IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

KAO CORPORATION and THE ANDREW JERGENS COMPANY,)))		
Plaintiffs,)		
ν.)))	Civ. No.	01-680-SLR
UNILEVER UNITED STATES, and CONOPCO, INC.,	INC.)))		
Defendants.)		

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OPINION

Dated: September 3, 2004 Wilmington, Delaware

ROBINSON, Chief Judge

I. INTRODUCTION

On October 9, 2001, Kao Corporation and The Andrew Jergens Company (collectively "plaintiffs") filed a patent infringement action under 35 U.S.C. § 271 against Chesebrough-Pond's USA Co. (D.I. 1) Plaintiffs allege that Chesebrough-Pond's USA Co. infringed U.S. Patent No. 6,299,605 (the "`605 patent") by manufacturing and selling its Pond's clear pore strips in the United States. (Id. at \P 6) On May 12, 2001, plaintiffs filed a first amended complaint to remove Chesebrough-Pond's USA Co. as a defendant and to add Unilever United States, Inc. and Conopco Inc. as defendants (collectively "defendants").¹ (D.I. 3) On November 15, 2001, plaintiffs filed a second amended complaint alleging inducement of infringement of U.S. Patent No. 6,306,382 (the "`382 patent"). (D.I. 25 at \P 7)

On December 14, 2001, defendants answered plaintiffs' three complaints denying all infringement allegations. (D.I. 12) Defendants raised affirmative defenses of noninfringement and invalidity of the '605 and '382 patents for failure to comply with the patent laws of the United States and unenforceability of the '382 patent due to inequitable conduct. (Id. at ¶¶ 10, 11, 12) Defendants likewise filed a declaratory judgment counterclaim against plaintiffs seeking a declaration that the

¹Chesebrough-Pond's USA Co. is a division of Conopco Inc. (D.I. 77, ex. A) It markets and sells Pond's clear pore strips. (<u>Id.</u>)

`605 and `382 patents are not infringed and invalid and that the `382 patent is unenforceable due to inequitable conduct. (Id. at $\P\P$ 13-15) Defendants further counterclaimed that plaintiffs infringed U.S. Patent No. 6,106,857 (the ``857 patent") by the sale and offer for sale of Biore ULTRA nose strips in the United States. (Id. at \P 17)

On January 25, 2002, plaintiffs denied defendants' counterclaims and asserted affirmative defenses. (D.I. 14) Plaintiffs also filed a counterclaim seeking a declaratory judgment of noninfringement and invalidity of the '857 patent. (<u>Id.</u>) On February 14, 2002, defendants responded to plaintiffs' counterclaim re-asserting infringement of the '857 patent and denying that the '857 patent is invalid. (D.I. 16) The court has jurisdiction over this suit pursuant to 28 U.S.C. §§ 1331, 1338(a).

During fact discovery, the parties agreed to dismiss all claims relating to both the '605 patent and the '857 patent. (D.I. 66 at 1) Subsequently, plaintiffs withdrew their claim for damages related to the '382 patent, leaving only claims for injunctive relief and attorney fees in suit. (<u>Id.</u> at 2)

For three days in October 2003, the parties tried before the court the issues of: (1) claim construction; (2) infringement; (3) invalidity based upon inadequate written description, indefiniteness, and obviousness; and (4) unenforceability based on inequitable conduct. The following are the court's findings

of fact and conclusions of law pursuant to Fed. R. Civ. P. 52(a).

II. FINDINGS OF FACT

A. The Parties

 Plaintiff Kao Corporation is a Japanese corporation with its corporate headquarters in Tokyo, Japan.
(D.I. 77 at ¶ 1)

2. Plaintiff The Andrew Jergens Company is a Delaware corporation with its corporate headquarters in Cincinnati, Ohio. (Id. at \P 2)

3. Defendant Unilever United States, Inc. is a Delaware corporation with its corporate headquarters in New York, New York. (Id. at \P 3)

4. Defendant Conopco, Inc. is a New York corporation with its headquarters in New York, New York. (Id. at \P 4)

B. The '382 Patent

5. The application which matured into the `382 patent was filed on November 12, 1996 and entitled "Keratotic Plug Remover."

6. The '382 patent was granted on October 23, 2001.

7. The named inventors include Tomohiro Uemura, Masanori Tanahashi, and Yoshinao Kono. Plaintiffs jointly own the '382 patent. (<u>Id.</u> at Ex. A)

8. The '382 patent claims priority as a divisional application to U.S. Application No. 463,274 filed on June 5, 1995, which claims priority as a continuation-in-part of U.S.

³

Application No. 210,778² filed on March 21, 1994, which claims priority as a continuation-in-part of U.S. Application No. 882,979 filed on May 14, 1992.

9. The '382 patent generally discloses a keratotic plug remover composition and method of removing keratotic plugs from the skin. ('382 patent, col. 1 at 11. 13-16)

10. The specification describes eight examples relating to the preparation and use of a liquid or semi-solid copolymer preparation. The examples do not mention drying the liquid or semi-solid copolymer onto a substrate, but instead discuss applying the copolymer directly to the face. Example 1 specifically states: "A panel washed their face and used the preparation on their faces at an application rate of 0.1 ml/cm²." ('382 patent, col. 6 at ll. 6-8) Example 2 states: "The polymers were individually prepared into an aqueous 20-30% by weight solution, and members of the panel used in the same manner as in Example 1." ('382 patent, col. 7 at 11. 21-23) Similarly, example 3 describes liquid formulations that were applied as described in example 1. Examples 4-8 do not expressly state that the keratotic plug remover was applied as a liquid formulation. Nevertheless, these examples offer formulations in terms of percent weight, like the formulations described in examples 1-3.

²U.S. application 210,778 granted as U.S. Patent No. 5,512,277 (the "`277 patent"). Plaintiffs did not assert the `277 patent against defendants.

11. The '382 patent contains seven claims in total.

Plaintiffs asserted only independent claim 1 and dependent claim

3 against defendants.

12. Claim 1 recites:

A method for removing keratotic plugs from skin with a cosmetic article, which comprises: wetting the skin or said cosmetic article; applying onto the skin said cosmetic article; and peeling off said cosmetic article after drying; wherein said cosmetic article comprises:

- a substrate selected from the group consisting of woven cloth, non-woven cloth and a plastic film; and
- ii) on said substrate, a layer comprising a copolymer, in an amount effective to remove keratotic plugs, wherein said copolymer is a poly(alkyl vinyl ether/maleic acid) copolymer or a polyalkylvinyl ether/maleic anhydride) copolymer.³

('382 patent col. 12 at 11. 58-66; col. 13 at 11. 1-9)

13. Claim 3 recites:

The method of claim 1, wherein said substrate is a non-woven cloth.

('382 patent, col. 13 at 11. 12-13)

14. Claims 6 and 7 are also dependent claims, each

reciting respectively:

- The method of claim 1, wherein said layer comprises 5 to 70 wt. % based on the total weight of said layer of said copolymer.
- 7. The method of claim 1, wherein said layer comprises 5 to 40 wt. % based on the total weight of said layer of said copolymer.

³The court abbreviates the terms "poly(alkyl vinyl ether/maleic acid) copolymer" and "polyalkylvinyl ether/maleic anhydride) copolymer" as "PVM/MA" in this opinion.

('382 patent, col. 14 at ll. 6-11)

15. The specification of the '382 patent does not define the term "cosmetic article" as used in claim 1. Instead, the specification states that "[t]he keratotic plug remover according to this invention may take a form of a poultice using cotton cloth, rayon cloth, tetron cloth, nylon cloth, either woven or non-woven, or using a plastic film sheet, beside pack preparations." ('382 patent, col. 5 at 11. 19-25) The specification further states that "[t]he manner of removing keratotic plugs by the use of the keratotic plug remover of the invention is the same as the manner of using ordinary packs and poultice. Namely, when a pack preparation is used, it is first applied to the part of the skin which has keratotic plugs, particularly likely to the nose, chin, and forehead, and after dried, it is peeled off."⁴ ('382 patent, col. 5 at 11. 26-28)

16. The specification of the '382 patent does not define the term "amount effective" as used in claim 1. The specification only states that "[t]he preferable amount of the polymer to be incorporated into the keratotic plug remover preparation according to the invention is from 0.01 to 70% by weight, preferably 5 to 40% by weight based on the total weight

⁴In the context of cosmetics, the term "pack" means "a cosmetic paste applied to the skin and allowed to dry." American Heritage Dictionary 891 (New College Ed. 1976). The term "poultice" means "a moist, soft mass of bread, meal, clay, cloth, or other adhesive substance, usually heated, spread on cloth, and applied to warm, moisten, or stimulate an aching or inflamed part of the body." <u>Id.</u> at 971.

of the preparation." ('382 patent, col. 3 at 11. 27-30) The specification also discloses that the polymers are dissolved in solvent and that the amount of solvent is modified depending on the properties of the polymer compounds and is generally from 30 to 99.99% by weight, and preferably from 60 to 95% by weight, based on the total weight of the composition. (See '382 patent, col. 3 at 11. 31-41) The examples describe polymer amounts in the 5 to 40% range by weight, primarily from 15 to 35% by weight. (See '382 patent, col. 6-col. 12)

C. The Prosecution History of the '382 Patent

17. Plaintiffs filed the application, which granted as the '382 patent, with eighteen claims. (<u>See</u> PX 41 at 45-47) On March 24, 1997, plaintiffs canceled claim 1 and added claims 19-28 by preliminary amendment. (<u>See id.</u> at 56-59)

18. On November 1, 1997, plaintiffs amended claim 19 and added new claims 29-31. (See id. at 86-87) Plaintiffs also submitted a declaration from Mr. Tomoshiro Uemura ("the 1997 Uemura declaration") to overcome the rejection of claims 19-28 as obvious under 35 U.S.C. § 103(a) over U.S. Patent No. 4,026,552 ("the Gueret '552 patent") or U.S. Patent No. 4,948,585 in view of JP 53-27344. (Id. at 87-95) Mr. Uermura compared the effectiveness of keratotic plug removal for various salt-forming polymers as claimed in the '382 patent and various non-ionic polymers. Mr. Uemura specifically tested the non-ionic polymer polyvinyl alcohol because the compound was the only one

exemplified in the Gueret '552 patent. (Id. at 72-85; see infra Conclusions of Law, Section C) In this regard, Mr. Uemura explained that pack preparations of the polymers were made. (Id. at 72) Test subjects washed their faces and then applied the polymer pack preparations at a rate of 0.1 ml/cm³. (Id.) Mr. Uemura stated that polyvinyl alcohol was evaluated to have less than a 5% removal ratio for keratotic plugs. (Id. at 74) In contrast, the select salt forming polymers disclosed in the '382 patent were evaluated to have a greater than 20% removal ratio for keratotic plugs. (Id.)

19. On March 4, 1998, the examiner maintained the obviousness rejection in a final rejection, despite the comparative test data presented in the 1997 Uemura declaration. (Id. at 100) The examiner reasoned that "[t]he polyacrylic salts of Gueret et al. are not distinguishable from 'salt-forming' group-containing polymers as claimed. The [1997] Uemura [d]eclaration results show improvement with use of certain copolymers which are comprised of critical monomers. Thus, the claims are not commensurate in scope with the [d]eclaration showing." (Id. at 101)

20. On March 27, 1998, the examiner participated in an interview with plaintiffs. (<u>Id.</u> at 104) The examiner noted in the interview summary that "[c]laims are suggested to be limited to the scope of copolymers of Uemura et al 5,512,277. Keratotic plug removal effectiveness is suggested as a necessary claim

limitation. Claims so limited may overcome the rejections of record." (Id.)

21. On August 10, 1998, plaintiffs filed a notice of appeal of the final rejection. (<u>Id.</u> at 106) On October 8, 1998, plaintiffs engaged in another interview with the examiner regarding the appeal. (<u>Id.</u> at 109) The examiner recorded in the interview summary that a continued prosecution application ("CPA") was to be filed. (<u>Id.</u>)

22. On October 8, 1998, plaintiffs filed a CPA cancelling claims 19-31 and adding new claims 32-38.⁵ (<u>See id.</u> at 116-117) Claims 32 and 38 recited respectively:

- 32. A cosmetic article, comprising:
 - a substrate selected from the group consisting of woven cloth, non-woven cloth and a plastic film; and
 - ii) a layer comprising 5 to 70 wt % based on the total weight of said layer of a copolymer comprising an alkyl vinyl ether and maleic acid or an anhydride on said substrate.
- 38. A method for removing keratotic plugs which comprises applying the keratotic plug remover composition of Claim 32 onto the nose, and peeling off said composition after said composition is dried.

