

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

Paper No. 25

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte HORST KIEF

Appeal No. 1996-2209
Application No. 08/031,346

ON BRIEF

Before SCHEINER, MILLS, and GRIMES Administrative Patent Judges.

MILLS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. §134 from the examiner's final rejection of claims 1-26, which are all of the claims pending in this application.

We reverse.

Claims 1, 25 and 26 are illustrative of the claims on appeal and read as follow:

1. A process for the production of germicidally treated suspensions comprising

taking body fluids from a person suffering from a member of the group of illnesses consisting of atopic neurodermatitis, bronchial asthma and nasal allergies, colitis ulcerosa, Parkinson, Morbus Crohn, Hepatitis, chronic Hepatitis, chronic Sinusitis, Psoriasis, rheumatic-type indications, carcinomas, multiple sclerosis, and scleroderma Sjögren syndrome and combinations thereof;

desaggregating the body fluids by reducing the body fluids to sub-cell size substances by cell lysis;

subjecting a member selected of the group consisting of body fluids, sub-cell size substances, and mixtures thereof to an oxidant by exposing the member selected of the group consisting of body fluids, sub-cell size substances to a member selected from the group consisting of ozone, oxygen, UV radiation, and mixtures thereof for obtaining suspensions exhibiting immune-modulatory active properties.

25. A process for the production of germicidally treated suspensions comprising

taking body fluids formed of tissue from a person suffering from a member of the group of illnesses consisting of atopic neurodermatitis, bronchial asthma and nasal allergies, allergies, colitis ulcerosa, Parkinson, Morbus Crohn, Hepatitis, chronic Hepatitis, chronic Sinusitis, Psoriasis, rheumatic-type indications, carcinomas, multiple sclerosis, and scleroderma Sjögren syndrome and combinations thereof;

fractionating the tissue by reducing the tissue to sub-cell size substances by cell lysis for obtaining a first fraction and a second fraction;

subjecting the first fraction to an oxidant with a member selected from the group consisting of ozone, oxygen, UV radiation and mixtures thereof;

subjecting a member selected from the group consisting of the second fraction, a separately generated fractionated sub-cell size substance, tissue, and mixtures thereof to an

oxidant with a member selected from the group consisting of ozone, oxygen, UV radiation and mixtures thereof;

recombining the treated first fraction and the treated second fraction.

26. A process for the production of germicidally treated suspensions comprising withdrawing blood from a person suffering from a member of the group of illnesses consisting of atopic neurodermatitis, bronchial asthma and nasal allergies, allergies, colitis ulcerosa, Parkinson, Morbus Crohn, Hepatitis, chronic Hepatitis, chronic Sinusitis, Psoriasis, rheumatic-type indications, carcinomas, multiple sclerosis, and scleroderma Sjögren syndrome and combinations thereof;

treating said blood with an oxidant;

centrifuging the erythrocytes out of said blood thereby removing plasma from the centrifuged erythrocytes;

treating the plasma with an oxidant;

treating the centrifuged erythrocytes with an oxidant;

partially suspending the oxidized erythrocytes in distilled water so as to burst these erythrocytes through osmosis;

treating a urine filtrate with oxidant;

adding the oxidized urine filtrate to the oxidized plasma;

combining the fraction containing the erythrocytes and the fraction containing the plasma and the urine filtrate for generating a combined suspension;

contacting an immune system with the combined suspension for modulating the immune-active properties of the immune system.

The prior art references relied upon by the examiner are:

Zee et al. (Zee)

4,632,980

Dec. 30, 1986

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Edelson	4,684,521	Aug. 4, 1987
Wieseahn	4,748,120	May 31, 1988
German Patent Application Kief (DT'91)	3,109,691	Sep. 23, 1982

OPINION

In reaching our decision in this appeal, we have given careful consideration to the appellant's specification and claims, to the applied prior art references, and to the respective positions articulated by the appellant and the examiner.

Rather than reiterate the conflicting viewpoints advanced by the examiner and the appellant regarding the noted rejections, we make reference to the examiner's Answer for the examiner's reasoning in support of the rejection, and to the appellant's Brief for the appellant's arguments thereagainst. As a consequence of our review, we make the determinations which follow.

Background

The claimed invention is directed to a process of production of a germicidally treated suspension which is useful for the treatment of illnesses such as atopic neurodermatitis, bronchial asthma, nasal allergies, allergies, colitis ulcerosa, Parkinson, Morbus Crohn, hepatitis, chronic hepatitis, chronic sinusitis, psoriasis, rheumatic-type indications, carcinomas, multiple sclerosis and scleroderma Sjögren syndrome. The process of

producing the germicidally treated suspension includes taking a body fluid, such as urine or blood from a person suffering from one of the indicated illnesses and desaggregating or fractionating the body fluids by reducing the body fluids to individual fractions of sub-cell size substances by cell lysis. The specification suggests that only after breaking up or destruction of the cell membrane are many very important immune-modulatory substances accessible to oxidation. Specification, page 13. Cell lysis can be performed mechanically, enzymatically and/or osmotically. More particularly, cell lysis may occur by means of homogenization, freezing, osmosis or by the use of proteolytic enzymes such as pepsin, papain or bromelain.

