

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opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.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. 45

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte Deleuran Merete

Appeal No. 97-1843
Application 08/092,574¹

ON BRIEF

Before WINTERS, WILLIAM F. SMITH and LORIN, Administrative Patent Judges.

WILLIAM F. SMITH, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 6 through 9, all the claims remaining in the application, which read as follows:

¹ Application for patent filed July 16, 1993. According to appellant, this application is a continuation of Application 07/794,707, filed November 20, 1991 (abandoned), which is a continuation of Application 06/908,802, filed September 4, 1986 (abandoned).

7. A method of treating eye infections comprising applying an effective amount of an ophthalmic gel composition comprising about 1% w/v of fusidic acid in the form of particles having a particle size of between 2 and 5 μm suspended in an aqueous vehicle containing from 0.2 to 2% w/v of Carbopol polymer, said composition having a viscosity of from 10 to about 20,000 cps at 25EC measured on a RVT Brookfield Viscosimeter and a pH of from 5.0 to 6.5, said composition being applied as an eye drop into the fornix inferior of the infected eye one or two times daily.

6. A method according to claim 7, said composition comprising

Fusidic acid	about 1% w/v
"Carbopol 934"	about 0.5% w/v
Mannitol	about 5% w/v
Benzalkonium chloride ²	about 0.01% w/v
Tetracemin disodium	about 0.05% w/v,

said composition also having a pH value of approximately 5.8.

8. A method according to claim 7, wherein the preparation is used in dosages of from 5 to 100 mg.

9. A method according to claim 8, wherein the preparation is used in dosages of from 20 to 50 mg.

The references relied upon by the examiner are:

Godtfredsen et al. (Godtfredsen)	3,072,531	Jan. 8. 1963
Schoenwald et al. (Schoenwald)	4,271,143	Jun. 2, 1981

The references relied upon by this merits panel are:

² The term "chloride" is not present in the record copy of claim 6. See Paper No. 21, filed Jul. 22, 1992. The omission appears to be inadvertent. In the event of further prosecution, appellant should take the appropriate action to clarify the claim language.

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Great Britain Patent Application (Kogyo) 2,007,091 A May 16, 1979

Hansen, S. (Hansen), "Intraocular penetration of fusidic acid with topical Fucithalamic®," European Journal of Drug Metabolism and Pharmacokinetics, Vol. 10, No. 4, pp 329-331 (1985)

MEDLINE abstract AN 86164451 of Hansen

Claims 6 through 9 stand rejected under 35 U.S.C. § 103. The examiner relies upon Godtfredsen and Schoenwald as evidence of obviousness. We reverse the rejection. In addition, we make a new ground of rejection under 37 CFR § 1.196(b) and raise other issues for the examiner and appellant to consider.

DISCUSSION

Claim 7 is directed to a method of treating an eye infection that comprises the step of applying an effective amount of an ophthalmic gel composition as an eye drop into the fornix inferior of the eye (an arched shaped roof (or roof portion) of the eye). The ophthalmic gel composition, requires, inter alia, a viscosity of from 10 to about 20,000 cps at 25EC.

To establish prima facie obviousness of claimed subject matter, all the claim limitations must be taught or suggested by the prior art. See In re Royka, 490 F.2d 981, 984, 180 USPQ 580, 582 (CCPA 1974). The examiner has not pointed to any specific reason, suggestion, or motivation stemming from the prior art which would have led a

person having ordinary skill to a gel composition having a viscosity of from 10 to about 20,000 cps at 25EC.

Godtfredsen discloses that fusidic acid is a well-known antibiotic, which is effective against a number of pathogenic microorganisms. See Godtfredsen, Table 1.

Godtfredsen also discloses that fusidic acid may be mixed with a liquid or a solid pharmaceutical carrier, and may be used in any conventional form. Godtfredsen, column 6, lines 18-46. However, Godtfredsen does not disclose or suggest that fusidic acid can be used in a gel composition that has a viscosity of from 10 to about 20,000 cps at 25EC.

