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BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte SAORI OTSUKA, KAZUKI HATCHO,
TOSHIHIRO MIZUKAMI, and SHINICHIRO OGUNI

Appeal 2018-005485
Application 14/061,333
Technology Center 1600

Before FRANCISCO C. PRATS, ULRIKE W. JENKS, and JOHN G. NEW, *Administrative Patent Judges*.

JENKS, *Administrative Patent Judge*.

DECISION ON APPEAL

Pursuant to 35 U.S.C. § 134(a), Appellant[1,2] appeals from the Examiner's decision to reject claims 8–19 for obviousness and on the ground of non-statutory obviousness type double patenting. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

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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 the real party in interest as Sysmex Corporation. Appeal Br. 2.

[2] A hearing was held on August 28, 2019. *See* Transcript ("Tr.").

STATEMENT OF THE CASE

Claims 8–19 are on appeal, and can be found in the Claims Appendix of the Appeal Brief. Claim 8 is representative of the claims on appeal, and reads as follows:

> 8. A reagent kit for classifying leukocytes comprising
>
> a first reagent containing a fluorescent dye capable of staining nucleic acid; and
>
> a second reagent containing cationic and nonionic surfactants for lysing erythrocytes and damaging cell membranes of leukocytes so as to be permeable to the fluorescent dye and an aromatic organic acid at a concentration of not less than 20 mM and not more than 50 mM,
>
> wherein when the second reagent contains the aromatic organic acid at a concentration of not less than 20 mM and less than 30 mM, the second reagent has pH of not lower than 5.5 and not higher than 6.4, and when the second reagent contains the aromatic organic acid at a concentration of not less than 30 mM and not more than 50 mM, the second reagent has pH of not lower than 5.5 and not higher than 7.0.

Appeal Br. 21 (Claims Appendix). Claim 14, the only other independent claim, recites a reagent composition containing a cationic and nonionic surfactant in conjunction with an aromatic organic acid. *See id.* at 22.

The claims stand rejected as follows:

I. Claims 8–19 are rejected under pre- AIA § 35 U.S.C. § 103(a) over Narikawa (EP 2202516 A1, published June 30, 2010)("EP'516") and Mizukami (EP 0882983 A2, published Sept. 12, 1998)("EP'983");

II. Claim 8 is rejected on the ground of non-statutory obviousness-type double patenting over claim 9 of US 6,004,816 (issued Dec. 21, 1999).

III. Claim 8 is rejected on the ground of non-statutory obviousness-type double patenting over claims 1, 2, 6−8, 16, and 18 of US 8,101,414 B2 (issued Jan. 24, 2012).

IV. Claims 8 and 13 are rejected on the ground of non-statutory obviousness-type double patenting over claim 8 of US 8,802,025 B2 (issued Aug. 12, 2014) in view of EP'516 and EP'983.

V. Claims 8 and 13 are rejected on the grounds of non-statutory obviousness-type double patenting over claim 8 of US 8,445,209 B2[3] (issued May 21, 2013) in view of EP'516 and EP'983.

VI. Claims 8 and 13 are rejected on the grounds of non-statutory obviousness-type double patenting over claim 8 of US 8,859,200 B2 (issued Oct. 14, 2014) in view of EP'516 and EP'983.

I. Obviousness over EP'516 and EP'983

Examiner finds that EP'516 teaches a kit for differentiating leukocytes, the kit comprising a first reagent containing fluorescent dye and a second reagent containing a cationic and a nonionic surfactant. Ans. 4 (citing EP'516 ¶¶ 12–15, 23–29, 32–46, 48, and 50–52). Examiner acknowledges that EP'516 does not disclose the pH range as presently claimed. *Id.* Examiner relies on the teaching of EP'983 for teaching a similar leukocyte differentiating composition, and specifically relies on EP'983 for teaching aromatic organic acids at a pH range between 5 to 10. *Id.* at 5. EP'983 exemplifies a leukocyte differentiating formulation having a pH of 7. *Id.* Based on this combination, Examiner concludes that "it would have been obvious to one of ordinary skill in the art to combine the claimed components together in a kit and as a reagent for classifying leukocytes because they are known in the art to exist together as a reagent

