloses studies "to evaluate RBC metabolism and physiology over an 11 week period," wherein "RBC units were grouped into sets of 4 ABO-matched units, each set was then pooled, mixed and realiquoted into identical pooled units" (Hess 6:44–50; *see id.* at ll. 46–48 ("Pooling reduces the largest source of variability in conventional blood storage studies, e.g. different donors"); *see also id.* 9:40–61 (describing the collection and pooling of blood from donors for experimental study); Final Act. 4).

FF 11. Cardoso discloses the collection of an "extra barcoded serum sample" from blood donors for nucleic acid testing (NAT)-based viral screening, wherein "[s]amples are pooled to a maximum of 96" and "[p]ositive results are resolved through intersecting subpools (a chessboard design)" (Cardoso 905; *see* Final Act. 4).

FF 12. Examiner relies on Zhang to disclose that "the concentration of RBCs in whole blood is between $4 - 6 * 10^6$ cells per µL" (Final Act. 9).

FF 13. Examiner relies on Beutler to disclose that "the concentration of hemoglobin in whole blood is about 12.88–15.43 $g * dL^{-1}$" (Final Act. 10).

ANALYSIS

The rejection over the combination of Fujihara, Hei, Hess, and Cardoso:

Based on the combination of Fujihara, Hei, Hess, and Cardoso, Examiner concludes that, at the time Appellants' invention was made, it would have been prima facie obvious to modify Fujihara by, *inter alia*, "pooling blood samples from multiple donors as taught by Hess and Cardoso" (Final Act. 4–5). We are not persuaded that such a modification would have resulted in the claimed subject matter.

To the contrary, we agree with Appellants' contention that none of Fujihara, Hei, Hess, and Cardoso "suggests processing pooled blood or blood components to produce blood component transfusion product units" as required by Appellants' claimed invention (App. Br. 18). In this regard, we agree with Appellants' contention that the discussions of pooling blood samples in the references relate to the preparation of experimental samples not transfusion products (*see e.g., id.* at 19 ("words like 'pooling' or pooled' are plucked out of the references [by Examiner without regard to the] context of what is being pooled . . . and why it is being pooled (clinical

testing in Cardoso; experimental testing in Hess"); *see also id.* at 20 ("in the cited references pooling is not associated with the production of transfusion product units at all. Rather pooling is conducted to create reagents for experimentation (as in Hess) or testing (as in Cardoso)")).

Appellants' claims call for the production of transfusion products. Thus, the product produced by Appellants' claimed methods must be useful for transfusion. For the reasons discussed above, we are not persuaded by Examiner's assertion that those of ordinary skill in this art would consider a "transfusion product" to represent "any sample which is capable of being administered to a subject *regardless of the outcome of said administration*" (Final Act. 2 (emphasis added); *see also* Ans.[12] 2). To the contrary, the evidence of record, as discussed above, establishes that transfusion products must be safe and acceptable for transfusion/infusion. Therefore, we are not persuaded by Examiner's assertion that Appellants' claimed invention does not limit the scope of the term "transfusion products" to those that are useful for transfusion because Appellants' claims do not recite a step of transfusing or administering the transfusion products (Ans. 8 and 10).

In sum, Examiner failed to establish an evidentiary basis on this record to support a conclusion that the combination of Fujihara, Hei, Hess, and Cardoso make obvious Appellants' claimed invention.

The rejection over the combination of Fujihara, Hei, Hess, Cardoso, and either of Zhang or Beutler:

Based on the combination of Fujihara, Hei, Hess, Cardoso, and either of Zhang or Beutler, Examiner concludes that, at the time Appellants'

[12] Examiner's Answer mailed July 19, 2017.

invention was made, it would have been prima facie obvious to "incorporat[e] the teachings of Zhang in Fujihara's method because Zhang is cited solely as evidence of the number of RBCs and platelets inherently present in a given volume of whole blood" (Ans. 9) or "incorporat[e] the teachings of Beutler in Fujihara's method because Beutler is cited solely as evidence of the concentration of hemoglobin inherently present in a given volume of whole blood" (*id.* at 10). We are not persuaded that such a combination would have resulted in the claimed subject matter.

Examiner failed to establish that either of Zhang or Beutler make up for the deficiencies in the combination of Fujihara, Hei, Hess, and Cardoso discussed above (*see* App. Br. 24 ("Zhang [or Beutler] offer[] nothing to repair the deficiencies discussed above of Fujihara, Hei, Hess, and Cardoso").

CONCLUSION

The preponderance of evidence relied upon by Examiner fails to support a conclusion of obviousness.

The rejection of claims 1–5, 9–14, and 18–21 under 35 U.S.C. § 103(a) as unpatentable over the combination of Fujihara, Hei, Hess, and Cardoso is reversed.

The rejection of claims 6, 8, 15, and 17 under 35 U.S.C. § 103(a) as unpatentable over the combination of Fujihara, Hei, Hess, Cardoso, and Zhang is reversed.

The rejection of claims 7 and 16 under 35 U.S.C. § 103(a) as unpatentable over the combination of Fujihara, Hei, Hess, Cardoso, and Beutler is reversed.

REVERSED