Schoenwald discloses that CARBOPOL polymers can be used as carriers for various antibiotics when the antibiotics are to be topically used. Schoenwald discloses that the use of such polymers with an antibiotic results in long-acting well-retained gel preparations which are especially suited for ophthalmic applications. Schoenwald, column 1, lines 59-62; column. 2, lines 57-59. Schoenwald discloses that such gel preparations have a viscosity of from about 40,000 to about 300,000 cps at 20 rpm (spindle 7) at 25EC generated by an RVT Brookfield Viscometer. Schoenwald, column 2, lines 21-26. Schoenwald does not disclose or suggest gel preparations having a viscosity of from 10 to about 20,000 cps as recited in claim 7.

Furthermore, the examiner has failed to consider the Jørgen Roed Jensen Rule 132 Declaration, Paper No. 25, filed Jan. 6, 1993, which is discussed by appellant to support

his arguments that the claims are not obvious over the prior art. See Brief, Paper No. 40, pages 8 and 13. “After evidence or argument is submitted by the applicant in response, patentability is determined on the totality of the record, by a preponderance of evidence with due consideration to persuasiveness of argument.”

In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). “If a prima facie case is made in the first instance, and if the appellant comes forward with reasonable rebuttal, whether buttressed by experiment, prior art references, or argument, the entire merits of the matter are to be weighed.” In re Hedges, 783 F.2d 1038, 1039-40, 228 USPQ 685, 686 (Fed. Cir. 1986).

The rejection under 35 U.S.C. § 103 is reversed.

NEW GROUND OF REJECTION UNDER 37 CFR § 1.196(b)

Under the provisions of 37 CFR § 1.196(b) we make the following new ground of rejection.

Claim 6 through 9 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.

Claim 7 requires that the gel composition comprise a CARBOPOL polymer.

Claim 6 requires that the gel composition comprise CARBOPOL 934. CARBOPOL and CARBOPOL 934 appear to be trademarks or trade names. As such, the scope of these terms is unclear because the terms do not identify any particular material or product. It is

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not clear whether appellant intends the claims to encompass only materials sold under the trademarks/trade names, or whether appellant intends the claims to encompass components of the type sold under those trademarks/trade names, regardless of the manufacturer. Also the use of a trademark in a claim to identify or describe a material or product may constitute an improper use of the trademark.

Claims 8 and 9 recite “the preparation,” which lacks unambiguous antecedent basis in claim 7 from which claims 8 and 9 depend. Claim 7 recites “an ophthalmic gel composition” and “fusidic acid in the form of particles.” It is not clear to what “the preparation” recited in claims 8 and 9 refers.

OTHER ISSUES

If prosecution is resumed on this subject matter in this application, the examiner and appellant should consider the following issues.

I. The examiner should consider whether Hansen is prior art under 35 U.S.C. § 102(a)³.

Hansen discloses applying FUCITHALMIC® to the eye in the form of drops to treat external eye infections. According to Hansen, FUCITHALMIC® is a one per cent microcrystalline suspension of fusidic acid in a “carbomer” gel, made isotonic with mannitol and pH adjusted to 5.6, and preserved with benzalkonium chloride and EDTA. Hansen, page 329, first paragraphs of columns 1 and 2. According to MEDLINE abstract AN 86164451, Hansen has a publication date of Oct-Dec 1985.

In a response filed in Paper No. 36, Oct. 27, 1994, to a rejection under 35 U.S.C. § 103 over Hansen, appellant argued that Hansen is not prior art for the following reasons: (1) the instant application has a foreign priority filing date of Jan. 7, 1985 (based on British patent application No. 8500310 (BP'310)), which precedes the Jan. 7, 1986 filing date of PCT/DK86/00002; (2) appellant's assignee in Denmark states that the relevant copy of Hansen was not received by them until March 10, 1986; and (3) FUCITHALMIC® is “appellant's assignee's product according to the invention.”

³ Chemical Abstracts (104) 199554 (1986) of Hansen was cited of interest in the Office action mailed Aug. 5, 1988, in the grandparent Application Serial No. 06/908,802. Hansen was cited as a reference in a prior art rejection set forth in Paper No. 35, mailed on Jul. 27, 1994.

In response, the examiner removed the rejection over Hansen, without comment.
See Final rejection, Paper No. 37, mailed Jan. 31, 1995.

(1) Under 35 U.S.C. § 119, the claims in a United States application are entitled to the benefit of a foreign priority date if the corresponding foreign application supports the claims in the manner required by 35 U.S.C. § 112, first paragraph. In re Gosteli, 872 F.2d 1008, 1010, 10 USPQ2d, 1614, 1616 (Fed. Cir. 1989).