[3] We note that the patent number cited in the Final Office Action and Answer appears to contain a typographical error. *See* Tr. 16:14–17:3.

and combined in a kit with the fluorescent dye." *Id.* Examiner further notes that the teachings of the combined prior art includes the claimed organic acid concentrations as well as the claimed pH. *Id.* Examiner finds "that adjusting the concentrations [of organic acid] and pH are result effective variables and it is well within the purview of one of ordinary skill in the art to adjust such as a practice of routine optimization to achieve a desired result." *Id.*, *see also id.* at 15 (EP'983 teaches "that if the pH is too low or too high, separation [of cells] is poor and it becomes difficult to classify into cell populations and can damage leukocytes.").

Appellant contends that Examiner has not presented a prima facie case but, and even if, the Board were to conclude that Examiner has met the initial burden of presenting a prima case, their unexpected results merit a reversal of the rejection. *See* Appeal Br. 11–19.

The issue is: (1) Does the preponderance of evidence of record support Examiner's conclusion that the combination of EP'516 and EP'983 renders the claimed kit for classifying leukocyte populations obvious; and (2) if so has Appellant provided sufficient evidence of unexpected results?

A. Findings of Fact (FF)

FF1. EP'983 teaches "[w]hen the reagent[/kit] and method of the present invention are used, not only can normal leukocytes be classified into at least 1–5 populations and counted by the type of population, but [] the classification and counting of abnormal cells [can] be performed simultaneously with their classification and counting." EP'983, 6:24–26. Example 6 of EP'983 discloses a formulation for differentiating leukocytes comprising:

HEPES
10 mM Commercially available product

BC30TX (polyoxyethylene (30) cetyf ether)
1500 ppm Nikko Chemicals
Lauryl trimethylammonium chloride
550 ppm Commercially available product
Dye Compound A
0.5 ppm
Acid [either citric acid or phthalic acid]
20 mM Commercially available product
pH adjusted to 7.0 with NaOH

Id. 10:36–46.

FF2. EP'983 teaches that "[w]hen phthalic acid (an organic acid having an aromatic ring in the molecular structure) was used as the acid, separation of neutrophils from eosinophils was improved compared with the use of citric acid." *Id.* 10:56–57. "[T]he incorporation into the hemolytic agent of at least one organic acid having at least one aromatic ring in a molecule or a salt thereof is preferred for the purpose of adjusting the scattered light intensity distribution of leukocytes so as to be more suitable for classification. For example, benzoic acid, phthalic acid, . . . or a salt of any of these acids can be used preferably as the organic acid or its salt." *Id.* 4:25–29.

FF3. EP'983 teaches sample preparation by mixing blood with hemolytic agent. "The purpose of this step is merely to form pores in the cell membrane of a leukocyte cell to be measured, the pores being of a sufficient size for at least dye molecules to pass through. The hemolytic agent used for this purpose is an aqueous solution of pH 4.5 to 11.0, preferably 5.0 to 10.0, which contains at least one cationic surfactant, at least one nonionic surfactant, and a buffer for maintaining a constant pH." *Id.* 3:40–44, *see id.* 4:32–33 ("The pH of the hemolytic agent is 4.5 to 11.0, preferably 5.0 to 10.0. To maintain

a constant pH, a buffer such as citrate, HEPES or phosphate is contained in the hemolytic agent").

FF4. EP'983 teaches that:

> [i]f the pH is too low, eosinophils and basophils are separated poorly, and it becomes difficult to classify normal leukocytes into 5 populations [, i.e. lymphocytes, monocytes, neutrophils, eosinophils, and basophils]. However, it is possible to classify normal leukocytes into 3 categories (lymphocytes, monocytes, granulocytes) and to classify and count immature leukocytes and abnormal leukocytes. Too high a pH is [also] not preferred because it will make leukocytes prone to damage.

Id. 4:34–38.

