

**UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT**

NICHOLAS V. PERRICONE, M.D., :	:	
Plaintiff	:	
	:	
v.	:	Civil Action No.
	:	3:99 CV 1820 (CFD)
MEDICIS PHARMACEUTICAL CORP., :	:	
Defendant	:	

RULING ON MOTIONS FOR SUMMARY JUDGMENT

The plaintiff, Nicholas V. Perricone, M.D., filed this action against the defendant, Medicis Pharmaceutical Corp., alleging infringement of U.S. Patent No. 5,409,693, entitled “Method for Treating and Preventing Sunburn and Sunburn Damage to the Skin” and U.S. Patent No. 5,574,063, entitled “Method and Compositions for Topical Application of Ascorbic Acid Fatty Acid Esters for Treatment and/or Prevention of Skin Damage.” The plaintiff has filed a Motion for Summary Judgment of Infringement [Doc. #215] and a Motion for Summary Judgment of Validity of U.S. Patent No. 5,409,693 and U.S. Patent No. 5,574,063 [Doc. #216]. The defendant has filed a Motion for Partial Summary Judgment of Invalidity of Certain Claims of Plaintiff’s U.S. Patent Nos. 5,574,063 and 5,409,693 on the Grounds of Double Patenting and Anticipation [Doc. #221] and a Motion for Partial Summary Judgment of Non-Infringement of Plaintiff’s U.S. Patent No. 5,409,693 [Doc. #226].

I. Background¹

A. Subject Matter of the Patents

¹The following facts are taken from the parties’ Local Rule 56(a) (formerly Local Rule 9(c)) statements, summary judgment briefs, and other evidence submitted by the parties. They are undisputed unless otherwise indicated.

The two patents which are the subject of this lawsuit, both owned by the plaintiff, Nicholas V. Perricone, M.D. (“Perricone”), concern methods for treating and preventing certain skin conditions by applying to the skin compositions containing a chemical compound known as a fatty acid ester of ascorbic acid. A fatty acid ester of ascorbic acid is formed by combining Vitamin C with a fatty acid. A fatty acid ester of ascorbic acid is sometimes referred to as an “ascorbyl fatty acid ester.” Ascorbyl palmitate, ascorbyl laurate, ascorbyl myristate and ascorbyl stearate are examples of fatty acid esters of ascorbic acid.

When an appropriate amount of a fatty acid ester of ascorbic acid is applied to the skin, it is capable of neutralizing highly reactive, oxygen-containing chemical entities known as “free radicals” that are created when ultraviolet radiation from the sun strikes the skin. Free radicals cause a number of harmful chemical reactions in the skin which can result in damage to collagen and other skin structures and an inflammation of the skin that is generally referred to as sunburn. Chemical compounds or substances such as fatty acid esters of ascorbic acid that have the ability to neutralize free radicals are known as “antioxidants.”

Both U.S. Patent No. 5,409,693 and U.S. Patent No. 5,574,063 are method patents² that concern the use of ascorbyl fatty acid ester compositions. Generally, U.S. Patent No. 5,409,693 concerns a method for treating and preventing sunburn, and U.S. Patent No. 5,574,063 concerns a

²A “method” or “process” patent discloses “a mode of treatment of certain materials to produce a given result. It is an act, or a series of acts, performed upon the subject-matter to be transformed and reduced to a different state or thing.” 1 D. Chisum, *Chisum on Patents*, § 1.03[1] (2002) (quoting *Cochrane v. Deener*, 94 U.S. 780, 787-88 (1877)); see also 35 U.S.C. § 100(b) (defining “process” so as to include a “process, art or method”).

method for treating a range of skin conditions, including psoriasis and the effects of aging.

B. History of the Patent Applications

Perricone filed U.S. Patent Application No. 07/420287 (the “Parent Application”)³ on October 12, 1989. Claim 1 of the Parent Application was directed to “a method for the treatment of skin disorders which are directly caused or mediated by collagen deficiency, and/or oxygen-containing free radicals and/or oxidative generation of biologically active metabolites, said treatment comprising topically applying to the affected skin areas an effective amount of a fat-soluble fatty acid ester of ascorbic acid.” Parent Application at 14. During prosecution of the Parent Application, the United States Patent and Trademark Office (“PTO”) rejected claim 1. The Parent Application was continued as U.S. Patent Application No. 08/024890.