(<u>Id.</u> at 116-117)

23. On December 30, 1998, the examiner indicated in an interview summary that the "claims [would] be amended by examiner's amendment to define the copolymer units and keratotic

⁵Claim 38 in the application leading to the '382 patent granted as claim 1 in the '382 patent. For sake of clarity, the court will refer to this claim as "claim 38" when referencing the prosecution history.

plug removal activity." (Id. at 125) The examiner also stated that claims 32-38 were allowable with the aforementioned changes. (Id.) Thereafter, the examiner provided a formal notice of allowability for claims 32-38. (Id. at 127)

24. On March 25, 1999, after paying the issue fee, plaintiffs filed a petition to withdraw the case from issue. (<u>Id.</u> at 133) Plaintiffs sought to submit additional references resulting from a prior art search.

25. On May 16, 1999, plaintiffs filed a second CPA and a preliminary amendment to revise claim 38.

- 38. (Amended) A method for removing keratotic plugs which comprises applying [the keratotic plug remover composition of Claim 32] <u>a cosmetic</u> <u>article, comprising:</u>
 - i) <u>a substrate selected from the group</u> <u>consisting of woven cloth, non-woven cloth</u> <u>and a plastic film; and</u>
 - ii) a layer comprising a copolymer based on monomer units comprising an alkyl vinyl ether and a monomer selected from the group consisting of maleic acid or an anhydride on said substrate, onto the [nose] skin, and peeling off said composition after said composition is dried.

(<u>Id.</u> at 141) (underlined texts shows additions and bracketed text shows deletions) Plaintiffs stated that "[a]pplicants have discovered that a cosmetic article having a substrate [] deposited thereon, said copolymer is unexpectedly superior in removing keratotic plugs, as compared with an article having deposited thereon a polymer which does not contain salt forming groups." (<u>Id.</u> at 142-143)

26. On May 21, 1999, plaintiffs submitted a second

declaration from Mr. Uemura ("1998 Uemura declaration") with test results describing keratotic plug removal. (<u>Id.</u> at 150-152) Mr. Uemura submitted data for two samples of a copolymer solution of a particular weight PVM/MA (i.e., Gantretz AN-169, molecular weight 70,000). Mr. Uemura discussed coating an aqueous solution of Gantretz AN-169 on a plastic liner and then covering the layer of copolymer with a sheet of non-woven rayon, thereby impregnating the copolymer solution onto the sheet. (<u>Id.</u>) Mr. Uemura explained:

[T]he impregnated rayon non-woven sheet was dried and the final product was obtained. The content of copolymer in the pack . . . was 78%. . . . The pack was used by wetting with water, then applied to the nose.

(<u>Id.</u> at 151) Mr. Uemura reported that the pack was removed after fifteen minutes with a keratotic plug removal ratio of 23%.

(<u>Id.</u>) Mr. Uermura concluded:

The data described above, demonstrating the effectiveness of a copolymer of methylvinylether and maleic anhydride is commensurate in scope for claims directed to a method of keratotic plug removal using a copolymer of an alkyl vinyl ether and maleic acid or an anhydride thereof, as there is no reason to expect any significant difference in keratotic plug removal for other polymers within the claimed genus.

(<u>Id.</u>)

27. On November 3, 1999, plaintiffs participated in another interview with the examiner.⁶ (Id. at 168) The examiner

⁶There is no formal interview summary form prepared by the examiner to document the occurrence of this November 3, 1999 interview. Plaintiffs, however, appear to have documented the interview in their request for reconsideration.

stated that the application was in condition for allowance provided that the claims were amended to recite that the polymer was present in an amount sufficient to remove keratotic plugs. (Id.)

28. On November 19, 1999, plaintiffs amended claim 38 for a second time to add the language suggested by the examiner.

- 38. (Twice Amended) A method for removing keratotic plugs which comprises applying a cosmetic article, comprising:
 - a substrate selected from the group consisting of woven cloth, non-woven cloth and a plastic film; and
 - ii) a layer comprising a copolymer, <u>in an</u> <u>amount effective to remove keratotic plugs</u>, based on monomer units comprising an alkyl vinyl ether and a monomer selected from the group consisting of maleic acid or an anhydride <u>thereof</u> on said substrate, onto the [nose] skin, and peeling off said composition after said composition is dried[, wherein said article possesses keratotic plug removal activity].

(<u>Id.</u> at 167-168) (underlined text shows additions and bracketed text shows deletions)

29. On March 23, 2000, plaintiffs submitted preliminary remarks to the examiner in conjunction with an information disclosure statement and a petition to correct inventorship. (Id. at 191-93) Plaintiffs also supplemented the test data originally presented to the examiner in the 1998 Uemura declaration. Plaintiffs explained that Gantretz AN-119, a copolymer of PVM/MA having a molecular weight of 20,000, has been tested for the ability to remove keratotic plugs in addition to the samples of Gantretz AN-169. Plaintiffs shared that the

Gantretz AN-119 had a keratotic removal ratio of 14%. Plaintiffs

also stated:

Although the molecular weight of 20,000 is not as close to the molecular weight of 70,000 previously reported, the copolymer at a molecular weight of 20,000 still showed an increased effectiveness at this much lower molecular weight. . . The additional test results provides further support of the effectiveness of the claimed copolymer based on monomer units comprising an alkyl vinyl ether and a monomer selected from the group consisting of maleic acid or an anhydride thereof.

(<u>Id.</u> at 192)

30. On September 29, 2000, plaintiffs submitted a third amendment to claim 38 in response to an office action issued by the examiner on June 1, 2000.

- 38. (Three times amended) A method for removing keratotic plugs which comprises applying a cosmetic article, comprising:
- a substrate selected from the group consisting of woven cloth, non-woven cloth and a plastic film; and
- ii) a layer comprising a copolymer, in an amount effective to remove keratotic plugs, based on monomer units comprising an alkyl vinyl ether and a monomer selected from the group consisting of maleic acid or an anhydride thereof on said substrate, onto the skin, and the peeling off said [compositing] <u>cosmetic article</u> after said composition is dried.

(<u>Id.</u> at 206-207)) (underlined texts shows additions and bracketed text shows deletions) Plaintiffs explained that this amendment was intended to clarify the claim and correct a typographical error in the last line. (<u>Id.</u> at 207) Plaintiffs also submitted a declaration from Mr. Tomohiro Fukita to clarify the data presented in the 1998 Uemura declaration. (<u>Id.</u> at 214-215) Mr.

Fukita performed additional testing with the same polymer solution used by Mr. Uemura (i.e., Gantretz AN-169). (Id.) Mr. Fukita described neutralizing the copolymer solution by adding NaOH to bring the pH of the solution to a pH of 6 prior to impregnating the sheet with polymer. (Id. at 215) Mr. Fukita explained: "The polymer solution was quickly covered with a sheet of non-woven . . . and dried. In order to determine the keratotic plug removal effectiveness, the pack was wetted with water and applied to the nose of four subjects. After nose application, the pack was allowed to dry for about [fifteen] minutes." (Id.) Mr. Fukita tested two packs and measured the polymer content to be 78.8% and 79.6%.⁷ (Id. at 216) Mr. Fukita reported that the average keratotic plug removal was 24%. (Id.)

31. On January 16, 2001, plaintiffs participated in another interview with the examiner. In the interview summary, the examiner acknowledged that Japanese reference 25871 "has carboxylic copolymer but no showing of effectiveness to remove keratotic plugs or substrate. Copolymers will be limited to maleic anhydride/methyl vinyl ether and maleic acid/methyl vinyl ether with terms such as 'based on' or 'comprising monomers' being deleted." (Id. at 247) The examiner also documented that

⁷Mr. Fukita also explained that Mr. Uemura assumed the polymer content in his testing to be 78%. (<u>Id.</u> at 216) Mr. Fukita commented that "the assumptions used to estimate the polymer levels in the prior [d]eclarations were reasonable assumptions and gave good estimates of the polymer level." (<u>Id.</u>)

plaintiffs agreed to clarify the wetting and drying steps of claim 38. (Id. at 248-249) The examiner noted that the claims so limited were allowable. (Id.)

32. On February 22, 2001, plaintiffs amended claim 38 for the fourth time pursuant to their agreement with the examiner.

- 38. (Four times Amended) A method for removing keratotic plugs <u>from skin with a cosmetic article</u>, which comprises: <u>wetting the skin or said cosmetic article</u>; applying <u>onto the skin</u> [a] <u>said</u> cosmetic article; <u>and</u> <u>peeling off said cosmetic article after drying</u>; <u>wherein said cosmetic article comprises;</u>[, comprising:]
 - a substrate selected from the group consisting of woven cloth, non-woven cloth and a plastic film; and
 - ii) <u>on said substrate</u>, a layer comprising a copolymer, in an amount effective to remove keratotic plugs, <u>wherein said copolymer is a</u> <u>poly(alkyl vinyl ether/maleic acid) copolymer</u> <u>or a poly(alkyl vinyl ether/maleic anhydride)</u> <u>copolymer</u> [based on monomer units comprising an alkyl vinyl ether and a monomer selected from a group consisting of maleic acid or an anhydride thereof on said substrate, onto the skin, and peeling off said cosmetic article after said composition is dried].

(<u>Id.</u> at 266) (underlined test shows additions and bracketed text shows deletions) Plaintiffs explained that "[t]he claim has further been amended to clarify the steps of the method. The addition of the wetting step is not further limiting since the wetting step was implied in the previously submitted claim. No new matter would be added by entry of this amendment." (<u>Id.</u> at 260)

D. History of the 1998 Uemura Declaration

33. In 1998, under the supervision of Mr. Uemura, Mr. Fukita tested the keratotic plug removal capacity of Gantretz AN-119, Gantretz AN-169, and polyvinyl alcohol. (DTX 192) He reported the results of this testing in his laboratory notebook. The low molecular weight Gantretz AN-119 sample had a keratotic removal ratio of 14.2% with an error of 5.2%, whereas the higher molecular weight Gantretz AN-169 sample had a keratotic removal ration of 23.3% with an error of 7.1%. (Id.) Mr. Fukita also documented that the polyvinyl alcohol sample had a keratotic removal ratio of 3.7%; he did not record a margin of error for this sample. (Id.)

34. Mr. Fukita could not remember why he opted to test two different molecular weights of PVM/MA. (D.I. 88 at 715)

35. The persons involved in the 1998 Uemura declaration are not able to explain how the data was selected for presentation to the examiner. In this regard, Mr. Uemura could not remember why he did not report the results for the low weight Gantretz AN-119 or the margins of error in his declaration. (<u>Id.</u> at 694-695, 697; 719) Mr. Uemura testified in his deposition as follows:

- Q: Did you decide not to include the margin of errors in the results that you reported in your declaration?
- A: I don't remember.
- Q: Do you know if anyone knows why the margin of error was not included in the results that you reported in your declaration marked as Exhibit 22?

A: That's the document I declared, and I don't know. * * *

- Q: So you're the only person who can explain why the margin of error was not included in your declaration; is that what you are saying?
- A: I declared the document, and I could be the only one who knows why.
- Q: But as you sit here today, you're not able to explain to me why a margin of error was not included in the declaration; is that correct?
- A: No. I have not said such a thing.
- Q: Then please explain to me why a margin of error was not included in your declaration.
- A: I said I don't remember.

(Id. at 694-95) Similarly, Mr. Fukita stated in his deposition:

- Q: And did you provide these results to Mr. Uemura?
- A: I don't remember.
- Q: Do you know if these results were ever
- incorporated into a declaration?
- A: I don't remember. May I take a break?

(<u>Id.</u>) Mr. Richard Chinn, the patent attorney who helped to prepare the 1998 Uemura declaration, likewise testified in his

deposition:

- Q: Do you know whether the results that appear in this declaration reflect all the results that were obtained in experiments performed to obtain these results?
- * * *
- A: I cannot recall.
- Q: Do know if additional results were transmitted to you, but you - but chosen not to be submitted to the PTO at the time that that declaration was being prepared?
- A: I can't recall.
- Q: Is it possible that additional results were transmitted to and chosen by you not to submit to the PTO?
- A: I don't recall.
- Q: You don't recall if that's possible?
- A: I can't recall the time frame, so I can't recall.

