

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 23

UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte THOMAS RUSSELL, JAMES C. HUDSON,
WALLACE H. COULTER, CARLOS M. RODRIGUEZ and
CONSTANCE M. HAJEK

Appeal No. 1999-1397
Application No. 08/303,924

ON BRIEF

Before SCHEINER, MILLS and GRIMES, Administrative Patent Judges.

SCHEINER, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 129 through 132 and 134 through 140, the only claims remaining in the application.

Claim 129 is representative of the subject matter on appeal and reads as follows:

129. A method for differentiating first and second subpopulations of blood cells in a blood sample, said first and second subpopulations of blood cells being of similar volume, electrical conductivity and/or light scattering properties, said method comprising the steps of:

a) providing a plurality of microspheres having a reactant bonded thereto, said reactant specifically binding to a moiety present on only the blood cells of said first subpopulation, said microspheres having a size between about 0.65 and 3.0 microns;

b) mixing said microspheres with said blood sample to cause a plurality of said microspheres to bind each of the blood cells of said first subpopulation, whereby a plurality of microsphere/cell complexes are formed in said blood sample; and

c) differentiating said complexes from unbound blood cells in said blood sample by passing said complexes and unbound blood cells seriatim through a sensing zone while measuring the respective volume, electrical conductivity and light scattering properties of said complexes and blood cells as each passes through said zone.

The references relied on by the examiner are:

Rodriguez et al. (Rodriguez)	5,125,737	Jun. 30, 1992
Kortright et al. (Kortright)	5,223,398	Jun. 29, 1993

Claims 129-132 and 134-140 stand rejected under 35 U.S.C. § 103 as unpatentable over Kortright and Rodriguez.

We reverse the examiner's rejection of the claims.

DISCUSSION

"The invention . . . addresses the technical problem of differentiating different subpopulations of white blood cells (WBC's) in a whole blood sample . . . [T]here are essentially five different types of WBC's or 'leukocytes' in whole blood . . . lymphocytes, monocytes, eosinophils, neutrophils and basophils. Each type of WBC[] exhibits characteristic volume . . . electrical conductivity . . . and light scattering properties . . . by which each cell type can be differentiated from other types of cells . . . While it is now

relatively straightforward to differentiate and enumerate the basic WBC types, the differentiation of different kinds of cells of the same subtype (i.e. subpopulations) is not so simple.” At times, “it is desirable to periodically monitor the relative proportion of two different subpopulations of lymphocytes,” for example, T4 and T8 lymphocytes, but “all lymphocytes look very similar in terms of their volume, conductivity and light scatter.” Brief, pages 2-3.

According to appellants, Kortright “addresses the exact problem noted above, namely, . . . distinguish[ing between] two different subpopulations (e.g. T4 and T8 lymphocytes) of the same type of cells,” but does so without measuring light scatter. Brief, page 3. That is, Kortright “discloses a method in which a multitude of ‘microspheres’, each labeled with antibodies which are specific to only one of the two subpopulations, are mixed with a whole blood sample. After mixing, the labeled microspheres couple to those cells . . . of a selected subpopulation to form cell/microsphere complexes . . . [S]ince the cell/microsphere complexes have volume and conductivity characteristics that differ from the non-complexed cells alone, a desired subpopulation of cell can be differentiated by . . . measur[ing] only cell volume (DC), cell conductivity (RF), and cell opacity (RF/DC).” Id.

Rodriguez describes an instrument that differentiates between lymphocytes, monocytes, eosinophils, neutrophils and basophils using volume, conductivity and light scatter measurements.

According to the examiner, “[i]t would have been obvious . . . to measure both light scatter and the DC and RF electronic signals taught by Rodriguez . . . in the method of Kortright . . . because Rodriguez [teaches] the combination of light scatters

and electronic detection means provides for a more complete analysis of the cells because together, these measurements provide the ability to differentiate at least five types of leukocytes,” and “[t]he three sensing parameters are conventional in the art . . . and thus a skilled artisan would have had a reasonable expectation of success in combining all three for a complete analysis of the WBC subsets.” Examiner’s Answer, page 4.

Appellants argue that all of the claims on appeal require microspheres between about 0.65 and 3.0 microns in diameter, but “this size range is nowhere to be found in the cited references.” Brief, page 7. We note that this size range is not mentioned in the statement of the rejection either. Nevertheless, in responding to appellants’ argument, the examiner concludes that even though Kortright “does not specifically teach the size of the microspheres, it is obvious from [Kortright’s] description that the microspheres should be smaller than the cells so that a plurality of microspheres is attached to the cells.” Examiner’s Answer, page 6.

On first impression, the examiner’s conclusion does not appear to be unreasonable, but there is no objective evidence of record to support it. It is improper for this board, and for that matter the examiner, to hold claims unpatentable for obviousness based on conclusory statements about what can be characterized as “common knowledge” or “common sense,” without objective evidence in support of that knowledge. See In re Lee, 277 F.3d 1338, 1344, 61 USPQ2d 1430, 1434-1435 (Fed. Cir. 1992). In any case, there is evidence of record, which the examiner has not addressed, that would seem to undermine the examiner’s position. According to appellants (Reply Brief, page 1), Suzuki “expressly discloses attaching microspheres to

cells for differentiation purposes, and the sizes of such microspheres are clearly outside the range recited by the claims on appeal.” Appellants acknowledge that “a general statement is made that the particles (microspheres) could have a size range of ‘1/10 to ten times’ that of the particles to be measured” (Id.), but point to the two embodiments described in the reference as evidence that it would not have been obvious from Kortright’s description that the microspheres should be smaller than the cells, much less that they should have diameters in the range of 0.65 to 3.0 microns. Specifically, “[i]n [Suzuki’s] first embodiment, latex particles of 19.8 and 44.1 microns are used, . . . and it is stated that particles having a size larger than the size of blood cells are ‘preferable’,” while in Suzuki’s “second embodiment . . . the latex particles (microspheres) are 0.33 microns in size . . . significantly smaller than those recited by the claim on appeal.” Id.

Nor are we persuaded by the examiner’s argument that the specification teaches that “other types and sizes of microspheres . . . may be utilized in the method of the instant invention,” thus, appellants “fail[] to provide support for the criticality of the argued parameters.” Examiner’s Answer, page 7. The flaw in this reasoning is that it puts the cart before the horse, effectively negating an explicit limitation in the claims based solely on appellants’ disclosure, rather than the teachings of the prior art. The criticality of a limitation is immaterial if there is nothing in the prior art to suggest it in the first place.

The initial burden of presenting a prima facie case of obviousness rests on the examiner. In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). The rejection of claims 129-132 and 134-140 under 35 U.S.C. § 103 is reversed because the examiner has not established that all of limitations of the claims on appeal

were taught or would have been suggested by the prior art.

REVERSED

Toni R. Scheiner)
Administrative Patent Judge)
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) BOARD OF PATENT
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Demetra J. Mills) APPEALS AND
Administrative Patent Judge)
) INTERFERENCES
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Eric Grimes)
Administrative Patent Judge)