From a review of the priority document BP'310, it does not appear that BP'310 adequately describes the subject matter recited in claims 6 through 9 in the manner required by 35 U.S.C. § 112, first paragraph, for the following reasons:

(a) In claim 7, the limitation “viscosity of from 10 to about 20,000 cps at 25EC measured on a RVT Brookfield Viscosimeter” of the gel composition is not described in BP'310.

(b) In claim 7, the recited fusidic acid particle size of between 2 and 5 μm is not described in BP'310.

(c) In claim 7, the recited amount “about 1 % w/v” (emphasis added) of fusidic acid is not described in BP'310. Compare BP'310, page 2, line 25, which discloses the amount of “1 % w/v” of fusidic acid.

(d) In claim 6, the various recited amounts “about ___% w/v” are not described in BP’310. Compare BP’310, page 4, line 7, which discloses a composition comprising specific amounts (e.g., 10 mg) of the components recited in claim 6.

(e) In claim 8, the recited dosage of “from 5 to 100 mg” is not described in BP’310. Compare BP’310, page 3, lines 11-12, which discloses the dosage from 5 to 50 mg.

Accordingly, it does not appear that appellant is entitled to claim priority under 35 U.S.C. § 119. Thus, it appears that the effective filing date of the subject matter of claims 6 through 9 is, at best, the PCT filing date of Jan. 7, 1986.

(2) Appellant’s statement with respect to the availability of Hansen is unsupported on the present record. Appellant has not provided any evidence to support his assertion that Hansen was first available March 10, 1986. More relevant evidence would be a statement from the publisher of the journal as to the mailing date to all subscribers of the journal, not just to those in Denmark.

(3) Appellant’s statement that FUCITHALMIC® is “appellant’s assignee’s product according to the invention” does not appear to remove Hansen as prior art under 35 U.S.C. § 102(a), since Hansen is not a named co-inventor of this application. Further explanation of appellant’s position is needed.

II. The examiner and appellant should consider whether the marketing of FUCITHALMIC® has created prior art under 35 U.S.C. §§ 102(a) or 102(b). From the

disclosure in Hansen and appellant's statement that FUCITHALMIC® is "appellant's assignee's product according to the invention," it is not clear when FUCITHALMIC® was first known by the public. If product brochures, marketing advertisements, package data, etc. were publicly available prior to the effective filing date, such material would be relevant in considering the patentability of claims 6 through 9. Determining the circumstances surrounding the marketing of FUCITHALMIC® would be relevant in determining whether the product brochures, marketing advertisements, package data, etc. are prior art under 35 U.S.C. § 102.

III. The examiner and appellant should also review the disclosure of Kogyo⁴, and determine whether this reference combined with the disclosure of Godtfredsen or other relevant prior art renders obvious claims 6 through 9 under 35 U.S.C. § 103. The following is a list of some of the relevant teachings of Kogyo and Godtfredsen that the examiner should consider.

(1) Kogyo discloses ophthalmic gel compositions that comprise an aqueous solution of a carboxyvinyl polymer, a water-soluble basic substance, and an ophthalmic drug admixed therewith. Said gel compositions can have a pH of 5 to 8 and a viscosity of

⁴ Kogyo is the British equivalent of French Patent Application 2,407,214. The French Patent Application was cited as a "Y" reference in the PCT search report of PCT/DK86/00002.

1,000 cps to 100,000 cps at 20EC. Kogyo discloses that the carboxyvinyl polymer can be a CARBOPOL polymer. Kogyo, page 1, lines 40-54.

(2) Kogyo discloses that the carboxyvinyl polymer is used in the form of an aqueous solution having a concentration of 0.05 to 5.0% by weight. Kogyo, page 2, lines 99-102.

(3) Kogyo discloses that the ophthalmic drug used in the gel compositions can be insoluble or soluble in water. Kogyo, page 1, lines 87-89. Kogyo discloses that the ophthalmic drug includes antibiotics. Kogyo, page 1, line 129, to page 2, line 3. Said ophthalmic drug can be dissolved or dispersed in the aqueous carboxyvinyl polymer solution. Kogyo, page 2, lines 11-15.

(4) Kogyo discloses that the gel compositions that have a viscosity of from 1,000 to 10,000 cps have good flowability. Said gel compositions can be applied as drops directly on to the mucous membrane around the eyeball. Kogyo, page 2, lines 46-49.