(<u>Id.</u> at 766-67)

36. Mr. Chinn was unable to explain any of the

circumstances surrounding the late disclosure of the keratotic removal ratio for the Gantretz An-119 sample. He stated the following during his deposition:

- Q: Whose decision was it to submit the results that are reported here in the last two paragraphs of Page 2 of Exhibit 23 [referring to the preliminary remarks dated March 23, 2000]?
- A: I cannot recall.
- Q: Where did you get the data that you reported in the preliminary remarks on Page 2 of the preliminary remarks?
- A: I cannot recall.

(<u>Id.</u> at 782)

E. Plaintiffs' Other Patent Filings

37. Five years after filing the application which granted as the '382 patent, plaintiffs filed U.S. Application No. 843,857 on April 30, 2001. This application granted on August 19, 2003 as U.S. Patent No. 6,607,719 (the "'719 patent") and claimed priority as a continuation of the '382 patent. It has the same specification as the '382 patent and contains four claims. Claim 1 is directed to a method for removing keratotic plugs from skin with a cosmetic article. This claimed method recites the exact steps and substrate disclosed in claim 1 of the '382 patent. Claim 1 of the '719 patent, however, changes the copolymer composition. In particular, claim 1 of the '719 patent recites: "wherein said copolymer is a copolymer containing units obtained from (a) a member selected from the group consisting of alkyl vinyl ethers and derivatives thereof and (b) at least one

member selected from the group consisting of maleic acid, maleic anhydride, and derivatives thereof, or a salt of said copolymer." ('719 patent, col. 10 at 11. 48-53) Claim 4 of the '719 patent is dependent on claim 1 and recites:

The method of claim 1, wherein said effective keratotic plug removal amount is in a range of from 0.01 to 70% by weight of total polymer composition.

('719 patent, col. 10 at 11. 59-61)

F. The Accused Infringing Product

38. Defendants' Pond's clear pore strips are advertised to remove blackheads and unclog pores. (<u>See</u> PTX 66; <u>see also</u> DTX 44)

39. The Pond's clear pore strips consist of a coated non-woven fabric. (PX 73 at CP014324)

40. The product lists the ingredients⁸ used in the manufacture of defendants' product as PVM/MA copolymer and aminomethyl propanol ("AMP"). (PTX 66; DTX 44)

41. The coating for the Pond's clear pore strips is specifically prepared by mixing 98% by weight of a solution of PVM/MA with 2% by weight of AMP. (PX 73 at CP014328; D.I. 208, 211) The AMP reacts with the PVM/MA to form a salt, as shown in the figures below, designated as the "AMP-Reacted PVM/MA Salt" and "Acid-Salt Copolymer," respectively. (D.I. 86 at 215-216; D.I. 87 at 417-418, 422; DTX 508; DTX 509)

⁸Pursuant to 21 C.F.R. 700.3(e), "[t]he term ingredient means any single chemical entity or mixture used as a component in the manufacture of a cosmetic product."





Nevertheless, the neutralization reaction does not go to 100% completion; only 15% of the acid groups include a salt. (<u>See</u> D.I. 86 at 102-103) Put differently, 29% of the repeating PVM/MA monomer units include a salt while 71% of the repeating PVM/MA momomer units do not include a salt. (<u>See id.</u> at 223)

42. The PVM/MA acid-salt⁹ has physical and chemical properties distinct from the PVM/MA starting material. Specifically, the PVM/MA acid-salt has a different solubility, viscosity, chemical spectra, acidity, and plasticity than the claimed PVM/MA.¹⁰ First, the claimed PVM/MA and AMP are separately soluble in the solvent tetrahydrofuran ("THF")¹¹ whereas the PVM/MA acid-salt forms an insoluble gel in THF. (See <u>id.</u> at 207-210; 242-243; <u>see also</u> DTX 507) This solubility difference indicates that the chemical bonding in the PVM/MA acid-salt is different from the chemical bonding in the claimed PMV/MA. (<u>See</u> D.I. 86 at 212) Second, the viscosity of the PVM/MA acid-salt is 100% greater than the viscosity of the

⁹The resulting salt product does not have a particular name and is referred to as the "PVM/MA acid-salt" by the parties. (<u>See</u> D.I. 87 at 421)

¹⁰Solubility, viscosity, and infrared spectral analysis are common testing methods used to distinguish copolymers. (D.I. 86 at 126, 130, 131, 196, 243-244; D.I. 87 at 433-434) "[I]nfrared spectroscopy basically shows the fingerprint of the molecule, which is basically clear identification of covalent bonds or of chemical bonds." (D.I. 86 at 235-236)

¹¹THF is commonly used as the solvent of choice in testing the solubility of polymers. (D.I. 86 at 210)

claimed PVM/MA. The viscosity of the PVM/MA acid-salt is also greater than the viscosity of the AMP. (See id. at 229-234; see also DTX 511) Third, the PVM/MA acid-salt displays a spectral peak at approximately 1702 centimeters⁻¹ that is smaller than the spectral peak for the claimed PVM/MA at this same retention. (See D.I. 86 at 236-242; see also DTX 512) This spectral peak corresponds to the carboxylic acid group. The PVM/MA acid-salt also shows the presence of a spectral peak at 1520 centimeters⁻¹ corresponding to a salt group. (Id.) The formation of the salt peak indicates that the some of the acid groups present in PVM/MA are consumed when PVM/MA is reacted with AMP to form the acidsalt. (Id.) Finally, the PVM/MA acid-salt is also less brittle and less acidic than the claimed PVM/MA. (See, e.g., D.I. 87 at 314)

43. The instructions provided on the Pond's clear pore strips product state:

After washing your face, simply remove a [c]lear [p]ore [s]trip from foil pack and:

- 1. Wet your finger with water and use it to moisten the smooth side of the strip.
- Apply wetted strip to face. Smooth out air bubbles, ensuring good contact with skin. Let dry about 15 minutes-the strip should feel dry and stiff.
- 3. For best results, slowly and carefully peel off strip. Instantly see the results!
- You'll feel clearer, smoother skin with smaller pores as blackheads, dirt and oil are removed from clogged pores.

(PTX 66; DTX 44)

III. CONCLUSIONS OF LAW

A. Claim Construction

The parties dispute the meaning of three terms 1. present in claim 1: (1) cosmetic article; (2)copolymer; and (3) amount effective. First, plaintiffs argue that the term "cosmetic article" refers to a dried pore strip product. Ιn contrast, defendants assert that the term refers to a liquid or semi-solid pack preparation or a poultice upon which a liquid copolymer preparation has been layered, but not dried. Second, plaintiffs contend that the term "copolymer" includes the two copolymers recited in claim 1, as well as the salt forms of these copolymers. Defendants, in rebuttal, claim that the term "copolymer" covers only the two specifically enumerated copolymers, namely, (1) poly(alkyl vinyl ether/maleic acid); and (2) poly(alkyl vinyl ether/maleic anhydride), not salt forms thereof. Finally, plaintiffs aver that the term "effective amount" refers to any amount of copolymer whereas defendants argue that this term means that the amount of copolymer must be between 0.01 and 70% copolymer by weight based on the total weight of the copolymer layer.

2. Claim construction is question of law. <u>Markman v.</u> <u>Westview Instruments, Inc.</u>, 52 F.3d 967, 979 (Fed. Cir. 1995) (*en banc*).

3. In interpreting the claims, a court should begin with the intrinsic evidence of record (i.e., the patent itself,

including the claims, the specification, and the prosecution history). <u>Vitronics Corp. v. Conceptronic, Inc.</u>, 90 F.3d 1576, 1582 (Fed. Cir. 1996). "Such intrinsic evidence is the most significant source of the legally operative meaning of disputed claim language." <u>Id.</u>

4. First, a court should look to words of the claims themselves to define the scope of the patented invention. <u>Id.</u> There is a heavy presumption that the claim terms carry their ordinary and customary meanings as would be understood by one of ordinary skill in the art. <u>Markman</u>, 52 F.3d at 986. In other words, the court must determine how a person of experience in the field of the invention would, upon reading the patent documents, understand the words used to define the invention. <u>Toro Co. v.</u> <u>White Consol. Indus., Inc.</u>, 199 F.3d 1295, 1299 (Fed. Cir. 1999). Dictionaries and scientific treatises may help to supply the pertinent context and usage for claim construction. <u>Tex. Digital Sys., Inc. v. Telegenix, Inc.</u>, 308 F.3d 1193, 1201, 1202 (Fed. Cir. 2002).

5. Second, because a patentee may choose to be his own lexicographer and use a term in a manner either more or less expansive than its general usage in the relevant art, the court also should review the specification to determine whether an inventor has used any term in a manner other than its ordinary meaning. <u>Vitronics</u>, 90 F.3d at 1582. The specification may act as a dictionary when it either expressly defines terms used in

the claims or when it defines terms by implication. Id.

6. Third, a court may consider the prosecution history of a patent, if in evidence. <u>Id.</u> "The prosecution history limits the interpretation of claim terms so as to exclude any interpretation that was disclaimed during prosecution." <u>Id.</u> (quoting <u>Southwall Tech., Inc. v. Cardinal IG Co.</u>, 54 F.3d 1570, 1576 (Fed. Cir. 1995)). That is, a court must look to the prosecution history to determine if the patentee has limited the scope of the claims by disclaiming a particular interpretation during prosecution. <u>Biodex Corp. v. Loredan Biomed, Inc.</u>, 946 F.2d 850, 862 (Fed. Cir. 1991).

7. Additionally, if the meaning of a term is not clear from the intrinsic evidence, then a court may consult extrinsic evidence, such as expert testimony, in construing claim terms as they would be understood in the relevant art. <u>Markman</u>, 52 F.3d at 980-81.

8. When construing the claims, courts must take great care to avoid importing unnecessary limitations into the claims from the specification. <u>Amgen Inc. v. Hoechst Marion Roussel,</u> <u>Inc.</u>, 314 F.3d 1313, 1325 (Fed. Cir. 2003). "If we once begin to include elements not mentioned in the claim in order to limit such claim . . . we should never know where to stop." <u>Johnson</u> <u>Worldwide Assocs., Inc. v. Zebco Corp.</u>, 175 F.3d 985, 990 (Fed. Cir. 1999) (quoting <u>McCarty v. Lehigh Val. R.R.</u>, 160 U.S. 110, 116 (1895)). Nevertheless, a court should look to the specification

to determine whether it refers to a limitation only as a part of less than all possible embodiments or whether it suggests that the very character of the invention requires the limitation be a part of every embodiment. It is impermissible to read the one and only disclosed embodiment into a claim without other indicia that the patentee so intended to limit the invention. <u>Teleflex,</u> <u>Inc. v. Ficosa N. Am. Corp.</u>, 299 F.3d 1313, 1327 (Fed. Cir. 2002). On the other hand, where the specification makes clear at various points that the claimed invention is narrower than the claim language might imply, it is entirely permissible and proper to limit the claims. <u>SciMed Life Sys., Inc. v. Advanced</u> <u>Cardiovascular Sys., Inc.</u>, 242 F.3d 1337, 1345 (Fed. Cir. 2001).

9. The court construes the term "cosmetic article" to mean a liquid, semi-solid, or dried preparation used to beautify the body by application. At the outset, the court observes that the adjective "cosmetic" means "a preparation, such as skin cream, designed to beautify the body by direct application." American Heritage Dictionary 328 (New College Ed. 1976). Thus, the use of this term imparts the idea that an "article" is applied to the skin for purposes of beautification. While defendants contend that the "article" is limited to liquid and semi-solid preparations based upon the use of the terms "pack" and "poultice" in the specification, the court notes that the specification, through the use of the term "may," offers these two formulations as examples only. "The keratotic plug remover

according to this invention **may** take a form of a poultice . . . beside pack preparations." ('382 patent, col. 5 at 11. 19-22) (emphasis added) This permissive "may" language does not restrict the claimed invention to a particular formulation, but instead expressly leaves open the possibility of other formulations. Further, the court declines to limit the claimed invention to a liquid formulation based upon the examples alone, despite the fact that each example discloses either expressly or implicitly a liquid formulation. Indeed, the Federal Circuit has cautioned against restricting the claims based upon the embodiments described in the specification, stating "[e]ven when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using 'words or expressions of manifest exclusion or restriction.'" Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 906 (Fed. Cir. 2004) (quoting <u>Teleflex</u>, 299 F.3d at 1327). The court, therefore, concludes that it would be improper to limit plaintiffs to a liquid formulation, particularly since the prosecution history reveals that plaintiffs submitted data for dry formulations; i.e., in amending claim 1 to include the wetting language, plaintiffs argued that the "the addition of the wetting step is not further limiting since the wetting step was implied in the previously submitted claim." (PX 41 at 260)

10. The court construes the term "copolymer" to mean

either poly(alkyl vinyl ether/maleic acid) copolymer or poly(alkylvinyl ether/maleic acid anhydride) copolymer, but not the salt form thereof. While the written description sets forth a variety of copolymers, including ones with mixtures of anionic monomers,¹² cationic monomers, and amphoteric monomers, plaintiffs opted to narrowly define the term copolymer in claim 1 as being either the acid or anhydride form of poly(alkyl vinyl ether/maleic acid) by stating "said copolymer is a poly(alkyl vinyl ether/maleic acid) copolymer or a polyalkylvinyl ether/maleic anhydride) copolymer." ('382 patent, col. 13 at 11. 6-8) The court declines to broaden the plain language of the claim by reading a salt limitation into it, especially since a salt copolymer is a distinct chemical entity from both an acid copolymer and an anhydride copolymer.