Id.

Ozonation or irradiation of each individual fraction is conducted to provoke a substantially stronger alteration process of the proteins, lipids and other structures, than occurs from ozonation of untreated (unfractionated) blood. Specification, page 10. After separate treatment of the fractions with ozone or irradiation, either part or all of the fractionated initial substances are then recombined to form a uniform suspension.

Specification, page 14.

Grounds of Rejection

1. Claims 1-26 stand rejected under 35 U.S.C. § 112, first paragraph as unpatentable for lack of enablement.
2. Claims 1-26 stand rejected under 35 U.S.C. § 101 as unpatentable for lack of utility.

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3. Claims 1-26 stand rejected under 35 U.S.C. § 103 as unpatentable for obviousness over DT'91 in view of Zee, Wieseahn and Edelson.

DECISION ON APPEAL

35 U.S.C. § 112, first paragraph

Claims 1-26 stand rejected under 35 U.S.C. § 112, first paragraph as unpatentable for lack of enablement.

In order to establish a prima facie case of non-enablement, the examiner must provide a reasonable explanation as to why the scope of protection provided by a claim is not adequately enabled by the disclosure. See In re Wright, 999 F.2d 1557, 1561-62, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). The threshold step in resolving this issue is to determine whether the examiner has met his burden of proof by advancing acceptable reasoning inconsistent with enablement.

Factors to be considered by the examiner in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman, 230 USPO 546, 547 (Bd. Pat. App. & Int. 1986). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). We

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note that all of the factors need not be reviewed when determining whether a disclosure is enabling. Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1213, 18 USPQ2d 1016, 1027 (Fed. Cir.), cert. denied, 112 S. Ct. 1696 (1991)(noting that the Wands factors "are illustrative, not mandatory. What is relevant depends on the facts.").

In this regard, the following passage from PPG Indus. Inc. v. Guardian Indus. Corp., 75 F.3d 1558, 1564, 37 USPQ2d 1618, 1623 (Fed. Cir. 1996) is instructive here.

In unpredictable art areas, this court has refused to find broad generic claims enabled by specifications that demonstrate the enablement of only one or a few embodiments and do not demonstrate with reasonable specificity how to make and use other potential embodiments across the full scope of the claim. See, e.g., In re Goodman, 11 F.3d 1046, 1050-52, 29 USPQ2d 2010, 2013-15 (Fed. Cir. 1993); Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d. 1200, 1212-14, 18 USPQ2d 1016, 1026-28 (Fed. Cir.), cert. denied, 502 U.S. 856 (1991); In re Vaeck, 947 F.2d at 496, 20 USPQ2d at 1445. Enablement is lacking in those cases, the court has explained, because the undescribed embodiments cannot be made, based on the disclosure in the specification, without undue experimentation. But the question of undue experimentation is a matter of degree. The fact that some experimentation is necessary does not preclude enablement; what is required is that the amount of experimentation "must not be unduly extensive." Atlas Powder Co., v. E.I. DuPont De Nemours & Co., 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed. Cir. 1984). The Patent and Trademark Office Board of Appeals summarized the point well when it stated:

The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the invention claimed.

Ex parte Jackson, 217 USPQ 804, 807 (1982).

In the present case, it is the examiner's position that the specification does not set forth sufficient guidance and teachings to enable the use of the claimed process for the production of germicidally treated suspensions. The examiner has determined that the disclosure is too broad, vague and unclear to allow the practitioner skilled in the art to practice the claimed invention without undue experimentation. Answer, page 4. The examiner argues 1) there is no teaching as to how to select the particular composition for the particular immunomodulatory effect, 2) it is unclear as to what type of immunomodulatory and immuno-suppressive processes the invention is drawn, and 3) there is no specific and defined teaching of any therapeutic composition in the specification. Answer, pages 5-6.

