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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte RAJESH SHAH.[1]

Appeal 2015-006045
Application 12/083,228
Technology Center 1600

Before JEFFREY N. FREDMAN, JOHN G. NEW, and
JOHN E. SCHNEIDER, *Administrative Patent Judges*.

SCHNEIDER, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134(a) involving claims to a composition for treating respiratory infections which have been rejected as being directed to non-statutory subject matter, as indefinite and as obvious. We have jurisdiction under 35 U.S.C. § 6(b).

We affirm.

STATEMENT OF THE CASE

The present invention is directed to a composition for treating respiratory infections. Spec. 1. The composition comprises a

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[1] Appellant identifies the Real Party in Interest as the inventor, Rajesh Shah. Br. 3.

Mycobacterium complex containing two or more mycobacteria in a diluent which has been serially diluted and potentized. Spec. 15–15

Claims 1, 3, 5, and 11–13 are on appeal. Claim 1 is illustrative and reads as follows:

> 1. A composition for the treatment of respiratory tract infection (RTI), containing a homogenized mixture of at least two potentized substances, as herein described, selected from the following isolated and purified cultured strains of *Mycobacterium*:
>
> A. *Mycobacterium tuberculosis* of 5c potency,
> B. *Mycobacterium bovis* of 5c potency,
> C. *Mycobacterium microti* of 5c potency,
> D. *Mycobacterium [a]fricanus* of 5c potency and
> E. ethanol killed *Mycobacterium [l]aprae* of 5c potency,
>
> and optionally a vehicle selected from a group consisting of normal saline, distilled water and ethyl alcohol, wherein said composition is characterized by a potency ranging between 5c and 200c.

The claims stand rejected as follows:

Claims 1, 3, 5, and 11–13 stand rejected under 35 U.S.C. § 101 as being directed to non-statutory subject matter.

Claims 1, 3, 5, and 11–13 stand rejected under 35 U.S.C. § 112, second paragraph as indefinite.

Claims 1, 3, 5, 11, and 12 stand rejected under 35 U.S.C. § 103(a) as obvious over Convit[2] in view of Ratliff[3] or Hudson[4].

Claims 1, 3, 5, 11, and 12 stand rejected under 35 U.S.C. § 103(a) as obvious over Wright[5] in view of Ratliff or Hudson.

THE REJECTION UNDER 35 U.S.C. § 101

In rejecting claim 1, 5, 11, 12, and 13 as directed to non-statutory subject matter the Examiner finds that for dilutions beyond 12c, the dilutions are simply solvent, which can be water. Non-Final Act. 3. The Examiner finds that water is a product of nature and is thus non-statutory subject matter. *Id.*

Alternatively, the Examiner finds that for claims 1, 3, 5, and 11–13, the claims do not recite something significantly different from a product of nature. Non-Final Act. 5–6. The Examiner finds that all the bacteria strains recited in the claims are found in nature. Non-Final Act. 6. The Examiner goes on to find that the claimed product of the strains in water or saline is not marked different than the same bacteria found in nature such as in contaminated water. *Id.* The Examiner finds that the requirement that the dilutions be "potentized" or serially diluted does not significantly change the structure of the stains to differentiate them from nature. Non-Final Act. 6–7.

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[2] Convit et al., *Immunoprophylactic trial with combined Mycobacterium leprae/BCG vaccine against leprosy: preliminary results,* 399 THE LANCET 446 (1992) ("Convit").
[3] Ratliff et al., US 5,194,257, issued Mar. 16, 1993 ("Ratliff").
[4] Hudson et al., *Choice of an optimal diluent for intravesical bacillus Calmette-Guerin administration,* 142 J. UROL. 1438 (1989) ("Hudson").
[5] Wright et al., WO 03/051288 A2, published June 26, 2003 ("Wright").

Appellant contends that the diluted strains do not contain merely solvent even for high levels of dilutions. Br. 9. Appellant argues that the process of potentization "causes the molecular imprint of the active material to be left behind on the solvent and these molecular imprints have a powerful impact of specific pathogens." Br. 9–10. Appellant argues that the clinical data in the Specification demonstrates that the potentized dilutions are effective against respiratory infections demonstrating that the dilutions are more than just solvent. Br. 10–11. Appellant also points to evidence in the records which supports Appellant's contention that potentization results in molecular imprints being imparted to the diluent. Br. 12–13.