11. The prosecution history of the '382 patent supports the court's construction of the term "copolymer." Claim 1 of the '382 patent originally was written to cover only maleic acid and maleic anhydride, not the salt form. To this end, claim 1 originally recited "a copolymer comprising an alkyl vinyl ether and maleic acid or an anhydride on said substrate." Claim 1 later was amended to recite "monomer units comprising an alkyl vinyl ether and a monomer selected from the group consisting of

¹²The specification specifically recites maleic acid as one type of anionic monomer, stating "[a]crylic acid (AA), [m]ethacrylic acid (MA), [m]aleic acid, itaconic acid and the like, which are unsaturated carboxylic acid monomers or their anhydrides or their salts." (`382 patent, col. 2 at 11. 25-28)

maleic acid or an anhydride thereof." (PX 41 at 116-177; 141) This claim did not contain any express or inherent recitation of a salt form. Plaintiffs ultimately amended this language to eliminate the terms "monomer units" pursuant to an interview with the examiner wherein he specifically limited the claims to maleic acid/methyl vinyl ether and maleic anhydride/methyl vinyl ether. (<u>See id.</u> at 248-249) Subsequently, plaintiffs filed the '719 patent with claims specifically directed to salts of the copolymers claimed in the '382 patent. If applicants had intended the claims of the '382 patent to include these salt forms, then there would have been no need to file the '719 patent as a continuation of the '382 patent. Otherwise, the '719 patent would contain claims to an invention previously claimed in the '382 patent.

12. The court construes the term "amount effective" in the context of an invention pertaining to beautification of the skin to mean "an amount sufficient to have a cosmetic benefit by removing keratotic plugs." This construction aligns with both the plain meaning and customary usage of the term. Contrary to defendants' assertion that the amount of copolymer present must be between 0.01 and 70% by weight based on the total weight of the copolymer layer, the language in claim 1 does not expressly require a minimum or maximum amount of copolymer to be effective. The concept of claim differentiation provides added support for the instant claim construction. Dependent claims 6 and 7 recite

the preferred embodiments, namely, copolymer of 5 to 70 wt. % and 5 to 40 wt. % based on total weight. (See '382 patent, col. 14 at 11. 6-11) Although defendants argue in favor of a slightly lower limit on the polymer weight range, i.e., 0.01% as opposed to the 5% recited in claims 6 and 7, the court, nonetheless, infers that the juxtaposition of independent claim 1 lacking any reference to a weight percentage of copolymer with two dependent claims containing weight percentages of copolymer implies that plaintiffs did not intend to require a weight percentage of copolymer in claim 1. Indeed, "the presence of a dependent claim that adds a particular limitation raises a presumption that the limitation in question is not found in the independent claim." Liebel-Flarsheim, 358 F.3d at 910 (citing <u>Wenger Mfg., Inc. v.</u> Coating Mach. Sys., Inc., 239 F.3d 1225, 1233 (Fed. Cir. 2001)). Additionally, the specification does not mandate a limited interpretation of the disputed claim language, even though the written description discloses copolymer weight ranges in preferred embodiments and all of the examples recite copolymers of less than 70% by weight. As mandated by the Federal Circuit, the court shall read the claims in light of the specification, but will not read limitations found in the specification into the claims absent a clear manifestation that the applicants intended for their claimed invention to be limited in such fashion. Furthermore, the prosecution history substantiates the court's construction of the term "amount effective." In submitting the

second CPA in May 1999, plaintiffs cancelled the pending claims 32-37 and amended claim 38 to remove its dependency on claim 32, presenting it as the broadest independent claim. In doing so, plaintiffs eliminated the limitation requiring the polymer layer to comprise 5 to 70 % based on total weight and added dependent claims reciting both the 5 to 70 wt. % and the 5 to 40 wt. % limitations. The court concludes that this amendment evidences plaintiffs' belief that their invention, in its absolute broadest form, was not contingent upon a particular weight range of copolymer.

B. Literal Infringement of the '382 Patent

13. Plaintiffs assert that the Pond's clear pore strips product meets all of the limitations found in claims 1 and 3 of the '382 patent. Defendants contend in response that their product does not meet the "cosmetic article," "copolymer," and "amount effective" limitations of claims 1 and 3. In this regard, defendants argue that Pond's clear pore strips are not a cosmetic article because they are sold in dry form. Defendants also assert that the coating of its pore strips is not either form of PVM/MA disclosed in claim 1. Instead, defendants contend that AMP reacts with PVM/MA forming a salt. Additionally, defendants charge that their product contains more than 70% by weight copolymer and, therefore, would not meet the "amount effective" limitation if it is construed to mean a copolymer of from 0.01 to 70% by weight.

14. A patent is infringed when a person "without authority makes, uses or sells any patented invention, within the United States . . . during the term of the patent." 35 U.S.C. § 271(a).

15. A court should employ a two-step analysis in making an infringement determination. <u>Markman</u>, 52 F.3d at 976. First, the court must construe the asserted claims to ascertain their meaning and scope. <u>Id.</u> Claim construction is a question of law subject to de novo review. <u>See Cybor Corp. v. FAS Techs.</u>, 138 F.3d 1448, 1454 (Fed. Cir. 1998). Second, the trier of fact must compare the properly construed claims with the accused infringing product. <u>Markman</u>, 52 F.3d at 976. This step is a question of fact. <u>See Bai v. L & L Wings, Inc.</u>, 160 F.3d 1350, 1353 (Fed. Cir. 1998). Literal infringement occurs where each limitation of at least one claim of the patent is found exactly in the alleged infringer's product. <u>Panduit Corp. v. Dennison</u> <u>Mfg. Co.</u>, 836 F.2d 1329, 1330 n. 1 (Fed. Cir. 1987).

16. The patent owner has the burden of proving infringement and must meet its burden by a preponderance of the evidence. <u>SmithKline Diagnostics, Inc. v. Helena Lab. Corp.</u>, 859 F.2d 878, 889 (Fed. Cir. 1988) (citations omitted).

17. The court finds that defendants' accused product meets the "cosmetic article" limitation of the asserted claims of the '382 patent. The court construed the term "cosmetic article" to include liquid, semi-solid, and dry preparations applied to

beautify the body. Since defendants' product is a dry, solid pore strip applied to the body for purposes of beautification, it meets the cosmetic article limitation.

18. The court finds that defendants' accused product also meets the **"amount effective"** limitation of the asserted claims of the '382 patent. As construed by the court, the term "amount effective" means "an amount sufficient to have a cosmetic benefit by removing keratotic plugs" and is not restricted to a 0.01 to 70% copolymer by weight range as advocated by defendants. The undisputed evidence shows that defendants' product contains 93% by weight copolymer, an amount sufficient to remove keratotic plugs.

19. The court has construed the "copolymer" limitation to mean either poly(alkyl vinyl ether/maleic acid) copolymer or poly(alkylvinyl ether/maleic anhydride) copolymer, but not the salt form thereof. The experts agree that the defendants' product contains PVM/MA copolymer and AMP and that the AMP reacts with the maleic acid to neutralize a number of the PVM/MA monomer units, thereby forming PVM/MA acid-salt. The experts also agree that the claimed PVM/MA copolymer and the PVM/MA acid-salt have different chemical compositions which can be characterized by differences in their solubility, viscosity, and infrared spectra data.¹³

¹³There is no evidence of record as to whether the differences in chemical composition and properties have any

20. Despite the uncontested differences in chemical composition between the claimed PVA/MA and the PVA/MA acid-salt, plaintiffs assert that the PVA/MA acid-salt literally¹⁴ infringes the copolymer limitation of claim 1 of the '382 patent. In support of their assertion, plaintiffs direct the court to the Federal Circuit's decision in Merck & Co., Inc. v. Teva Pharms. <u>USA, Inc.</u>, 347 F.3d 1367 (Fed. Cir. 2003). In that case, the claim at issue addressed the administration of an effective amount of "4-amino-1-hydroxybutane-1, 1-biphosphonic acid" for the treatment of urolithiasis and to inhibit bone reabsorption. In concluding that the salt form of the claimed acid literally infringed, the Federal Circuit relied on: (a) a specification that contained numerous references to the salt form of the claimed acid; (b) consistent testimony from "all the qualified witnesses" that "persons in this field would understand that the acid is the active agent and that the acid is administered when it is in the form of the salt;" and (c) "extensive evidence that persons experienced in this field use the same lexicography as did the inventors in referring to the active ingredient 'in the form of' the salt." Id. at 1371. As described by the Federal Circuit,

[t]he question is not whether a general chemist

effect on keratotic plug removal.

¹⁴Plaintiffs have only asserted literal infringement; there is no claim of infringement by equivalents.

would know the difference between an acid and a salt. The question is whether a person experienced in the field of the invention and familiar with the usages of pharmacology and the prior art, reading the patent specification, would know that for the treatment of urolithiasis and to inhibit bone reabsorption, the statement that 4-amino-1hydroxybutane-1,1-biphosphonic acid is administered to treat these diseases, encompasses administration as the acid salt. All of the pharmacologist witnesses agreed that this was the correct reading.

<u>Id.</u> at 1371-72.

21. Clearly, the record at bar does not include such compelling evidence.¹⁵ Neither is the evidence of record consistent with the reasoning of the Federal Circuit in <u>Stiftung</u> <u>v. Renishaw PLC</u>, 945 F.2d 1173 (Fed. Cir. 1991). In that case, the Federal Circuit held that

> one cannot avoid infringement merely by adding elements if each element recited in the claims is found in the accused device. For example, a pencil structurally infringing a patent claim would not become noninfringing when incorporated into a complex machine that limits or controls what the pencil can write.

Id. at 1178 (quoting <u>A.B. Dick Co. v. Burroughs Corp.</u>, 713 F.2d 700, 703 (Fed. Cir. 1983)). The question at bar is whether, by adding AMP to the claimed PVA/MA copolymer, the resulting product (PVA/MA acid-salt) is still literally within the scope of claim 1 of the '382 patent. Although plaintiffs' expert testified generally that the claimed PVA/MA copolymer and the PVA/MA acid-

 $^{^{15}}$ The specification of the '382 patent makes one mention of salt, that is, the salt of maleic acid as an example of one of the possible anionic monomers to be included in the polymer. ('382 patent, col. 2, 11. 24-32)
salt "fall[] under the family of the copolymer" (see, e.g., D.I. 86 at 108), this evidence, when compared to the record as a whole, fails to make the scales tip even somewhat on plaintiffs' side. To put the point differently, plaintiffs have failed to carry their burden of proving by a preponderance of the evidence that the accused product literally meets the copolymer limitation of claim 1 of the '382 patent.¹⁶

C. Invalidity

22. Defendants assert that the '382 patent is invalid for: (1) lack of an adequate written description of the claim language "wetting the skin or said cosmetic article" and "amount effective;" (2) indefiniteness in use of the term "amount effective;" and (3) obviousness. "A patent shall be presumed valid." 35 U.S.C. § 282. To overcome this presumption, the party challenging a patent must prove facts supporting a determination of invalidity by clear and convincing evidence. Apotex USA, Inc. v. Merck & Co., 254 F.3d 1031, 1036 (Fed. Cir.