FF5. EP'516 teaches a reagent kit for classifying leukocytes containing cationic surfactant a nonionic surfactant and an aromatic carboxylic acid in conjunction with a fluorescent dye. EP'516, Abstract. EP'516 explains that cell membranes of blood cells must be damaged so that the fluorescent dye can permeate into the cell. *Id.* ¶ 16.

FF6. EP'516 teaches that "[t]he concentration of the aromatic carboxylic acid or a salt thereof in the first reagent is not specifically limited as long as the pH of the first reagent is within the range described below, and [the aromatic carboxylic acid] is preferably 0.1 to 100 mM and more preferably 0.5 to 50 mM." *Id.* ¶ 51. "[T]he pH of the first reagent is preferably acidic, such as preferably 2.0 to 4.5, more preferably 2.0 to 3.5. Within this pH range, granules of basophils are stable. In addition, within this pH range, erythrocytes can be efficiently lysed without excessively affecting leukocytes, nucleated erythrocytes and the like." *Id.* ¶ 54.

B. Analysis

Appellant contends: (1) that "the pHs used in EP'516 and EP'983 are incompatible with each other" (Appeal Br. 11); (2) that none of the cited documents disclose pH as a result effective variable (*id.* at 11–12); (3) that EP'516 teaches away from the presently recited pH (*id.* at 13); (4) that the invention exhibits unexpected results (*id.* at 15–17); and (5) that there is no reasonable expectation of success in the combination of references (*id.* at 17–19).

We have reviewed Appellant's contentions and arguments that Examiner erred in rejecting the claims. *See* Appeal Br. 11–19; *see* Reply Br. 4–7. We disagree with Appellant's contentions and adopt the findings concerning the scope and content of the prior art as well as conclusion as set forth in Examiner's Answer and the Final Office Action mailed June 22, 2017. The findings of fact reproduced above are referenced to highlight certain pertinent evidence. We address Appellant's arguments below:

1. Incompatible pH values

That "the pHs used in EP'516 and EP'983 are incompatible with each other" does not persuade us that the Examiner erred in determining that the cited references would have suggested a composition having the pH recited in Appellant's claim 1. Appeal Br. 10–11. Appellant contends that EP'516 is directed to separation of basophils from nucleated erythrocytes while EP'983 is directed to separating eosinophils from basophils. *Id.* at 10.

In the appeal before us, the claims are directed to a product. *See* Ans. 17. The claims do not recite the separation of a particular cell type; instead, the claims generically recite "classifying leukocytes" that can include lymphocytes, monocytes, neutrophils, eosinophils, and basophils.

See Spec. ¶15 ("Normal leukocytes are generally classified into four types: lymphocytes, monocytes, eosinophils and granulocytes other than eosinophils, or five types: lymphocytes, monocytes, neutrophils, eosinophils and basophils"). Therefore, even if we were to interpret the claims as requiring separation between cell types, the claims would encompass separation between any one of lymphocytes, monocytes, neutrophils, eosinophils, and basophils.

EP'983 teaches differentiating leukocyte populations using a dye and a hemolytic agent. FF1–FF4. EP'983 teaches that the hemolytic agent is between pH 4.5 and pH 11. FF3. EP'983 also teaches that the use of phthalic acid (an organic acid with aromatic ring) over citric acid improves separation of neutrophils from eosinophils. FF2.

The pH range disclosed in EP'983 entirely overlaps the 5.5–6.4 and 5.5–7.0 ranges recited in Appellant's claims. That overlap is sufficient to establish a prima facie case of obviousness. *See In re Peterson*, 315 F.3d 1325, 1329 (Fed. Cir. 2003) ("[W]e and our predecessor court have consistently held that even a slight overlap in range establishes a *prima facie* case of obviousness."). Such a prima facie case may be rebutted "by establishing that the claimed range is critical, generally by showing that the claimed range achieves unexpected results relative to the prior art range." *Id.* at 1330 (citations omitted). But, as explained further below (*see* I.B.4), Appellant has not shown that the claimed pH and aromatic acid concentration achieves unexpected results as compared to those taught in EP'516 and EP'983 or otherwise established that the claimed range is critical. Accordingly, the record supports Examiner's obviousness

determination and, as explained below, we are not persuaded by Appellant's arguments to the contrary.