The issue with respect to this rejection is whether the Examiner has established by a preponderance of the evidence that claims 1, 3, 5, and 11– are directed to non-statutory subject matter.

Determination of subject matter eligibility involves a two-step test. First one must determine if the claimed subject matter is directed to judicially recognized exception such as a product of nature. *Mayo Collaborative Servcs. v. Prometheus Lab., Inc.* 132 S.Ct. 1289. 1297 (2012). If the claims address a product of nature, the next step is to determine if the claims recited additional elements that transform the nature of the claim. *Id.*

Applying this test, we agree with the Examiner that the present claims are directed to non-statutory subject matter.

Looking to the first step, the claims address a product of nature in that they cover bacteria which exist in nature. We do not find any principled difference between the instant claim to a composition comprising diluted

mycobacteria and the composition comprising a mixture of six isolated *Rhizobium* bacterial strains in *Funk Brothers* that was found to be non-statutory. *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 US 127, 131 (1948). As in *Funk Brothers*, Appellant did not create or alter the mycobacteria in any structural way, but at most simply isolated them from their natural source. And these components existed in nature before Appellant isolated them. At best, Appellant's contribution, if any, was recognizing that the natural products may have clinical uses in certain patient populations. However, the claims are not drawn to methods of treatment, but rather are drawn to a composition that comprises the natural products.

In terms of the isolation itself, the isolated natural components in the composition are altered less than the nucleic acid in *Myriad* because unlike the nucleic acid, which required severing chemical bonds to release the nucleic acid from the chromosome in *Myriad*, these components are chemically unchanged by their isolation process. *See Ass'n for Molecular Pathology v. Myriad Genetics, Inc.,* 133 S.Ct. 2107, 2118 (2013).

The next step is to see if the claims recite additional elements which transform the nature of the claims. We find that they do not.

The instant claims call for serial dilutions of from 5c to 200c. As taught in the Specification, 'homeopathic preparation in a potency higher than l4c are found to have no physical traces or any molecules of the original source." Spec. 13. Thus the composition comprises nothing but diluent at those concentrations. That is, the claims solely comprise water, a natural product.

Like *Myriad* and *Funk Brothers*, and unlike *Chakrabarty*, the composition, whether containing solely water or *de minimis* amounts of mycobacteria, was not a creation of Appellant, but rather a product of nature mixture. And there is nothing markedly different between the claimed composition and naturally occurring mycobacteria in water other than purification and mixture together. Supreme Court precedent teaches that neither isolating natural products nor combining them together represents an act of invention unless the combination results in something "markedly different", and no such result has been demonstrated in the instant case. *See Myriad*, 133 S.Ct. at 2117; *Funk Brothers*, 333 U.S. at 132.

We further find that the utility of treatment of respiratory tract infection by administration of a composition that has been so diluted as to remove essentially all molecules of mycobacteria leaving solely solvent reasonably constitutes an incredible utility.

"[I]f the alleged operation seems clearly to conflict with a recognized scientific principle as, for example, where an applicant purports to have discovered a machine producing perpetual motion, the presumption of inoperativeness is so strong that very clear evidence is required to overcome it." *In re Chilowsky*, 229 F.2d 457, 462 (CCPA 1956). Here, the recognized scientific principle underlying mycobacterial vaccines is the interaction of the antigen with antigen presenting cells that induce either T cell activity or B cells to generate antibodies. In either case, antigen must be present to allow binding to antigen presenting cells, and, as noted above, in the diluted compositions of the claims, no antigen would be expected to be present (see

Spec. 13). Therefore, the operation of the claims conflicts with the scientific principles underlying the field of immunology.

Appellant contends that the compositions do not constitute mere diluent but have been transformed through the potentization process. Br. 9–11. Appellant argues that "potentization causes the molecular imprint of the active material to be left on the solvent and these molecular imprints have a powerful impact on specific pathogens. " Br. 9–10.

We find this argument unpersuasive because Appellant provides no persuasive evidence that water differs after being "potentized." In particular, Appellants provide no physical comparison showing a physical, chemical, or biological test that demonstrates a difference between the "potentized" water and "ordinary" water used as solvent.