¹⁶ This conclusion is supported by the Federal Circuit's analysis in Johnson & Johnson Associates, Inc. v. R.E. Service <u>Co., Inc.</u>, 285 F.3d 1046 (Fed. Cir. 2002), a case involving the doctrine of equivalents but instructive nonetheless. In Johnson, the Federal Circuit held that, "when a patent drafter discloses but declines to claim subject matter, . . . this action dedicates that unclaimed subject matter to the public. Application of the doctrine of equivalents to recapture subject matter deliberately left unclaimed would 'conflict with the primacy of the claims in defining the scope of the patentee's exclusive right.'" <u>Id.</u> at 1054 (quoting <u>Sage Prods. Inc. v. Devon Indus., Inc.</u>, 126 F.3d 1420, 1424 (Fed. Cir. 1997)). Therefore, absent compelling evidence in the record, as existed in the <u>Merck</u> case, disclosed but unclaimed subject matter cannot be the basis for a finding of infringement, literally or by equivalents.

2001) (citing <u>Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.</u>, 725 F.2d 1350, 1360 (Fed. Cir. 1984)). Based upon this teaching, defendants bear the burden of proving their invalidity claims by clear and convincing evidence.

a. Written Description Under 35 U.S.C. § 112, Paragraph 1

i. The Legal Standard

23. The written description requirement of 35 U.S.C. §

112, paragraph 1, is set forth as follows:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The written description requirement is distinct from the enablement and best mode requirements also provided for in § 112, paragraph 1. <u>See Univ. of Rochester v. G.D. Searle & Co.</u>, 358 F.3d 916, 921 (Fed. Cir. 2004).

24. "The "written description" requirement serves a teaching function, as a 'quid pro quo' in which the public is given 'meaningful disclosure in exchange for being excluded from practicing the invention for a limited period of time.'" <u>Id.</u> at 922 (citing <u>Enzo Biochem, Inc. v. Gen-Probe Inc.</u>, 323 F.3d 956, 970 (Fed. Cir. 2002)).

25. Compliance with the written description requirement is a fact-based inquiry that will "necessarily vary

depending on the nature of the invention claimed." <u>Id.</u> at 963 (citing <u>In re Di Leone</u>, 436 F.2d 1404, 1405 (C.C.P.A. 1971)).

26. The Federal Circuit has employed a fairly uniform standard for determining whether the written description requirement is satisfied. "Although [the applicant] does not have to describe exactly the subject matter claimed, . . . the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563 (Fed. Cir. 1991) (citations omitted). In other words, "the applicant must convey to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention." Id. То show possession, an applicant must describe the invention, with all its claimed limitations, and not only what makes it obvious. Lockwood v. Am. Airlines, 107 F.3d 1565, 1572 (Fed. Cir. 1997). The Federal Circuit has observed that an applicant may proffer such description by way of words, structures, figures, diagrams, and formulas. Id.

ii. "Wetting the Skin or Said Cosmetic Article"

27. Applying these standards to the arguments advanced by defendants, the court finds that plaintiffs complied with the written description requirement in using the language "wetting the skin or said cosmetic article" in the asserted claims. These words plainly and directly satisfy the standard employed by the Federal Circuit in assessing written description. That is, the

phrase "wetting the skin or said cosmetic article" fairly appraises persons of ordinary skill in the cosmetic field that either the cosmetic article or the skin where the cosmetic article is to be applied must be wet prior to application of the article.

28. Defendants focus their written description challenge on the language in the specification wherein plaintiffs stated that "[t]he manner of removing keratotic plugs by the use of the keratotic plug remover of the invention is the same as the manner of using ordinary packs and poultice." ('382 patent, col. 5 at 11. 26-28) Defendants argue that packs and poultices are liquid or semi-solid objects that do not need to be wetted prior to use. By comparing the claimed invention to such objects, defendants assert that plaintiffs failed to describe their invention. Defendants, however, ignore the further description in the specification elaborating what is meant by the language "the manner of using ordinary packs and poultice." In this regard, plaintiffs stated: "Namely, when a pack preparation is used, it is first applied to the part of the skin which has keratotic plugs, particularly likely to the nose, chin and forehead, and after dried, it is peeled off." ('382 patent, col. 5 at 11. 28-31) Thus, the court concludes that plaintiffs intended to communicate that the claimed invention must be applied to the skin in the area plaqued by keratotic plugs and then removed to draw out the keratotic plugs. The wetting step,

which appears necessary to aid in the adhesion of the claimed cosmetic article, is so straightforward that a detailed description in the specification is not necessary. Therefore, the court concludes that the '382 patent complies with the written description requirement of § 112, paragraph 1, for the phrase "wetting the skin or said cosmetic article."

iii. "Effective Amount"

29. The court finds that defendants' argument concerning that the phrase "amount effective" rehashes their claim construction position. Nevertheless, giving defendants the benefit of the doubt, the court observes that the phrase "amount effective" readily communicates to persons of ordinary skill in the cosmetic field that the claimed invention must employ an amount of polymer sufficient to remove keratotic plugs from the skin, thereby improving the appearance of the skin in the treated region. As such, the court finds that this phrase meets the written description requirement, even though neither the precise words "amount effective" nor a particular definition for these words appear in the specification. The specification provides two preferred embodiments for the amount of polymer to be used in the keratotic plug remover preparation. The examples likewise describe polymer in specific ranges by weight. Taken together, these teachings help to show that plaintiffs were "in possession" of the claimed invention. Accordingly, the court concludes that the '382 patent is not invalid for lack of written description

based upon the use of the phrase "amount effective."

b. Indefiniteness under 35 U.S.C. § 112, Paragraph 2

30. The definiteness requirement of 35 U.S.C. § 112, paragraph 2, is set forth as follows: "A patent specification shall conclude with one or more claims that "particularly [point] out and distinctly [claim] subject matter which the applicant regards as his invention."

31. The Federal Circuit has explained that a claim satisfies § 112, paragraph 2, if one skilled in the art would understand the bounds of the claim when read in light of the specification. <u>See Miles Lab., Inc. v. Shandon, Inc.</u>, 997 F.2d 870, 875 (Fed. Cir. 1993). In determining whether this standard is met, the Federal Circuit has advised that a claim is not indefinite merely because it poses a difficult issue of claim construction. <u>Exxon Research & Eng'g Co. v. United States</u>, 265 F.3d 1371, 1376 (Fed. Cir. 2001). Rather, the Federal Circuit has held that a claim is sufficiently clear to avoid invalidity on indefiniteness grounds "if the meaning of the claim is discernible, even though the task may be formidable and the conclusion may be one over which reasonable persons will disagree." <u>Id.</u>

32. "A determination of claim indefiniteness is a legal conclusion that is drawn from the [c]ourt's performance of its duty as the construer of patent claims." <u>Personalized Media</u> <u>Communications, LLC v. Int'l Trade Comm'n</u>, 161 F.3d 696, 705

(Fed. Cir. 1998). "By finding claims indefinite only if reasonable efforts at claim construction prove futile, [the court] accord[s] respect to the statutory presumption of patent validity, . . . and [the court] protects the inventive contribution of patentees, even when the drafting of their patents has been less than ideal." <u>Id.</u>

33. Defendants assert that the phrase "amount effective" is indefinite because persons of ordinary skill in the cosmetic field cannot determine what minimum keratotic plug removal ratio is covered by the asserted claims. The court disagrees. The court construed the phrase "amount effective" to mean "an amount sufficient to have a cosmetic benefit by removing keratotic plugs." Under this construction, any keratotic plug removal has the cosmetic benefit of improving the appearance of the skin; there is no specific minimum keratotic plug removal ratio required by the asserted claims. In other words, the phrase "amount effective" is a functional limitation and covers all embodiments performing the recited function, to wit, all amounts of copolymer that lead to the removal of keratotic plugs. See In re Swinehart, 439 F.2d 210, 213 (C.C.P.A. 1971) (holding that a functional limitation covers all embodiments performing the recited function).

34. The Federal Circuit has stated that the phrase "`effective amount' is a common and generally acceptable term for pharmaceutical claims and is not ambiguous or

indefinite, provided that a person of ordinary skill in the art could determine the specific amounts without undue experimentation." Geneva Pharms., Inc. v. GlaxoSmithKline PLC, 349 F.3d 1373, 1383-1384 (Fed. Cir. 2003) (citing In re Halleck, 422 F.2d 911, 914 (C.C.P.A. 1970)). While the Federal Circuit particularly mentioned pharmaceutical type claims, the court concludes that this holding is applicable to the facts at bar, given that the asserted claims are directed at treating a skin condition much in the same way that pharmaceutical claims are directed at treating human diseases. Turning, therefore, to consider whether undue experimentation is required to determine the amount of copolymer necessary to achieve the stated function of removing keratotic plugs, the court finds simple procedures could be employed to test copolymers at a variety of % weights. Indeed, the examples describe very elementary experiments that could be easily repeated (i.e., preparing a polymer preparation using basic weighing and mixing techniques, applying the preparation to a region of skin, and then counting the number of keratotic plugs in the skin before and after administration of the preparation). Thus, the court concludes that undue experimentation is not implicated and that the '382 patent is not invalid for indefiniteness under § 112, paragraph 2, based upon the phrase "amount effective."

c. Obviousness under 35 U.S.C. \S 103

35. Defendants contend that the '382 patent is

rendered obvious by: (1) the combination of the Gueret '552 patent and U.S. Patent No. 5,811,107 ("the Gangadharan '107 patent"); (2) the combination of the Gueret '552 patent, the Gangadharan '107 patent, and the 1985 and 1986 GAF Chemical product catalogs ("the GAF catalogs"); (3) U.S. Patent No. 4,631,227 ("the Nakamura '227 patent") and the Gangadharan '107 patent; and (4) Japanese Laid-Open Patent No. Sho 60/165902 (the JP '902 patent) and the Gangadharan '107 patent.

i. The Legal Standard

36. In pertinent part, 35 U.S.C. § 103 provides that

a patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter 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 said subject matter pertains."

37. The question of obviousness turns on four factual inquiries: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) any objective indicators of non-obviousness, more commonly termed secondary considerations. <u>Graham v. John Deere Co.</u>, 383 U.S. 1, 17-18 (1966); <u>B.F. Goodrich Co. v. Aircraft Braking Sys. Corp.</u>, 72 F.3d 1577, 1582 (Fed. Cir. 1996). The existence of each limitation of a claim in the prior art does not, by itself, demonstrate obviousness. Instead, there must be a "reason, suggestion, or motivation in the prior art that would lead one of ordinary skill

in the art to combine the references, and that would also suggest a reasonable likelihood of success." <u>Smiths Indus. Med. Sys.</u>, <u>Inc. v. Vital Signs, Inc.</u>, 183 F.3d 1347, 1353 (Fed. Cir. 1999). "Such a suggestion or motivation may come from the references themselves, from knowledge by those skilled in the art that certain references are of special interest in a field, or even from the nature of the problem to be solved." <u>Id.</u> at 1356.

38. To rebut a prima facie case of obviousness, objective evidence of nonobviousness may be used. <u>Tec Air, Inc.</u> v. Denso Mfg. Mich, Inc., 192 F.3d 1353, 1360 (Fed. Cir. 1999). This objective evidence includes: (1) a long-felt and unmet need in the art for the invention; (2) failure of others to achieve the results of the invention; (3) commercial success of the invention; (4) copying of the invention by others in the field; (5) whether the invention was contrary to accepted wisdom of the prior art; (6) expression of disbelief or skepticism by those skilled in the art upon learning of the invention; (7) unexpected results; (8) praise of the invention by those in the field; and (9) independent invention by others. Graham, 383 U.S. at 17-19. "The objective evidence of nonobviousness . . . should when present always be considered as an integral part of the analysis." Demaco Corp. v. F. Von Langsdorff Licensing Ltd., 851 F.2d 1387, 1393 (Fed. Cir. 1988) (quoting <u>W.L. Gore & Assoc. Inc.</u> v. Garlock, Inc., 721 F.2d 1540, 1555 (Fed. Cir. 1983)).