Considering the Forman factors set forth above individually, it would appear that the nature of the invention described in claim 1 is a process for the production of a germicidally treated suspension. The specification, particularly Tables 4-6, pages 29-32 of the original disclosure and Amendment C, pages 2-13 (Paper No. 5, October 20, 1993), sets forth specific conditions treated, and compositions and dilutions to be administered to treat the specific conditions using suspensions prepared by the process of the invention. Thus, the specification would appear to provide direction and guidance in some detail as to how to use the claimed invention for the treatment of various medical conditions, in the form of working examples. In addition, the state of the prior art, as reflected in the cited references of record,

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also appears to indicate that ozonated or irradiated blood and blood component suspensions are known in the prior art for the treatment of hyperimmune and autoimmune conditions. For example, Edelson evidences methods and systems for externally treating blood components with photoactive and chemical agents for the purpose of reducing lymphocyte populations in blood which may be found in conditions such as lymphocytic anemia, allergies, thyroiditis, hemolytic and pernicious anemias and collagen vascular diseases. Column 1, lines 13-45. While the nature of the art lacks a degree of predictability, we find the disclosure, through its examples, provides sufficient guidance to those of ordinary skill in the art to practice the claimed process without undue experimentation. In view of the above, the rejection of the claims for lack of enablement is reversed.

35 U.S.C. § 101

Claims 1-26 stand rejected under 35 U.S.C. § 101 as unpatentable for lack of utility. It is the examiner's position that the evidence of record is insufficient to support claims of treatment of conditions such as arthritis, asthma, bronchitis and neurodermatitis. Answer, page 7.

In the present case, the appellant claims a process for the production of a germicidally treated suspension and need only show one credible utility for such process. Raytheon Co. v. Roper Corp., 724 F.2d 951, 958, 220 USPQ 592, 598 (Fed. Cir. 1983) (citing Treatise:

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“When a properly claimed invention meets at least one stated objective, utility under § 101 is clearly shown.”).

In our view, the specification pages 22-32, provides test data which, when assessed from the perspective of one of ordinary skill in the art, is probative of the appellant's assertion of utility for the claimed process. For example, the specification pages 26 and 32 provides data associated with a 2 ½ year study of patients with neurodermatitis treated with the autohemologous immune treatment of the invention. In view of the above, at least a single credible utility for the claimed process for the production of germicidally treated suspensions is provided in the specification and the rejection of the claims for lack of utility is reversed.

35 U.S.C. § 103

Claims 1-26 stand rejected under 35 U.S.C. § 103 as unpatentable for obviousness over DT'91 in view of Zee, Wieseahn and Edelson.

In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a prima facie case of obviousness. See In re Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). It is well-established that the conclusion that the claimed subject matter is prima facie obvious must be supported by evidence, as shown by some objective teaching in the prior art or by knowledge generally available to one of ordinary skill in the art that would have led that individual to combine the relevant teachings of the references to arrive at the claimed invention. See In re Fine, 837 F.2d 1071, 1074, 5

USPQ2d 1596, 1598 (Fed. Cir. 1988). With this as background, we analyze the prior art applied by the examiner in the rejection of the claims on appeal.

The examiner indicates that DT'91 provides evidence of a device for extracorporeal germicidal action and peroxide formation in the blood which works by oxygenating or irradiating blood. Answer, page 8; DT '91 translation pages 5-6. The examiner recognizes that DT'91 ozonizes untreated blood, whereas in the method of the claimed process, the ozonation occurs with fractionated (desaggregated) blood wherein the fractions are exposed to uninhibited attack of ozone. Answer, page 8, paragraph 3.

In order to cure the above noted deficiency of DT'91, the examiner relies on Zee to establish evidence that blood and blood components may be disinfected by means of ozone treatment in the presence of ascorbic acid. Similarly, Wieseahn is relied on for the disclosure of the treatment of biological compositions, such as whole blood or blood components, with radiation in the presence of psoralens, which are aromatic carbonyl carriers. Edelson is relied on as evidence of immunomodulatory extracorporeal treatment of blood by exposure to ultraviolet radiation in the presence of carbonyl carriers, such as psoralens and ascorbic acid, for the treatment of hyperimmune and autoimmune diseases.

Appellant argues that a prima facie case of obviousness has not been established by the examiner, as none of the cited references disclose a process of producing a suspension, as claimed, which requires desaggregating or fractionating the body fluids by reducing the

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body fluids to sub-cell size substances by cell lysis (claims 1 and 25). We agree. While Zee and Wieseahn indicate that blood components may be treated with ozone we do not find a specific indication in the cited references of reducing the body fluids to sub-cell size substances by cell lysis to obtain suspensions exhibiting immunomodulatory properties, as claimed. Nor do we find that the examiner has provided evidence of record to support a process of production of a germicidally treated suspension as set forth in claim 26, which includes a step of “combining the fraction containing the erythrocytes and the fraction containing the plasma and the urine filtrate for generating a combined suspension.”

We find the examiner has not established a prima facie case of obviousness on the record before us, or that the cited references both suggest the claimed subject matter and reveal a reasonable expectation of success to one reasonably skilled in the art. The rejection of the claims for obviousness of the claimed invention is reversed.

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CONCLUSION

The rejections of claims 1-26 under 35 U.S.C. § § 112, first paragraph, 101 and 103 are reversed.

REVERSED

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Administrative Patent Judge))
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