To the extent that Appellants rely upon Montagnier[6] to support their position, Montagnier teaches that "[s]ignal producing dilutions usually range from 10^{-8} to 10^{-12}" and dilutions up to 10^{-18} produced signals (Montagnier 84, col. 2). Montagnier never indicates dilutions that would remove every molecule of material. Thus, unlike Appellant's claim, the issue in Montagnier is not "potentization" but rather the presence of very small numbers of active molecules.

Appellants argue that the clinical data presented demonstrates the therapeutic activity of the potentized compositions.

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[6] Montagnier et al., *Electromagnetic Signals Are Produced by Aqueous Nanostructures Derived from Bacterial DNA Sequences*, 1 Interdiscp. Sci. Compt. Life Sci. 81–90 (2009).

We have reviewed all of the anecdotal cases identified as demonstrating treatment using 30c or more dilute, where 15c lacks any molecule of the original starting material and further dilutions simply dilute into more solvent (*see* Spec. 13, 18–26). There is no evidence that any immune response was generated. Nor was there any evidence of a comparison with a placebo or other control to demonstrate that any effect was the result of the active agent, and did not simply represent the natural course of disease in the patient population. That is, some fraction of patients will improve without any treatment, and this improvement does not evidence efficacy of the compound but simply represents the natural healing ability of the human body.

We agree with the Examiner that Appellant has provided no credible evidence that the potentized compositions of the invention have any impact on specific pathogens. While the Specification includes examples of cases in which "potentized" compositions were administered to patients suffering from respiratory infections, we find no basis from the information provided to conclude that any reported improvement was in fact due to the formulation administered. We find that the potentization step does not transform the dilute solutions in a way to render them patentable.

We conclude that the Examiner has established that claims 1, 3, 5, and 11–13 are directed to non-statutory subject matter.

THE INDEFINITENESS REJECTION

In rejecting the pending claims as indefinite the Examiner finds that the claims fail to particularly point out the initial concentrations of the solute

being diluted. Non-Final Act. 7. The Examiner finds that the starting amounts of the bacteria are not recited in the claims making it unclear how to correlate potency range to concentration. *Id.* The Examiner concludes that without a value for the bacteria initially present it is not possible to predict how many bacteria will be present after 5 serial dilutions. Non-Final Act. 8.

Appellant contends that the initial concentration is unimportant, in that the final concentration will contain untraceable amounts difficult to determine using known techniques. Br. 14. Appellant also points out the Specification provides sufficient disclosures to enable the preparation of the primary culture used in the dilutions. *Id.*

The issue with respect to this rejection is whether the Examiner has established that the claims are indefinite under 35 U.S.C. § 112, second paragraph.

Principles of Law

"[I]t is the language itself of the claims which must particularly point out and distinctly claim the subject matter which the applicant regards as his invention, without limitations imported from the specification. … Limitations in the specification not included in the claims may not be relied upon to impart patentability to an otherwise unpatentable claim." *In re Lundberg*, 244 F.2d 543, 548 (CCPA 1957).

Analysis

We agree with the Examiner that the claims are indefinite. One skilled in the art cannot determine what the concentration of bacteria are at any given dilution without knowing the initial concentration. Ans. 5–6. Thus, one skilled in the art cannot determine the metes and bounds of the claims.

Appellant argues that the initial concentration is irrelevant in that the final concentration is one where the composition contain untraceable substances which are difficult to determine using known techniques. Br. 14. We are unpersuaded. As the Examiner points out, the requirement that the final concentration contains substances that are untraceable is not a limitation of the claims. Ans. 5. Moreover, as taught in the Specification, the bacteria will only be present in untraceable amounts for dilutions of 14c or greater. Spec. 23. The claims embrace dilutions starting at 5c. Appellant's argument regarding untraceable amounts is not commensurate with the scope of the claims.

Appellant also argues that the Specification teaches the preparation of the primary cultures used in the dilution process. Again, we are not persuaded. Limitations in the Specification cannot be read into the claims. *In re Lundberg*, 244 F.2d at 548.

We conclude that the Examiner has established that claims 1, 3, 5, and 11–13 are indefinite under 35 U.S.C. § 112, second paragraph.