39. Unexpected results exist when "the claimed

invention exhibits some superior property or advantage that a person in the relevant art would have found surprising or unexpected." <u>In re Soni</u>, 54 F.3d 746, 750 (Fed. Cir. 1995). The Federal Circuit has explained the rationale for finding that unexpected results rebuts a contention of obviousness as follows: "that which would have been surprising to a person of ordinary skill in a particular art would not have been obvious." <u>Id.</u>

40. When unexpected results are used as evidence of nonobviousness, the results must be shown to be unexpected as compared with the closest prior art. <u>In re Baxter Travenol Labs</u>, 952 F.2d 388, 392 (Fed. Cir. 1991) (citing <u>In re De Blauwe</u>, 736 F.2d 699, 705 (Fed. Cir. 1984)). "It is well settled that unexpected results must be established by factual evidence. Mere argument or conclusory statements in the specification does not suffice." <u>Id.</u> (citing <u>In re Lindner</u>, 457 F.2d 506, 508 (1972)).

ii. The Prior Art¹⁷

(a) The Gueret '552 Patent

41. The Gueret '552 patent, entitled "Sheet Material For Performing A Skin or Hair Treatment, Method For Its Manufacture, and Articles Made of This Material," granted on June 25, 1991 from an application filed on September 26, 1988. (<u>See</u> DTX 11)

42. The Gueret `552 patent is generally directed

 $^{^{17} \}rm The$ parties do not dispute the references involved in this obviousness discussion properly constitute prior art under 35 U.S.C. § 102.

to a dry mask to be used in skin therapy and scalp treatments. (`552 patent, col. 1 at 11. 61-68; col. 2 at 11. 1-4)

43. It is undisputed that the Gueret '552 patent discloses each and every limitation of the '382 patent, except for the claimed copolymer of PVM/MA. (D.I. 87 at 515-516; D.I. 88 at 820-821) The Guerret '552 patent instead discloses the use of a water-soluble or water-expandable polymer having a dry extract between 0.5 and 50% by weight. ('552 patent, col. 3 at 11. 24-26) More specifically, the Gueret '552 patent states:

Polymers that can be used for this purpose are advantageously selected from the group including polyvinyl alcohol, alkaline metal salts of cross-linked carboxymethylcellulose, alkaline metal salts of polyacrylic acid, cross-linked polyalkylene oxide, alkaline metal salts of grafted acrylnitrile cellulose or acrylonitrile starch polymers containing carboxylic groups, gum tragacanth, gum arabic, guar gum and its derivatives, alginates, xanthan gum, other cellulose derivatives, albumin, gelatin, galactomannan and polyacrylamide.

('552 patent, col. 3 at 11. 26-26)

44. The Gueret '552 patent teaches applying the dry mask, which optionally may contain active substances in a gel layer, to the face after the face has been moistened. The mask is then lifted from the face to clean the pores of the skin by sloughing off the horny layer. ('552 patent, col. 1 at 64-68) If gel is present, active substances in the gel layer may be transferred to the skin to provide a complementary skin treatment. ('552 patent, col. 2 at ll. 1-4)

45. The Gueret '552 patent exemplifies using only

polyvinyl alcohol as the active substance in the gel layer. To this end, the Gueret '552 patent states: "By way of example, a material 2 according to the invention can now be described somewhat more precisely. The mesh 3 may be a netlike fabric including 85 holes per centimeter and made with polyamide threads 150 .m in diameter; it is filled with a polyvinyl alcohol which is spread by the drum, from 10 to 30% by weight of dry extract and dried to 98% by weight of dry extract." ('552 patent, col. 7 at 11. 21-28)

(b) The Gangadharan `107 Patent¹⁸

46. The Gangadharan '107 patent, entitled "Skin Cleanser," granted on September 22, 1998 from an application filed on May 9, 1995. (DTX 9)

47. The Gangadharan '107 patent is generally directed to a polymer-based cleanser for superficial and deep cleansing of skin. ('107 patent, col. 1 at 11. 8-9) To this end, the Gangadharan '107 patent discloses a composition for forming an applique for cleaning and treating skin comprising a lower

¹⁸During the prosecution of the '382 patent, the examiner rejected the claimed invention as obvious in light of the Gangadharan '107 patent. (D.I. 41 at 202) The examiner stated: "Claims 38-44 rejected under 35 U.S.C. § 103(a) as being unpatentable over Gangadharan et al 5,811,107 or Crotty et al 5,935,596." (Id.) Plaintiffs overcame the rejection, arguing that the Gangadharan '107 patent did not constitute prior art. Plaintiffs stated: "Gangadharan et al has a U.S. filing date of May 18, 1994. . . Neither of these references qualifies as prior art under any section of 35 U.S.C. § 102 against the present invention." (See id. at 209) Subsequently, on September 22, 1998, the priority date of the Gangadharan '107 patent was corrected via a certificate of correction to September 19, 1991.

alcohol or alcohol/water solvent in which between 0.1 to 20% by weight/volume polymer is dissolved. (`107 patent, col. 1 at 11. 43-49)

48. The Gangadharan '107 patent specifically discloses the use of PVP [polyvinyl pyrrolidone], VP/vinyl acetate, alkylvinyl ethers, alkylvinyl ether/maleic acids and acid salts, or carboxymethyl celluloses as polymers of choice. ('107 patent, col. 2 at 11. 6-10) In particular, the Gangadharan '107 patent states: "The most preferred polymers are PVPs and methylvinyl ether/maleic acid and acid salts sold by International Speciality Polymers of Wayne N.J. U.S.A." ('107 patent, col. 2 at 11. 10-14)

49. The Gangaharan '107 patent discloses a particular procedure for cleansing or treating the skin using the claimed applique.

To clean skin, a dollop of liquid or gel is placed on the skin and spread into an applique by hand or a soft pliable device. For example, a small amount of material is dispensed onto the fingers and spread over the cheek or the face. Body heat, air flow and ambient heat will evaporate the solvent leaving behind an elastic, pliable essentially dry applique. This should take several minutes, e.g., 3-10, after which the applique can be removed. This is accomplished by pulling it off; simply grasp the edge of the applique with the fingers and steadily pulling it from the face. An alternative, and preferred method is to take a piece of adhesive tape, or similar material and touch it to the dried applique. Both are then pulled from the skin with steady, gentle pressure.

('107 patent, col. 2 at 11. 53-65)

50. The Gangadharan '107 patent explains that the

claimed invention provides a way to remove debris that clogs hair follicles resulting in clogged pores, comedones, and blackheads (aka, keratotic plugs). ('107 patent, col. 1 at 11. 19-26)

51. The Gangadharan '107 patent exemplifies one applique formulation with PVP as the polymer. ('107 patent, col. 3 at 11. 14-31)

(c) The Nakamura '227 patent

52. The Nakamura `227 patent, entitled "Toilet Article," granted on December 23, 1986 from an application filed on December 5, 1983. (DTX 12)

53. The Nakamura '227 patent is generally directed to a toilet article comprised of a sheet-like material, an adhesive layer formed on the sheet-like material, and a layer of hydrogel formable polymer formed on the adhesive layer onto which a cosmetic is applied. ('227 patent, col. 2 at ll. 31-34)

54. The Nakamura '227 patent discloses that cosmetics are often applied to bare skin after make-up is removed and left on for relatively long periods of time to refresh the skin. ('227 patent, col. 1 at 11. 20-24) The Nakamura '227 patent explains that these cosmetics are sold under the name of a night lotion or a night cream or pack. ('227 patent, col. 1 at 11. 28-29) The Nakamura '227 patent discusses two main problems in using night lotions or night creams: "Commonly spread usage of such cosmetics has problems that the applied cosmetics are easily dried by virtue of a body temperature, which results in decrease

of the effects of cosmetics, and that the cosmetics are rubbed off onto clothing or bed linen during sleep and that the effects of the cosmetics are lost." ('227 patent, col. 1 at 11. 36-41)

55. The Nakamura '227 patent suggests that the claimed invention solves the above stated problems.

An object of the present invention is to provide a toilet article which serves to prevent the applied cosmetics from being easily dried by virtue of a body temperature, which maintains effects of the cosmetics for a long time, and which effectively achieves the pack effects. Some examples of the pack effects referred to above are prevention of moisture evaporation from the surface of the skin, plasticization of the outer dead layer of the epidermis and expansion of pores in the skin so as to facilitate the absorption of the valid ingredients into the skin, and remov[ing] skin debris and blackheads from the face, when the pack is removed.

('227 patent, col. 1 at 11. 46-57)

56. The Nakamura '227 patent discloses that the sheetlike material may be a film obtained from a flexible synthetic resin, a sheet of an unwoven fabric or a woven fabric, or a porous film. ('227 patent, col. 3 at 11. 16-23)

57. The Nakamura '227 patent defines a "hydrogel formable polymer" as "a substance which forms gel when water is applied to it and has a water retention characteristic of between ten times and one hundred times." ('227 patent, col. 3 at 11. 40-44) The Nakamura '227 patent discloses that "usable hydrogel substances are crosslinked substances of alkali metal salt of carboxymethylcellulose, alkali metal salt of polyacrylic acid, crosslinked substances of polyalkylene oxide, carboxylic alkali

metal salt formed from cellulose-acrylonitrile graft polymer, carboxylic alkali metal salt formed from starch-acrylonitrile graft polymer and the like, any of which has a good water absorption and water retention." ('227 patent, col. 3 at 11. 60-68) The Nakamura '227 patent further discloses that "[h]ydrogel substance usually takes the form of either a sheet or powder under the conditions wherein it is dry." ('227 patent, col. 4 at 11. 4-6)

58. The Nakamura '227 patent explains that when a cosmetic is applied to the hydrogel formable polymer layer, a gel forms and swells due to the water contained in the cosmetic. ('227 patent, col. 6 at 11. 17-20) In this state, the toilet article is applied to the face and the pressure-sensitive adhesive layer is pressed to the skin to adhere the toilet article onto the skin during sleep. ('227 patent, col. 6 at 11. 21-28)

(d) The JP '902 Patent

59. The JP '902 patent, entitled "Beauty Pack Material and Its Manufacturing Method and Method of Use," published on August 29, 1985. (DTX 13)

60. The JP '902 patent is generally directed to a beauty pack material consisting of a flexible film with a thin layer of dried paste that is nontoxic to skin. (<u>Id.</u> at 13)

61. The JP '902 patent discloses that the film may be a plastic raw material such as polyacetate,

polybutadiene, ionomer, polyamide, polyvinylidene chloride, ethylene-vinyl acetate copolymer, polyvinyl chloride, polyethylene, polypropylene, and polyester. (<u>Id.</u> at 4) The JP '902 patent states that this material may either be unaltered such that it is not air permeable or altered to contain minute perforations offering air permeability. (<u>Id.</u>) The JP '902 patent further discloses that the film may be permeable or nonpermeable paper-like products made from cellophane paper, machine-made paper fiber, woven fiber, Japanese paper fiber, and fiber-like plastic or products where a thin plastic coating has been applied. (<u>Id.</u> at 5)

62. The JP '902 patent specifically recites the use of hydrophilic paste that is nontoxic to skin and demonstrates viscosity with only small water content. (Id. at 6) The JP '902 patent offers "-starch, polyacrylic soda, CMC, methylcellulose, gelatin, casein, and gum arabic as examples of suitable hydrophilic pastes. (Id.) The JP '902 patent also states that "there is affinity with polyvinyl chloride and polyethylene, although the viscosity is somewhat inadequate, and as substances that dissolve in nonacqueous solvents, there is polyvinyl pyrolidone, polyacrylic acid, and so on." (Id.) The JP '902 patent further discloses the use of lipophilic pastes. (Id.)