(5) Kogyo discloses that when its ophthalmic gel compositions are applied, the tears liquefy the gel to give a liquid which can be readily absorbed by the mucous membrane and cornea. Kogyo, col. 2, lines 56-59. Kogyo discloses that conventional eye lotions, which have a viscosity of less than 1,000 cps, are likely to be washed away by tears. However, Kogyo also discloses that its gel compositions ensure the adsorption of the ophthalmic drug on the mucous membrane of the eye or the like. Accordingly, Kogyo

discloses that the gel compositions can produce sufficient medicinal effects without being washed away by tears. Kogyo, page 2, lines 64 to 71.

(6) Kogyo further discloses that the gel compositions cause no discomfort to the patient since they are free from oleophilic base ingredients. Kogyo, page 2, lines 82-84.

(7) Kogyo discloses that when gel compositions that have a viscosity of from 1,000 to 10,000 cps are applied to the eye, the mucous membrane of the eye absorbs the drug rapidly. Kogyo, page 2, lines 84-87.

(8) Kogyo discloses that when sustained efficacies are desired, a small amount of sodium chloride can be added to the gel compositions to “delay” the breakdown of the gel when the compositions are applied to the mucous membrane of the eye. Kogyo discloses that although the addition of a small amount of sodium chloride to the aqueous solution of the gel compositions converts the gel to a liquid, greatly reducing its viscosity, the amount of carboxyvinyl polymer can be increased to compensate for this reduction of viscosity. Kogyo, page 2, lines 107-125.

(9) Godtfredsen discloses that fusidic acid and certain salts thereof are well known antibiotics which are effective against a number of pathogenic microorganisms. See Godtfredsen, Table 1.

(10) Godtfredsen also discloses that fusidic acid and salts thereof may be mixed with a liquid or a solid pharmaceutical carrier, and may be used in any conventional form. Godtfredsen, column 6, lines 18-46.

(11) Godtfredsen discloses that fusidic acid and salts thereof can be isolated in particulate form. Godtfredsen, column 2, lines 16-21; column 5, lines 41-46. Godtfredsen exemplifies a topical ointment in which the sodium salt of fusidic acid is used in particulate form. Godtfredsen, column 6, lines 56-74.

In reviewing the above facts, the examiner should determine whether the subject matter recited in claims 6 through 9 as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which this subject matter pertains over the combined disclosures of Kogyo and Godtfredsen. In determining the patentability of claims 6 through 9, the examiner should also consider the facts presented in the Jensen Rule 132 Declaration. Patentability is determined on the totality of the record, by a preponderance of evidence with due consideration to persuasiveness of argument. See Oetiker, supra. "If the appellant comes forward with reasonable rebuttal, whether buttressed by experiment, prior art references, or argument, the entire merits of the matter are to be weighed." Hedges, supra.

IV. From a review of the application file, it is noted that priority under 35 U.S.C. § 119 is claimed to British patent application 8500310 filed Jan. 7, 1985. See the substitute

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Declaration filed Jul. 16, 1993, attached to Paper No. 31. However, the application file cites that priority is claimed to Denmark patent application 8500310 filed Jan. 7, 1985. Upon return of the application, the examiner should ensure that all appropriate PTO records, including the application file, are updated to reflect the correct priority document.

TIME PERIOD OF RESPONSE

This decision contains a new ground of rejection pursuant to 37 CFR § 1.196(b)(amended effective Dec. 1, 1997, by final rule notice, 62 Fed. Reg. 53,131, 53,197 (Oct. 10, 1997), 1203 Off. Gaz. Pat. & Trademark Office 63, 122 (Oct. 21, 1997)). 37 CFR § 1.196(b) provides that, "A new ground of rejection shall not be considered final for purposes of judicial review."

37 CFR § 1.196(b) also provides that the appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of proceedings (§ 1.197(c)) as to the rejected claims:

(1) Submit an appropriate amendment of the claims so rejected or a showing of facts relating to the claims so rejected, or both, and have the

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matter reconsidered by the examiner, in which event the application will be remanded to the examiner. . . .

(2) Request that the application be reheard under § 1.197(b) by the Board of Patent Appeals and Interferences upon the same record. . . .

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

REVERSED; 37 CFR § 1.196(b)

Sherman D. Winters)	
Administrative Patent Judge)	
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