THE OBVIOUSNESS REJECTIONS

The Examiner has rejected claims 1, 3, 5, 11 and 12 under 35 U.S.C. 103(a) as obvious over Convit combined with Ratliff or Hudson and over Wright combined with Ratliff or Hudson. As the arguments relating to these rejections are the same, we shall discuss the rejections together.

In rejection the claims, the Examiner finds that both Convit and Wright disclose vaccines comprising strains of *Mycobacterium* selected from the group of bacteria recited in claim 1. Non-Final Act. 12 and 18. Ratliff and Hudson teach the use of saline as a diluent for vaccines using mycobacterium. Non-Final Act. 12 and 18. The Examiner finds that it would have been obvious to one skilled in the art to use the diluents of Ratliff or Hudson in the vaccines of Convit or Wright.

The Examiner goes on to find that there is no difference in the compositions of the combined references and the dilute compositions of the claims. *Id.* 11. The Examiner finds that the term "potentized" should be read as a product by process limitation. *Id.* As such, absent evidence showing a difference between the claimed composition and the prior art, the product is unpatentable. *Id.*

Appellants contend that in both Convit and Wright, the diluent is used for reconstitution and not dilution. Br. 21 and 23. In addition, Appellant argues that the Examiner has not pointed to any motivation to substitute the diluent used in Wright with the saline used in Ratliff and Hudson. Br. 23. Finally, Appellant contends that none of the references teach the preparation of a serially diluted and potentized composition. Br. 22 and 24.

Findings of Fact

We adopt as our own the Examiner's findings and analysis. The following findings are included for emphasis and reference convenience.

FF1. Convit discloses the preparation of vaccine comprising bacillus Calmette-Guerin ("BCG") and Mycobacterium leprae. Convit 447.

FF2. Wright discloses the preparation of a vaccine comprising different Mycobacterium killed by formalin including BCG, M. tuberculosis, M. bovis, M. africanus, and M. microti. Wright 4.

FF3. Hudson discloses the use of saline as a diluent for vaccines containing BCG. Hudson, abstract.

FF4. Ratliff teaches the use of saline as a diluent for vaccines containing BCG. Ratliff col. 4, ll. 21-32.

FF5. The instant Specification teaches that "[f]or centuries, homeopathic practitioners have suggested that serially agitated dilutions of infectious agents such as bacteria (called 'nosodes') are effective in the prevention of infectious disease. . . . The prepration [sic] of nosodes derives from homotoxicology, a type of homeopathic therapy created by Hans~Heinrich Reckeweg in Germany in the first part of 18th century." Spec. 5.

FF6. The Specification teaches that "[a] 'nosode' is similar to an 'oral vaccine' in the sense that its purpose is to 'immunize' the body against a specific as well as related disease conditions. The major difference between

a nosode and a vaccine is, of course, the extremely small quantity of antigenic material in a nosode." Spec. 6.

Principles of Law

A proper § 103 analysis requires "a searching comparison of the claimed invention—including all its limitations—with the teaching of the prior art." *In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995).

When a *prima facie* case of obviousness has not been established, the rejection must be reversed. *In re Fine*, 837 F.2d 1071, 1075 (Fed. Cir. 1988).

Analysis

Claim 1 is representative of the rejected claims and is directed to a mixture of two potentized substances comprising strains of *Mycobacterium*.

We agree with the Examiner that the subject matter of claim 1 would have been obvious to one skilled in the art at the time the invention was made. Convit and Wright teach the preparation of vaccines using stains of *Mycobacterium*. FF1 & 2. Ratliff and Hudson teach the use of saline as a diluent for vaccines containing *Mycobacterum*. FF 3 & 4. The specification admits that it was well known in the art to prepare nosodes using potentization. FF5. The Specification also teaches that nosodes are similar to vaccines with the exception that nosodes are more dilute. FF6. We find that it would have been obvious to one skilled in the art to convert the vaccines of Convit or Wright into nosodes using potentization.

Conclusion of Law

We conclude that the Examiner has established by a preponderance of the evidence that claims 1, 3, 5, 11, and 12 would have been obvious over Convit combined with Ratliff or Hudson or Wright combined with Ratliff or Hudson under 35 U.S.C. § 103(a).

SUMMARY

We affirm the rejection under 35 U.S.C. § 101.

We affirm the rejection under 35 U.S.C. § 112, second paragraph.

We affirm both rejections under 35 U.S.C. § 103(a),

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