63. The JP '902 patent recites that "-starch and polyacrylic soda are preferred pastes because they demonstrate

sufficient viscosity even if used in a small quantity with a tiny amount of water. (<u>Id.</u>)

64. The JP '902 patent teaches utilizing the beauty pack material by applying it either "to the face in a wet state or to a face that is wet after washing or to a face provided with a cosmetic foundation containing medicinal ingredients." (Id. at 4) The JP '902 patent explains that the paste dries in the case of an air permeable film, but does not dry in the case of a non-permeable film. (Id. at 5) The JP '902 patent also reveals that the claimed methods require either washing or peeling the beauty pack material off after drying. (Id. at 3)

65. The JP '902 patent discusses using the claimed invention to tighten sags in the skin, absorb and remove contaminants on the surface of the skin, and smooth the skin. (<u>Id.</u> at 3) Specifically, the JP '902 patent states that "waste products and scales are removed in conjunction with the expansion of skin pores and hair pores." (<u>Id.</u>)

66. The JP '902 patent exemplifies using both polyacrylic soda, "-starch, and gum arabic as pastes with polyethylene, cellophane paper, and Japanese paper as films, respectively. (<u>Id.</u> at 7-8)

(e) The GAF Catalogs

67. The GAF catalogs were published in 1985 and 1986, respectively, by the GAF Corporation.¹⁹ (DTX 196; DTX 197)

68. Both catalogs state that poly(methyl vinyl ether/maleic acid) and poly(methyl vinyl ether/maleic anhydride) are water-soluble. (DTX 196 at 32-33; DTX 197 at 33-34)

iii. The Person of Ordinary Skill in the Art

69. A person of ordinary skill in the cosmetic field at the time when the application leading to the '382 patent was filed was a person with either a bachelor's degree in chemistry and two to three years of experience in cosmetic formulation or a master's degree in chemistry and one year of experience in cosmetic formulation.

iv. The Combination of the Gueret `552 Patent and the Gangadharan `107 Patent

70. The Gueret '552 patent coupled with the Gangadharan '107 patent disclose all of the limitations found in the asserted claims of the '382 patent. The parties did not dispute that the Gueret '552 patent discloses each and every limitation of the asserted claims with the exception of the claimed PVM/MA. The Gangadharan '107 patent discloses the use of the claimed poly(methyl vinyl ether/maleic acid) as one of the

¹⁹The GAF Corporation is headquartered in Wayne, New Jersey. (DTX 196 at 2) It later became International Specialty Polymers ("ISP"), which was referred to in the Gangadharan '107 patent as a source of poly(methyl vinyl ether/maleic acid).

most preferred copolymers for cleansing the skin. Obviousness, however, is not established merely by the presence of each limitation of the claimed invention in the prior art. As noted above, there must be some motivation to combine the references. As such, the court focuses its analysis with respect to the combination of the Gueret '552 patent and the Gangadharan '107 patent on whether there was a motivation to combine these two references to reach the invention claimed in the '382 patent and whether a person of ordinary skill in the cosmetic field could expect success from this combination.

71. The court finds that a person of ordinary skill in the cosmetic field as of the filing date of the application that led to the '382 patent would have sought to invent an improved keratotic plug remover after reviewing the Gueret '552 patent. In seeking to design around the Gueret '552 patent, a person of ordinary skill in the cosmetic field would have sought to use a water-soluble polymer distinct from those mentioned in the Gueret '552 patent. (See D.I. 87 at 527-531) Pursuant to the teaching of the Gangadharan '107 patent, a person of ordinary skill in the cosmetic field reasonably would have selected to use methylvinyl ether/maleic acid, since this polymer was disclosed to be one of the most preferred polymer embodiments. Therefore, the court agrees with defendants that the prior art references themselves and the nature of the problem to be solved provide the motivation to combine the Gueret '552 patent with the Gangadharan '107

patent.

72. The court also concludes that a person of ordinary skill in the cosmetic field would have enjoyed a reasonable expectation of success in combining the teachings of the Gueret `552 patent and the Gangadharan `107 patent. In this regard, the Gueret `552 patent recites using a water-soluble polymer to clean the pores of the skin by sloughing off the horny layer. Based upon this express teaching, a person of ordinary skill in the cosmetic art could have expected methylvinyl ether/maleic acid, as a water-soluble polymer, to successfully work in removing at least a minimum number of keratotic plugs. Thus, the court concludes that defendants have proven that the '382 patent is prima facie obvious under 35 U.S.C. § 103 in view of the combination of the Gueret `552 patent and the Gangdaharan `107 patent.

73. Before reaching a final conclusion as to the validity of the '382 patent, however, the court turns to consider whether any secondary considerations exists to rebut the prima facie case of obviousness. During the prosecution of the '382 patent, plaintiffs submitted data comparing the ability of Gantretz AN-169²⁰ and polyvinyl alcohol²¹ to remove keratotic

²⁰Gantretz AN-169 is the claimed methylvinyl ether/maleic anhydride having a molecular weight of 70,000.

²¹Polyvinyl alcohol was the only water-soluble polymer exemplified in the Gueret `552 patent.

pluqs.²² (See PTX 41 at 114) Treatment with Gantretz AN-169 resulted in a keratotic plug removal ratio of 23% whereas treatment with polyvinyl alcohol resulted in only a 4% removal The court concludes that this approximate twenty percent ratio. difference was unexpected as the Gueret '552 patent did not differentiate between the ability of different water-soluble polymers to clean pores or suggest that one type of polymer would work significantly better than others. Indeed, the Federal Circuit has explained that the doctrine of unexpected results "applies most often to the less predictable fields, such as chemistry, where minor changes in a product or process may yield substantially different results." Soni, 54 F.3d at 750. Accordingly, the court concludes that the '382 patent is not invalid for obviousness under 35 U.S.C. § 103 based on the Gueret '552 patent in combination with the Gangadharan '107 patent.

v. The Combination of the Gueret `552 Patent, the Gangadharan `107 Patent, and the GAF Catalogs

74. The above analysis applies as well to the combination of the Gueret '552 patent, the Gangadharan '107 patent, and the GAF catalogs. The GAF catalogs supplement the disclosure found in the Gangadharan '107 patent regarding watersoluble polymers. To this end, the Gangadharan '107 patent

 $^{^{\}rm 22} \rm The$ court concludes that the Gueret `552 patent was the closest prior art at the time of filing the application which granted as the `382 patent.

expressly refers to the GAF catalogs as a supplier for PVPs and methylvinyl ether/maleic acid and acid salts, the most preferred water-soluble polymers recited in the Gangadharan '107 patent. The GAF catalogs likewise increased the motivation that one of skill in the cosmetic field likely experienced to create an improved keratotic plug remover. Thus, the court finds that the combination of the Gueret '552 patent, the Gangadharan '107 patent, and the GAF catalogs also renders the invention claimed in the '382 patent prima facie obvious. Nevertheless, the secondary consideration of unexpected results discussed above exists to rebut this prima facie case of obviousness. Consequently, the court concludes that the '382 patent is not invalid for obviousness under 35 U.S.C. § 103 based on the Gueret '552 patent in combination with the Gangadharan '107 patent and the GAF catalogs.

vi. The Combination of the Nakamura `227 Patent and the Gangadharan `107 Patent

75. The court finds that the combination of the Nakamura '227 patent with the Gangadharan '107 patent discloses all of the limitations found in the asserted claims of the '382 patent. The Nakamura '227 patent discloses that the claimed toilet article may remove skin debris and blackheads from the face. The Nakamura '227 patent recites that the toilet article, composed of a sheet-like material consisting of a woven or unwoven fabric or porous film, is adhered by wetting the hydrogel

formable polymer with the cosmetic and then applying it to the skin. The Nakamura '227 patent, however, does not expressly or inherently disclose the drying and peeling limitation of claim 1 of the '382 patent, to wit, "peeling off said cosmetic article after drying." In fact, the Nakamura '227 patent teaches the opposite of drying. The Nakamura '227 patent explains that the claimed invention was designed to maintain moisture against the skin. ('227 patent, col. 1 at 11. 46-57) Based upon this language, the court understands that the disclosure found in the Nakamura '227 patent contemplates adhering the toilet article onto the skin for long periods of time in a moist state. The invention recited in the asserted claims, in contrast, specifically discusses drying and removing the cosmetic article to pull keratotic plugs from the skin.

76. The Gangadharan '107 patent, nevertheless, discloses the drying and peeling limitation. The Gangadharan '107 patent recites the application of an applique, necessarily a wet material, to the skin. The Gangadharan '107 patent explains that after the applique is applied and dried, it is removed either by peeling it from the surface of the skin or by adhering an adhesive tape type material to it and then pulling the applique/tape unit from the skin. The Gangadharan '107 patent also discloses the use of poly(methyl vinyl ether/maleic acid) as one of the most preferred copolymers for cleansing the skin, as noted above. Thus, the court finds that the Nakamura '227 patent

and the Gangadhara '107 patent together disclose all of the limitations of the asserted claims.

77. The court concludes that one of skill in the cosmetic field as of the filing date of the application that led to the '382 patent would not have been motivated to combine the Nakamura '227 patent with the Gangadharan '107 patent to achieve the claimed method of keratotic plug removal. After reading the Nakamura '227 patent, one of skill in the cosmetic field would not have been motivated to design around the claimed invention to create an improved keratotic plug remover. The Nakamura '227 is focused on solving the problems of long term delivery of a cosmetic to the skin for purposes of refreshing the skin, not on removal of keratotic plugs. The Nakamura '107 patent only mentions removal of skin debris and blackheads in a cursory way, in terms of the possible pack effects. Additionally, one of skill in the art likely would not read the Nakamura '107 patent and understand that the claimed polymer should be water-soluble. The Nakamura '107 patent offers a gamut of typical hydrogel substances, but does not disclose that water-solubility is of key importance. The Nakamura '107 patent merely describes the hydrogel formable polymer as "a substance which forms gel when water is applied to it and has a water retention characteristic of between ten times and one hundred times." ('227 patent, col. 3 at 11. 40-44) Based upon this, one of skill in the cosmetic field likely would not seek out the Gangadharan '107 patent for

its disclosure of preferred water-soluble polymers. Notably, defendants' expert, Dr. Joel L. Zatz testified:

- Q: And what would motivate you to combine Nakamura with Gangadharan as you've explained in that case?
- A: Gangadharan brings the possibility of different polymers, which are thought to be quite effective other than the ones that are mentioned specifically in Nakamura. However, I think that the previous patent, the Gueret is - is more directed in reaching out and saying try this, whereas the - the Nakamura, I think has a suggestion in it, but it's a weaker suggestion.

(D.I. 87 at 532) The court, therefore, is not convinced that one of skill in the cosmetic field would be motivated to utilize the teaching found in the Nakamura '227 patent and combine it with the teaching found in the Gangadharan '107 patent. Accordingly, the court concludes that the '382 patent is not invalid on obviousness grounds under 35 U.S.C. § 103 based on the Nakamura '227 patent in combination with the Gangadharan '107 patent.

vii. The Combination of the JP '902 Patent and the Gangadharan '107 Patent

78. The court finds that the JP '902 patent taken together with the Gangadharan '107 patent discloses each and every limitation of the asserted claims of the '382 patent. The JP '902 patent discloses all of the limitations of the asserted claims except the claimed copolymer and the concept of treating the skin for keratotic plugs. Specifically, the JP '902 patent discloses that a beauty pack material consisting of a film and a paste is adhered to the skin by either wetting the film or wetting the skin and then applying the film to the face. The JP

'902 patent also reveals that the beauty pack material is removed from the face by washing or peeling after it dries. Finally, while the JP '902 patent discusses using the disclosed invention to remove skin contaminants on the surface of the skin, the court, nevertheless, does not read this language to either expressly or inherently encompass the removal of keratotic plugs. Rather, the JP '902 patent contemplates removing contaminants from the surface of the skin, not from the pores of the skin where keratotic plugs exist.

79. The Gangadharan '107 patent discloses the two limitations missing from the JP '902 patent. The Gangadharan '107 patent specifically recites the use of the claimed PVM/MA as one of the most preferred copolymers for cleansing the skin. The Gangadharan '107 patent also reveals the use of appliques as a way to remove the debris that clogs hair follicles resulting in clogged pores, comdones, and blackheads.

80. The court finds that one of skill in the cosmetic field as of the filing date of the application that led to the '382 patent would not have been motivated to combine the JP '902 patent and the Gangadharan '107 patent to reach the claimed method of keratotic plug removal, despite the fact that these two reference together disclose all of the limitations of the asserted claims. The JP '902 patent does not mention keratotic plug removal; it only reveals using the claimed invention to tighten sagging skin, absorb and remove contaminants on the

surface of the skin, and smooth skin. One of skill in the cosmetic field, therefore, would not be motivated after reading this reference to create an improved keratotic plug remover. Moreover, because the JP '902 patent discloses using both hydrophilic and lipophilic pastes, although only exemplifies the use of hydrophilic ones, one of skill in the cosmetic field would not necessarily have consulted the Gangadharan '107 patent for its teaching regarding water-soluble polymers. Absent any reason, suggestion, or motivation to combine the JP '902 patent with the Gangadharan '107 patent, the court finds that the '382 patent is not invalid on obviousness grounds under 35 U.S.C. § 103.

