

THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 13

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte HANS F. BIENER

Appeal No. 1997-0003
Application No. 08/342,614

ON BRIEF

Before GARRIS, WARREN and ELLIS, Administrative Patent Judges.

ELLIS, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 9 through 12, 16 through 21 and 23 through 40, all the claims remaining in the application. Claims 1 through 8, 13 through 15 and 22 have been canceled. The claims are attached as an appendix to this decision.

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therapeutic agent and water. The examiner primarily relies on the table in col. 2 of the patent, which lists the preferred cations and anions as well as their respective concentrations, to demonstrate that Biener would have suggested a method of treating acne or seborrheic dermatitis using compositions comprising salt mixtures having anions and cations, and a therapeutic agent, within the claimed parameters to one of ordinary skill in the art at the time the invention was made. Answer, pp. 2-3. We agree, in part.

I.

Turning first to claims 18 through 20, 31, 32 and 33, we find that they encompass a method of treating acne or seborrheic dermatitis which comprises topically applying a therapeutic salt composition comprising a mixture of cations (sodium, magnesium, calcium and potassium) and anions (chloride, sulfate, hydrogen carbonate and carbonate), a therapeutic agent and a solvent (water). The salt composition must contain at least 50% by weight sodium chloride. Here, we agree with the examiner that the claimed method of treating acne or seborrheic dermatitis would have been obvious to one of ordinary skill in the art in view of the teachings of Biener.

First, the compositions described in the claims comprise ions which are within the range taught by the applied prior art. See, e.g., dependent claim 20. Under such circumstances, our appellate reviewing court has held that when “the difference between the claimed invention and the prior art is some range or other variable within the claims ... the applicant must show that the particular range is critical, generally by showing that the

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claimed range achieves unexpected results relative to the prior art range.” In re Woodruff, 919 F.2d 1575, 1578, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990). As to the limitation that the claimed compositions must contain at least 50% by weight sodium chloride, the examiner points out that Biener teaches that the ratio of sodium:magnesium can be as high as 266:20, thus, the preparation of the salt composition using a majority of sodium and chloride ions would result in the formation of the claimed amount of sodium chloride. In other words, since the concentration of sodium and chloride ions set forth in the claims, is within the range taught by Biener (see, e.g., claim 20), the preparation of a composition using the higher concentrations of sodium and chloride taught by the patent, manifestly, results in a composition having the claimed amount of sodium chloride. Thus, we agree with the examiner that a therapeutic composition comprising the claimed concentration of at least 50% by weight sodium chloride would have been obvious to one of ordinary skill in the art at the time the invention was made. In re Woodruff, 9191 F.2d at 1578, 16 USPQ2d at 1936.

Second, we point out that Biener discloses that the therapeutic compositions described therein can be used to treat psoriasis and other skin diseases, and expressly includes acne as one of said diseases. Biener, col. 2, lines 12-17; col. 3, lines 28-31. Accordingly, contrary to the appellant’s arguments, we find that the teachings of Biener would have suggested the use of the claimed therapeutic compounds for the treatment of acne to those of ordinary skill in the art. As to the claimed treatment of seborrheic

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dermatitis, we agree with the examiner that Biener's teaching of the treatment of psoriasis, and other skin diseases, using the disclosed therapeutic compositions would have suggested to those of ordinary skill in the art the use of the claimed compositions for seborrheic dermatitis. We point out that it is well established that a reference must also be considered in light of what it would have fairly suggested to those of ordinary skill in the art. In re Betz, 418 F.2d 942, 947, 163 USPQ 691, 695 (CCPA 1969)

("... the test of obviousness is not express suggestion of the claimed invention in any ... of the references but rather what the references ... would have suggested to those of ordinary skill in the art presumed to be familiar with them"). In our view, those of ordinary skill in the art would have understood the similarity between psoriasis and seborrhea and, thus, would have been motivated to employ the claimed compositions for such treatment.¹

Claims 12, 21, 34 and 40 are directed to methods of treating acne or seborrhea using compositions comprising a salt composition having an ionic content within the range disclosed by Biener, but which is free of added zinc. Claims 24 and 36 additionally require that the salt compositions be free of added iodide, fluoride, silicate, borate, lithium, aluminum, and iron ions. Here, we agree with the examiner that Biener discloses that the referenced ions are preferably present in the salt mixture; however, this does not mean that

¹ We point out that Cecil Textbook of Medicine, Vol. 2, 18th Edition, Wyngaarden et al., eds., W.B. Saunders Co., Philadelphia (1988), teaches the similarity between psoriasis and seborrhea dermatitis. According to the textbook, "[i]t is sometimes difficult to differentiate seborrhea from psoriasis when the latter is localized to the scalp, ears and face." Cecil Textbook of Medicine, p. 2321, col. 1, lines 2-5; copy attached to this decision.