2. Result effective variable

We are not persuaded by Appellant's contention that none of the cited documents disclose pH as a result effective variable. *See* Appeal Br. 11–12. The claimed formulation is intended for classifying leukocytes but does not further recite what particular leukocytes cell population to classify. EP'983 recognizes that the pH of the leukocyte differentiation formulation has an effect on the ability to separate some leukocyte populations, for example eosinophils and basophils. FF4; *see also* Ans. 16 ("depending on the cells to be classified, the pH is a result effective variable which can be optimized to provide for better separation of groups"), *see id*. at 5–6 (citing MPEP 2144.05). EP'983 recognizes that the inclusion of the organic acid in the differentiation formulation helps improve the scattered light intensity between cell populations. FF2. EP'983 also recognizes that in order to improve the separation between eosinophils and basophils the pH of the differentiation buffer should not be too low. FF4. These teachings would lead one of ordinary skill in the art to adjust the pH of a differentiation solution such that the separation between eosinophils and basophils is improved, while at the same time warning not to adjust the pH to high because it will lead to damage in another type leukocyte. FF4. Accordingly, we are not persuaded by Appellant's contention that EP'983, one of the cited references, does not suggest pH as a result effective variable for differentiation of a leukocyte population.

3. Teaches away

We are not persuaded by Appellant's contention that EP'516 teaches away from the presently recited pH. Appeal Br. 13. 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 by the applicant." *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994). Moreover, a teaching away requires a reference to actually criticize, discredit, or otherwise discourage the claimed solution. *See In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004) ("The prior art's mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed"). Finally, in an obviousness analysis, "all disclosures of the prior art, including unpreferred embodiments, must be considered." *Merck & Co., Inc. v. Biocraft Laboratories, Inc.*, 874 F.2d 804, 807 (Fed. Cir. 1989) (quoting *In re Lamberti*, 545 F.2d 747, 750 (C.C.P.A. 1976)).

EP'516 teaches that leukocyte differentiation reagent is *preferably* in a range from pH 2.0–4.5. FF5. A suggestion that some range is preferable is not a teaching that one should not work outside the particular range or that going outside the range is somehow detrimental to the assay. *See* Tr. 11–12. This is true, especially when read in light of the teaching of EP'983, a reference also directed at leukocyte differentiation but using reagents that are preferably in a range from pH 4.5–11. FF3. Here, Appellant's argument attacking the EP'516 reference individually is not proper when the rejection is based on the combination of EP'516 with EP'983. *See In re Keller*, 642 F.2d 413, 426 (CCPA 1981).

4. Unexpected results

Appellant contends that the classification kit of the present claims exhibit unexpected results. Appeal. Br. 15–17. Specifically, that the kit is "capable of separating the region where the signal of the monocytes appears on the scattergrams from the region where the signal of the lymphocytes appears on the same scattergrams, in order to differentiate between the blast cells and the atypical lymphocytes." *Id.* at 16.

We are not persuaded by Appellant's contention. Here, EP'983 teaches that the dye formulation allows for the classification of not only normal leukocytes but also counts abnormal cells. FF1. This would indicate that the prior art was interested in separating the various populations of cells for the purpose of counting and identifying the blood components. EP'983 teaches that separation between basophils and eosinophils, both a type of leukocyte, is improved when using phthalic acid instead of citric acid. FF2. EP'983 teaches that the use of an aromatic organic acid containing at least one aromatic ring in the molecule allows for improved classification of leukocytes because of the different scattered light intensity in the different populations. FF2. EP'983 also teaches that if the pH is too low then the separation of the leukocytes into 5 populations becomes difficult, but also cautions against having the pH to high because this causes more damage to the leukocyte. FF4. EP'983 therefore recognizes that pH affects the ability to separate various cell population for the purpose of classification. Thus, the references already recognize that adjusting the pH and organic acid affects the ability to separate various cell populations. The question before is whether the organic acid concentration and the pH ranges as claimed

provide results that are unexpectedly different from what is already disclosed in the art.