D. Enforceability Based Upon Inequitable Conduct

81. Defendants allege that plaintiffs committed inequitable conduct during the prosecution of the '382 patent by providing the examiner with misleading test results for the claimed copolymer in the 1998 Uemura declaration. More particularly, defendants contend that plaintiffs' failure to include the test results for the higher molecular weight Gantretz AN-119 in the 1998 Uemura declaration constituted a material misrepresentation intended to deceive the examiner into believing that the claimed invention offered an unexpected improvement in keratotic plug removal. Defendants also argue that plaintiffs committed inequitable conduct during the prosecution of the '382 patent by failing to disclose the Nakamura '227 patent.

1. The Legal Standard

82. Applicants for patents and their legal representatives have a duty of candor, good faith, and honesty in their dealings with the PTO. Molins PLC v. Textron, Inc., 48 F.3d 1172, 1178 (Fed. Cir. 1995); 37 C.F.R. § 1.56(a). This duty is predicated on the fact that "a patent is an exception to the general rule against monopolies and to the right of access to a free and open market." Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co., 324 U.S. 806, 816 (1945). The duty of candor, good faith, and honesty includes the duty to submit truthful information and the duty to disclose to the PTO information known to patent applicants or their attorneys which is material to the examination of a patent application. Elk Corp. of Dallas v. GAF Bldg. Materials Corp., 168 F.3d 28, 30 (Fed. Cir. 1999). A breach of this duty constitutes inequitable conduct. Molins, 48 F.3d at 1178.

83. If it is established that a patent applicant engaged in inequitable conduct with respect to one claim, then the entire patent application is rendered unenforceable. <u>Kingsdown Med. Consultants v. Hollister Inc.</u>, 863 F.2d 867, 877 (Fed. Cir. 1988). Additionally, "[a] breach of the duty of candor early in the prosecution may render unenforceable all claims which eventually issue from the same or a related application." <u>Fox Indus., Inc. v. Structural Pres. Sys., Inc.</u>, 922 F.2d 801, 803-04 (Fed. Cir. 1991).

84. A finding of inequitable conduct is "an equitable determination" and, therefore, "is committed to the discretion of the trial court." <u>Monon Corp. v. Stoughton</u> <u>Trailers, Inc.</u>, 239 F.3d 1253, 1261 (Fed. Cir. 2001).

85. In order to establish unenforceability based on inequitable conduct, a defendant must establish by clear and convincing evidence that: (1) the omitted or false information was material to patentability of the invention; or (2) the applicant had knowledge of the existence and materiality of the information; and (3) the applicant intended to deceive the PTO. <u>Molins</u>, 48 F.3d at 1178.

86. A determination of inequitable conduct entails a two step analysis. First, the court must determine whether the withheld information meets a threshold level of materiality. A reference is considered material if there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent. <u>Allied Colloids, Inc. v. American Cyanamid Co.</u>, 64 F.3d 1570, 1578 (Fed. Cir. 1995) (citations omitted); <u>see also</u> 37 C.F.R. 1.56(b)(2)("[I]nformation is material to patentability when it. . . establishes . . . a prima facie case of unpatentability of a claim; or . . . refutes, or is inconsistent with, a position the applicant takes in [o]pposing an argument of unpatentability relied on by the [o]ffice, or [a]sserting an argument of patentability."). A reference, however, does not

have to render the claimed invention unpatentable or invalid to be material. <u>See Merck v. Danbury Pharmacal</u>, 873 F.2d 1418 (Fed. Cir. 1989).

87. After determining that the applicant withheld material information, the court must then decide whether the applicant acted with the requisite level of intent to mislead the PTO. See Baxter Int'l, Inc. V. McGaw Inc., 149 F.3d 1321, 1327 (Fed. Cir. 1998). "Intent to deceive cannot be inferred solely from the fact that information was not disclosed; there must be a factual basis for finding a deceptive intent." Hebert v. Lisle Corp., 99 F.3d 1109, 1116 (Fed. Cir. 1996). That is, "the involved conduct, viewed in light of all the evidence, including evidence indicative of good faith, must indicate sufficient culpability to require a finding of intent to deceive." Kingsdown, 863 F.2d at 876. A "smoking gun" is not required in order to establish an intent to deceive. See Merck, 873 F.2d at 1422. An inference of intent, nevertheless, is warranted where a patent applicant knew or should have known that the withheld information would be material to the PTO's consideration of the patent application. Critikon, Inc. v. Becton Dickinson Vascular Access, Inc., 120 F.3d 1253, 1256 (Fed. Cir. 1997).

88. Once materiality and intent to deceive have been established, the trial court must weigh them to determine whether the balance tips in favor of a conclusion of inequitable conduct. <u>N.V. Akzo v. E.I. DuPont de Nemours</u>, 810 F.2d 1148, 1153 (Fed.

Cir. 1988). The showing of intent can be proportionally less when balanced against high materiality. <u>Id.</u> In contrast, the showing of intent must be proportionally greater when balanced against low materiality. <u>Id.</u>

89. Because a patent is presumed valid under 35 U.S.C. § 282, inequitable conduct requires proof by clear and convincing evidence. <u>Manville Sales Corp. v. Paramount Sys., Inc.</u>, 917 F.2d 544, 551 (Fed. Cir. 1990).

2. Inequitable Conduct Based Upon the 1998 Uemura Declaration

90. Considering the materiality element, the prosecution history of the '382 patent reveals that plaintiffs submitted the 1998 Uemura declaration containing data for two samples of Gantretz AN-169 to overcome an obviousness rejection issued pursuant to 35 U.S.C. § 103. (See D.I. 41 at 63-66) То this end, the examiner rejected claims 19-28 as obvious over Gueret et al. 5,026,552 or Schlein 4,948,585 in view of Japan 53-27344. Plaintiffs responded to this rejection by arguing that the data contained in the 1998 Uemura declaration showed that the claimed invention exhibited unexpected improvement in keratotic plug removal. (See id. At 87-95) The examiner, nevertheless, maintained the rejection stating: "The polyacrylic salts of Gueret et al are not distinguishable from 'salt-forming' group containing polymers as claimed. The Uemura [d]eclaration results show improvement with use of certain copolymers which are comprised of certain critical monomers. Thus, the claims are not

commensurate in scope with the [d]eclaration showing." (Id. at 101) Based upon the examiner's response, it is clear that he considered the data presented in the 1998 Uemura declaration in addressing the question of obviousness, or more likely, whether any secondary considerations existed to rebut a prima facie obviousness finding. The court concludes, therefore, that the Gantretz AN-119 test data showing a keratotic plug removal ratio of 14% and the corresponding margins of error were important in deciding whether to allow the application to issue as a patent. Accordingly, the court finds defendants have shown by clear and convincing evidence that the materiality element is satisfied.

91. Turning to consider the intent element, the evidence of record does not show that plaintiffs purposefully withheld the data for the Gantretz AN-119 lower molecular weight methyl vinyl ether/maleic acid copolymer or for the margins of error associated with the comparative testing presented in the 1998 Uemura declaration. Mr. Uemura and Mr. Fukita testified that they did not know the reason why this information was not presented to the examiner. Similarly, Mr. Chinn could not explain this omission. While plaintiffs' failure to proffer some sort of explanation for their omission could be construed to mean that they intentionally sought to mislead the examiner by selectively reporting test results as argued by defendants, the court declines to accept this adverse suggestion. The court notes that plaintiffs ultimately presented the keratotic plug

removal ratio of 14% for the Gantretz AN-119 copolymer to the examiner, albeit over one year after the 1998 Uemura declaration was submitted and without the margin of error. Based upon this submission, the court infers that plaintiffs were not trying to conceal the lower ratio from the examiner. As such, the court concludes that defendants have failed to carry their burden of proof as to the intent element.

92. In balancing the materiality and intent showings, "[a]n equitable judgment must be made that, in light of all the particular circumstances, the conduct of the patentee is so culpable that its patent should not be enforced." <u>LaBounty</u> <u>Mfg. v. United States ITC</u>, 958 F.2d 1066, 1070 (Fed. Cir. 1992). The facts at bar do not show that plaintiffs' conduct during the prosecution of the '382 patent rises to the requisite level of culpability for a judgment of inequitable conduct, particularly absent a finding of intent. Accordingly, the court concludes that the '382 patent is not unenforceable based upon the 1998 Uemura declaration.

3. Inequitable Conduct Based Upon the Failure to Disclose the Nakamura `227 Patent to the Examiner

93. The court finds that a reasonable examiner would have considered the Nakamura '227 patent to be material in deciding whether plaintiffs' claimed keratotic plug remover invention was obvious under 35 U.S.C. § 103. The Nakamura '227 patent is directed to a toilet article of a sheet-like material

with an adhesive layer and a layer of hydrogel formable polymer attached thereto. The Nakamura '227 patent also discloses that the claimed toilet article is designed for skin treatment. Such disclosure was relevant to the patentability of the invention claimed in the '382 patent in that the claimed cosmetic article recites a substrate onto which a layer of copolymer is attached and is used to remove keratotic plugs from the skin. The court, consequently, concludes that the materiality element is satisfied.

94. As to the intent element, the court finds that defendants failed to prove, by clear and convincing evidence, the requisite deceptive intent. Plaintiffs submitted an English language abstract of JP-B-60-45522, the Japanese counterpart of the Nakamura '227 patent, to the examiner on September 29, 2000. (D.I. 41 at 221) The Manual of Patent Examining Procedure ("MPEP") instructs with regard to a foreign language reference that

an information disclosure statement filed under 37 C.F.R. § 1.97 shall include [a] concise explanation of the relevance, as it is presently understood by the individual designated in § 1.56(c) most knowledgeable about the content of the information, of each patent, publication, or other information listed that is not in the English language.

United States Patent and Trademark Office, United States Department of Commerce, Manual of Patent Examining Procedure § 609. The MPEP further instructs that "[s]ubmission of an English language abstract of a reference may fulfull the requirement for
a concise explanation." <u>Id.</u> In light of this teaching, the court concludes that plaintiffs complied with the requirements for submitting the Japanese counterpart of the Nakamura '227 patent to the examiner and did not intend to conceal the teaching of this reference from the examiner.

95. While the facts at bar establish the materiality element, the court declines to find inequitable conduct. The degree of materiality does not outweigh the absence of intent. The court, consequently, concludes that plaintiffs' conduct was not so culpable as to hold the '352 patent unenforceable based upon the failure to disclose the Nakamura '227 patent to the examiner.

E. Attorneys' Fees Award in Exceptional Cases

96. "The court in exceptional circumstances may award reasonable attorney fees to the prevailing party." 35 U.S.C. § 285. In deciding whether to award attorneys' fees, the court must undertake a two-step inquiry. <u>See Interspiro USA, Inc. v.</u> <u>Figgie Intern. Inc.</u>, 18 F.3d 927, 933 (Fed. Cir. 1994). First, the court "must determine whether there is clear and convincing evidence that the case is 'exceptional.'" <u>Id.</u> Second, the court must determine whether "an award of attorney fees to the prevailing party is warranted." <u>Id</u>. Exceptional cases include: "[i]nequitable conduct before the PTO; litigation misconduct; vexatious, unjustified, and otherwise bad faith litigation; a frivolous suit or willful infringement." <u>Epcon Gas Sys., Inc. v.</u>

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Bauer Compressors, Inc., 279 F.3d 1022, 1034 (Fed. Cir. 2002).

97. The court concludes that the case at bar is not exceptional such that defendants merit an award of attorneys fees. Nothing in the record suggests that plaintiffs engaged in bad faith litigation.

IV. CONCLUSION

For the reasons stated, the court finds the '382 patent is not literally infringed by defendants' accused infringing product, is not invalid for inadequate written description, indefiniteness, or obviousness, and is not unenforceable due to inequitable conduct. An appropriate order shall issue.

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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

KAO CORPORATION and THE)			
ANDREW JERGENS COMPANY,)			
)			
Plaintiffs,)			
)	~ '		01 600 875
V .)	ClV.	NO.	01-680-SLR
)			
	TNC)			
and CONORCO INC	INC.)			
and conorco, inc.,)			
Defendants)			
Detendants.)			

ORDER

At Wilmington this 3rd day of September, 2004, consistent with the opinion issued this same date;

IT IS ORDERED that defendants do not literally infringe U.S. Patent No. 6,306,382 (the "`382 patent").

IT IS FURTHER ORDERED that the '382 patent is not invalid or unenforceable for inequitable conduct.

IT IS FURTHER ORDERED that, on or before **September 30**, **2004**, the parties shall submit a joint proposed order of judgment for the court's signature.

> Sue L. Robinson United States District Judge