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they must be present. Biener, col. 2, lines 62-65. Moreover, when we turn to the table in col. 2, we find that the referenced ions are present in amounts as low .001 grams in the 1000 gram (1 kilogram) composition taught by Biener. That is to say, they are only present as trace elements. In our view, such teachings would have suggested to one of ordinary skill in the art that the ions provided by trace elements are not essential for the treatment of acne and seborrhea since the claimed compositions additionally contain at least one additional therapeutic agent and a solvent. In addition, the appellant acknowledges in the specification that it is well known that salt solutions exert an osmotic effect on the skin which is responsible for skin shrinkage. Specification, p. 3, para. 1. Thus, in view of the role of the salt component in the treatment of skin, and given that the osmotic effect is due to the total ion concentration present in the composition, we find that it would have been obvious to those of ordinary skill in the art that said effect would still occur in the absence of the trace elements.

Claims 25 and 37 are directed to a method of treating acne using the compositions of claims 21 and 34 wherein the salt composition comprises at least 67 weight % sodium chloride. We recognize that the compositions taught by Biener comprise less than the claimed amount of sodium chloride; however, the actual difference in concentration between the prior art and claimed compositions is negligible. We point out that the claims require as few as four (4) grams more sodium (270 grams) in a 1000 gram (1 kilogram) composition than the amount taught by Biener (266 grams/kg). In our view, those of

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ordinary skill in the art would have reasonably expected that a composition comprising 4 additional grams of sodium ions would act in the same, or substantially the same, manner as the composition taught by Biener, especially since sodium chloride is not the only active ingredient in the claimed therapeutic composition. Titanium Metals Corp. of America v. Banner, 778 F.2d 775, 782, 227 USPQ 773, 779 (Fed. Cir. 1985). Accordingly, absent an unexpected result, we find that the claimed concentration of sodium chloride would have been obvious to one of ordinary skill in the art at the time the invention was made.

Claims 26, 27, 38 and 39 are directed to a method of treating acne using the compositions of claims 21 and 34 wherein said compositions contain 1 to 2.5 grams/kilogram bromide ions or 0.1 to 0.3 grams/kilogram of strontium ions. Again, we find the claimed range of bromide and strontium ions are within the range taught by Biener and, thus, would have been obvious to one of ordinary skill in the art. As discussed above, when “the difference between the claimed invention and the prior art is some range or other variable within the claims ... the applicant must show that the particular range is critical, generally by showing that the claimed range achieves unexpected results relative to the prior art range.” In re Woodruff, 919 at 1578, 16 at 1936.

As to claims 16 and 17, which are directed to methods of treating seborrheic dermatitis using the compositions described in claim 34, we direct attention to our discussion above with respect to claim 33 as to why the teachings of Biener with respect

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to the treatment of psoriasis and other skin diseases would have been suggested the treatment of seborrhea to those of ordinary skill in the art. We further direct attention to our discussion with respect to claim 32 and Biener's express teaching of the treatment of acne. Biener, col. 3, lines 28-31.

Claims 22 and 35 are directed to a method of treating acne or seborrheic dermatitis using compositions having the limitations of claims 21 and 34 and which further comprise surface active agents. Claim 22 further requires the presence of sufficient surface active agents to form a shampoo. Here, we agree with the appellant that shampoos and surface active agents are not expressly disclosed by Biener; however, as discussed above, a reference must also be considered in light of what it would have fairly suggested to those of ordinary skill in the art. In re Betz, 418 F.2d at 947, 163 USPQ at 695 (CCPA 1969). Here, because one common location for the occurrence of seborrheic dermatitis is the scalp, we find that the suggested use of the claimed compounds for seborrhea by Biener would have fairly suggested the addition of surface active agents for topical application as a shampoo.

The appellant argues that Biener discloses a composition which is analogous to the composition of Dead Sea water and the use of said composition to treat psoriasis. Brief, p. 4. According to the appellant, one of ordinary skill in the art would not look to the Biener composition and expect it to be useful for the treatment of acne or seborrheic dermatitis. Id., p. 5. The appellant relies on the declaration of Dr. Peter which states that he has not

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read of, nor observed, “any positive effect of Dead Sea water or salt on acne or seborrheic dermatitis.” Declaration, attached to Paper No. 9. We do not find this argument and the declaration to be persuasive.