During oral argument, Appellant directed our attention to the figures and Table 5 of the Specification as allegedly providing evidence of unexpected results based on the centroid distance measured between monocytes and lymphocytes. *See* Tr. 5–6; *see also* Appeal Br. 18–19 (citing "Examples of the present specification" and "Figs. 2–4"). Table 5 of the Specification, which discusses certain of Appellant's exemplified compositions, is reproduced below:

Name of reagent	Centroid distance	Phthalate (mM)	Benzoic acid (mM)	pH
Second reagent A	37.9	20	0	7.2
Second reagent G	44.7	20	0	6.0
Second reagent R	46.3	20	20	6.0
Second reagent S	47.0	20	30	6.0

Spec. ¶ 92. The Specification explains the leukocytes form clusters in the scattergrams. The table measures the centroid distance between monocytes and lymphocyte clusters. Spec. ¶ 93. "These clusters are analyzed with an appropriate analysis software to identify the leukocyte clusters and calculate the number of cells in the respective leukocyte clusters, ... From the positions of the centroid of the respective leukocyte clusters, the distance between the centroids (hereinafter referred to as the centroid distance) is calculated." Spec. ¶ 70.

We are not persuaded by Appellant's unexpected results argument. *See Estee Lauder Inc. v. L'Oreal, S.A.*, 129 F.3d 588, 595 (Fed. Cir. 1997) ("[A]rguments of counsel cannot take the place of evidence lacking in the record."). At best, Table 5 of the Specification shows that when the pH is changed from pH 7.2 to pH 6.0 the centroid distance between the two populations tested has changed. What is not clear is whether this change in

distance is unexpected, especially given the teaching in the EP'983 that already suggests that a change in pH can affect the separation of a different type of leukocyte. FF2. Here, the claims are not limited to the separation between monocytes and lymphocytes, both cells are a type of leukocyte, but instead the claims are directed to a composition/kit for "classifying leukocytes" that are known to contain at least 5 cell populations.

The centroid distances given in Table 5 for reagents G, R, and S are numerically different; however, what has not been established on this record is whether these differences are significant. "'[D]ifferences in degree' of a known and expected property are not as persuasive in rebutting obviousness as differences in 'kind'—i.e., a new property dissimilar to the known property." *Bristol-Myers Squibb Co. v. Teva Pharms. USA, Inc.*, 752 F.3d 967, 977 (Fed. Cir. 2014) (citation omitted). Here, the evidence presented in Table 5 does not clearly "represent a 'difference in kind' that is required to show unexpected results." *In re Harris*, 409 F.3d 1339, 1344 (Fed. Cir. 2005); *see also Galderma Labs., L.P. v. Tolmar, Inc.*, 737 F.3d 731,739 (Fed. Cir. 2013) ("Unexpected results that are probative of nonobviousness are those that are different in kind and not merely in degree from the results of the prior art.") (internal quotations omitted). What is missing in Table 5 and the accompanying text in the Specification is an explanation of why the small numerical differences in the table between reagents G, R, and S rise to the level of being unexpected and thereby a difference in kind rather than a difference in degree. The Specification explains that it is the software that determines centroid distances but provides no further detail. Without knowing how the boundaries are determined in order to calculate the position of the centroid, from which to then calculate any distances between

centroids associated with different cell populations, it is impossible to say that any difference shown in the figures is significant. *See* Tr. 6–7. Would a different software program place the centroids at the same position? If the position of the centroid changes based on different software then the question is whether the numerical differences shown in Table 5 is an attribute of the software selection rather than an attribute to the reagent. When balancing the totality of the evidence presented in support of the unexpected results against the evidence of obviousness presented by Examiner, we find that the balance of the evidence weighs in favor of finding the claims unpatentable based on the teachings of EP'516 and EP'983.

5. Reasonable expectation of success

We are also not persuaded by Appellant's argument that there is no reasonable expectation of success in the combination of references. Appeal Br. 17–19. We agree with the Examiner that the claims are directed to a kit/composition and are not directed to a method of separating a particular cell population. As Examiner explains, "[t]he prior art references teach the reagents for the purpose of adjusting the scattered light intensity distribution of leukocytes to be more suitable for classification into different populations." Ans. 18.