First, Dr. Peter’s statements with respect to Dead Sea water is of no moment. The rejection is over the use of the compositions disclosed by Biener to treat acne, not the use of Dead Sea water. To that end, we point out that Biener (i) discloses the use of a composition which comprises a salt mixture, a therapeutic agent, and water, and (ii) expressly states that “[t]he invention’s salt mixture has a correspondingly positive effects [sic, effect] with acne.” Biener col. 3, lines 28-29. Second, we find that Dr. Peter’s statements are inconsistent with the specification which, as noted above, states that spontaneous healings of acne have been observed using Dead Sea water. Specification, p. 3, para. 2.

The appellant argues that it would not have been obvious to one of ordinary skill in the art “to modify the Biener composition to include sodium chloride at a level of at least 50% by weight, or least 67% by weight as required by claims 25 and 37.” The appellant points to the Amendment After Final (Paper No. 6) wherein it is allegedly state that “Dead Sea water and dried salts contain significantly less than 50 weight % of sodium chloride.” Brief, p. 5.

We addressed the issue of the claimed levels of at least 50% by weight, and at least 67% by weight, sodium chloride, above. Therefore, we comment only briefly on the

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appellant's statements in the amendment filed in Paper No. 6. In said amendment, the appellant allegedly compares the salt composition of Dead Sea water with the composition described in claim 34. The composition of Dead Sea water is said to be derived from a publication by Drugan. However, because the appellant has only provided a single page from said publication and that page is not in English, we have not considered the reference. Moreover, even assuming arguendo, that the composition of Dead Sea water and the appellant's calculations of the amount of sodium chloride present therein are correct, it is not material to the rejection. The rejection is over the use of the therapeutic compositions taught by Biener to treat acne, and not the use of Dead Sea water.

II.

As to claims 9 through 11 and 28 through 30, we do not find that the claimed ions are all within the ranges taught by Biener. In particular, we note that the claims are directed to use of 60 to 120 g/kg sulfate in the salt mixture; whereas, Biener discloses the use of 0.2 to 22 g/kg sulfate. The examiner has not provided any reasons as to why one of ordinary skill in the art would have been motivated to modify the composition taught by Biener by increasing the concentration of sulfate ions approximately three (3) to four (4)-fold. Rather, the examiner merely states that "[i]t is a matter of ordinary skill in the art to increase the proportion of sulfate ... to optimize the salt mixture for the treatment of a particular disease such as acne." Answer, p. 6. The examiner has not provided any

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factual basis for this statement based on the applied prior art, or otherwise. Thus, we agree with the appellant that the only suggestion for making such a modification is found in the specification. That is, the only way for the examiner to arrive at his conclusion of obviousness is by hindsight reconstruction of the invention using the present composition as a “template.” Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1138, 227 USPQ 543, 547 (Fed. Cir. 1985); W.L. Gore & Assocs. v. Garlock, Inc., 721 F.2d 1540, 1553, 220 USPQ 303, 312-13 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984) (“To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher”). Accordingly, we reverse the rejection of claims 9 through 11 and 28 through 30.

AFFIRMED-IN-PART

BRADLEY R. GARRIS
Administrative Patent Judge

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CHARLES F. WARREN
Administrative Patent Judge

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Appendix

9. The method of Claim 34 wherein said solvent comprises water and said mixture comprises salt components such that the salt components are present in the mixture in the following proportions, expressed as grams/kilogram of salt mixture in the ionic state:

| <u>CATIONS (g/kg)</u> | <u>ANIONS (g/kg)</u> |
|-----------------------|-----------------------------|
| Sodium 267 to 320 | Chloride 450 to 600 |
| Magnesium 30 to 40 | Sulfate 60 to 120 |
| Calcium 5 to 15 | Hydrogen Carbonate 3 to 4.2 |
| Potassium 6 to 14 | Carbonate 0.3 to 0.7 |

10. The method of Claim 9 which further contains from about 1 to 2.5 grams/kilogram of salt mixture of bromide ions.

11. The method of Claim 9 which further contains from about 0.1 to 0.3 grams/kilogram of salt mixture of strontium ions.

12. The method of Claim 34, wherein said salt mixture is dissolved in water as a carrier medium at a concentration within the range of from about 2.5 to about 12% by weight.

16. The method of Claim 34 wherein said skin disease is acne.

17. The method of Claim 34 wherein said skin disease is seborrheic dermatitis.

18. A method for treating acne or seborrheic dermatitis comprising topically applying to the affected skin areas a therapeutic salt composition solution, said solution comprising a mixture of:

(a) from about 1 to 30% by weight of a salt composition prepared by mixing salt composition prepared by mixing salt components such that, in the ionic state, a mixture comprising sodium, magnesium, calcium, potassium, chloride, sulfate, hydrogen carbonate and carbonate ions is formed, said ions constituting at least about 97.5% by weight of the ionic content of said salt composition and said salt composition containing at least 50% by weight of sodium chloride;

(b) from about 0.05 to about 10% by weight of a therapeutic agent at least partially soluble in said solution and effective for treatment of said skin disease; and

(c) a solvent for said salt composition.

19. The method of claim 18 wherein said solvent comprises water.

20. The method of claim 19 wherein said salt components are present in said composition in the following proportions, expressed as grams/kilogram of salt mixture in the ionic state:

CATIONS (g/kg)

Sodium 150-380
Magnesium 10-90
Calcium 1 to 30
Potassium 0.5 to 35

ANIONS (g/kg)

Chloride 150-750
Sulfate 20 to 200
Hydrogen Carbonate 1 to 5
Carbonate 0.1 to 2

21. The method of claim 20 wherein said salt composition is free of added Zinc.

23. The method of claim 21 wherein said composition is mixed with surface active agents sufficient to form a shampoo.

24. The method of claim 21 wherein said salt composition is also free of added iodide, fluoride, silicate, borate, lithium, aluminum and iron ions.

25. The method of claim 21 wherein said salt composition comprises at least 67% by weight sodium chloride.

26. The method of claim 21 wherein said salt composition further contains from about 1 to 2.5 grams/kilogram of salt mixture of bromide ions.

27. The method of claim 21 wherein said salt composition further contains from about 0.1 to 0.3 grams/kilogram of salt mixture of strontium ions.

28. The method of claim 20 wherein said mixture comprises salt components such that the salt components are present in the mixture in the following proportions, expressed as grams/kilogram of salt mixture in the ionic state:

CATIONS (g/kg)

ANIONS (g/kg)

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| | | | |
|-----------|------------|--------------------|------------|
| Sodium | 267 to 320 | Chloride | 450 to 600 |
| Magnesium | 30 to 40 | Sulfate | 60 to 120 |
| Calcium | 5 to 15 | Hydrogen Carbonate | 3 to 4.2 |
| Potassium | 6 to 14 | Carbonate | 0.3 to 0.7 |

29. The method of claim 28 wherein said salt mixture further contains from about 1 to 2.5 grams/kilogram of salt mixture of bromide ions.

30. The method of claim 28 wherein said salt mixture further contains from about 0.1 to 0.3 grams/kilogram or salt mixture of strontium ions.

31. The method of claim 20 wherein said salt composition is dissolved in water at a concentration within the range of from about 2.5 to about 12% by weight.

32. The method of claim 18 wherein said skin disease is acne.

33. The method of claim 18 wherein said skin disease is seborrheic dermatitis.

34. A method for treating acne or seborrheic dermatitis comprising contacting the affected skin areas with a composition prepared by mixing salt components such that the salt components are present in the mixture in the following approximate proportions, expressed as grams/kilograms [sic, kilogram] of salt mixture in the ionic state:

| <u>CATIONS (g/kg)</u> | | <u>ANIONS (g/kg)</u> | |
|-----------------------|------------|----------------------|------------|
| Sodium | 150 to 380 | Chloride | 150 to 750 |
| Magnesium | 10 to 90 | Sulfate | 20 to 200 |
| Calcium | 1 to 30 | Hydrogen Carbonate | 1 to 5 |
| Potassium | 0.5 to 35 | Carbonate | 0.1 to 2 |

said salt components comprising at least 50% by weight sodium chloride, said composition further characterized as being dissolved in a solvent and as being free of added Zinc.

35. The method of claim 34 wherein said composition further contains surface active agents.

36. The method of claim 34 wherein said composition is also free of added iodide, fluoride, silicate, borate, lithium, aluminum and iron ions.

37. The method of claim 34 wherein said salt components of said composition

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comprise at least 67% by weight of sodium chloride.

38. The method of claim 34 wherein said composition further contains from about 1 to 2.5 grams/kilogram of salt mixture of bromide ions.

39. The method of claim 34 wherein said composition further contains from about 0.1 to 0.3 grams/kilogram of salt mixture of strontium ions.

40. The method of claim 34 wherein said composition is dissolved in water solvent at a concentration within the range of from about 1 to about 30% by weight.