Example 6 of EP'983 teaches a formulation for differentiating leukocytes that contains HEPES a buffer, BC30TX (polyoxyethylene (30) cetyl ether) an anionic surfactant, lauryl trimethylammonium chloride a cationic surfactant, and 20 mM of an acid such as phthalic acid and organic aromatic acid, with the pH of 7.0. FF1. The question presented is whether the combination of references provides a reasonable expectation that the

concentration of organic aromatic acid can be increased to 30 to 50 mM while retaining the same pH?

EP'983 explains that the use of the organic acid is for the purpose of adjusting the scattered light intensity and distribution of leukocytes. FF3. EP'516 similarly teaches cell differentiation based on scattered light information. EP'516 ¶¶ 12–15. EP'516 teaches that it is important to first lyse erythrocytes in order to get a correct basophil count. *Id.* ¶ 49. EP'516 teaches that erythrocytes and other blood components have the same size and shape of basophils and thereby could contribute to a high basophil count if these other components are not properly removed from the samples. *See id.* ¶¶ 48–52. EP'516 teaches that aromatic carboxylic acids effectively lyse erythrocytes. *Id.* ¶ 48. There is nothing in the record that would suggest that increasing the concentration of aromatic organic acid from 20 mM shown in EP'983 up to 100 mM shown in EP'516 would be detrimental the leukocyte cells of interest. *See* FF1, FF2, FF6. Here, the records suggests that the inclusion of an aromatic acid is desirable for the removal of erythrocytes and for improving the light scattering in the remaining cells. FF6; EP'983 4:25–27 ("the incorporation into the hemolytic agent of at least one organic acid having at least one aromatic ring in a molecule or a salt thereof is preferred for the purpose of adjusting the scattered light intensity distribution of leukocytes so as to be more suitable for classification"). Based on these teachings, we determine that the combination of references provides a reasonable expectation that the use of an organic aromatic acid contributes to an improvement of the differentiation of the leukocyte population by at least removing erythrocytes from the sample and improving light intensity.

6. Hindsight

Finally, we are also not persuaded by Appellant's contention that the combination of references is a result of hindsight. *See* Reply Br. 5.

> Any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning, but so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made and does not include knowledge gleaned only from applicant's disclosure, such a reconstruction is proper.

In re McLaughlin, 443 F.2d 1392, 1395 (CCPA 1971). Here, Appellant has not explained what knowledge Examiner was relying on that could only be gleaned from Appellant's Specification in order to arrive at the conclusion of obviousness.

C. Conclusion

We conclude that the evidence cited by Examiner supports a prima facie case of obviousness with respect to claim 8, and Appellant has not provided sufficient rebuttal evidence that outweighs the evidence supporting the Examiner's conclusion of obviousness. As Appellant does not argue the claims separately, claims 9–19 fall with claim 8. 37 C.F.R. § 41.37 (c)(1)(iv).

II.–VI. Non-Statutory Obviousness Type Double Patenting

Appellant does not provide separate arguments with respect to the nonstatutory obviousness type double patenting rejection instead relying on the unexpected results arguments discussed in conjunction with the obviousness rejection. *See* Appeal Br. 19. For the reasons discussed in detail above (*see I.B.4*), we are not persuaded by Appellant's unexpected results argument. As Appellant does not provide any other arguments we

affirm the non-statutory obviousness-type double patenting rejections for the reasons set out by Examiner in the Final Office Action and Answer.

CONCLUSION

In summary:

Claims Rejected	Basis	Affirmed	Reversed
8–19	§ 35 U.S.C. 103 (a) over EP'516 and EP'983	8–19	
8	Obviousness-type double patenting	8	
8	Obviousness-type double patenting	8	
8, 13	Obviousness-type double patenting	8, 13	
8, 13	Obviousness-type double patenting	8, 13	
8, 13	Obviousness-type double patenting	8, 13	
Outcome		8–19	

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