On March 1, 1993, Perricone filed a Pre-Examination Amendment to U.S. Patent Application No. 08/024890 (the “Amendment”). In the Amendment, Perricone revised claim 1 of the Parent Application to direct it to “a method for treating skin sunburn comprising topically applying to the skin sunburn a fatty acid ester of ascorbic acid effective to scavenge therefrom free radicals present as a result of transfer of energy to the skin from the ultraviolet radiation which produced said sunburn.” Amendment at 2. On April 25, 1995, U.S. Patent No. 5,409,693 (the “693 patent”) issued to Perricone.

On March 17, 1995, Perricone filed U.S. Patent Application No. 08/407413. That application resulted in the issuance to Perricone of U.S. Patent No. 5,574,063 (the “063 patent”) on

³This application is referred to as the “parent” application in light of its relationship to the two subsequent, related patents.

November 12, 1996.

On September 15, 1999, Perricone filed the instant suit, claiming direct and induced infringement⁴ of the '693 and '063 patents by the defendant, Medicis Pharmaceutical Corporation ("Medicis"), in connection with Medicis' "LUSTRA" lines of prescription skin depigmenters, or skin whiteners.

Perricone has filed motions for summary judgment of validity and infringement of the '693 and '063 patents. Medicis has filed a motion for partial summary judgment of invalidity of claims 9, 11-13, 16, 18, and 19 of the '063 patent on the basis of double patenting,⁵ and of claims 1-4, 7-9, and 13 of the '693 patent and claims 1-19 of the '063 patent on the basis of anticipation by the prior art.⁶ In its

⁴Section 271 of Title 35 of the U.S. Code prohibits direct and induced infringement and provides, in relevant part:

- (a) Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.
- (b) Whoever actively induces infringement of a patent shall be liable as an infringer.

35 U.S.C. § 271. In order to succeed on a claim of induced infringement, the patentee must establish that (1) there has been direct infringement; and (2) the alleged infringer knowingly induced infringement and possessed the specific intent to encourage another's infringement. See Minn. Mining & Mfg. Co. v. Chemque, Inc., 303 F.3d 1294, 1304-05 (Fed. Cir. 2002). "In other words, the plaintiff has the burden of showing that the alleged infringer's actions induced infringing acts and that he knew or should have known his actions would induce actual infringements." Id. (internal quotation marks omitted).

⁵Though Perricone argues that Medicis's double patenting defense should not be heard because Perricone was not given notice of this affirmative defense, the Court concludes that Perricone was given adequate notice pursuant to Federal Rules of Civil Procedure 8(c) and 56.

⁶On January 25, 2001, this Court entered the Stipulation and Order the parties had executed to reflect their agreement to dismiss, with prejudice, Perricone's claims that Medicis had infringed claims 5, 6, 10-12 of the '693 patent and claims 20-25 of the '063 patent and that a declaratory judgment of non-

answer, Medicis also asserted defenses of obviousness, vagueness, noncompliance with applicable patent regulations, and failure to comply with certain requirements for seeking patent-related damages. These defenses do not appear to be addressed in the motion for partial summary judgment of invalidity, however.

II. Summary Judgment Standard

The general standard for summary judgment applies in a patent case. See Brown v. 3M, 265 F.3d 1349, 1350 (Fed. Cir. 2001) (general summary judgment standard applies to invalidity); TechSearch, L.L.C. v. Intel Corp., 286 F.3d 1360, 1369 (Fed. Cir. 2002) (same summary judgment standard applied to non-infringement). Accordingly, as to each motion for summary judgment, the burden is on the moving party to establish that there are no genuine issues of material fact in dispute and that it is entitled to judgment as a matter of law. See Fed. R. Civ. P. 56(c); Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 256 (1986). A court must grant summary judgment “‘if the pleadings, depositions, answers to interrogatories, and admissions on file, together with affidavits, if any, show that there is no genuine issue as to any material fact’” Miner v. Glen Falls, 999 F.2d 655, 661 (2d Cir. 1993) (citation omitted). A dispute regarding a material fact is genuine “‘if the evidence is such that a reasonable jury could return a verdict for the nonmoving party.’” Aldrich v. Randolph Cent. Sch. Dist.,

infringement of these claims should be entered in the defendant’s favor. However, the parties did not stipulate as to the validity or invalidity of these claims. Perricone’s motion for summary judgment of validity appears to request summary judgment of validity as to all claims of the ‘693 and ‘063 patents. Medicis’ motion for summary judgment of invalidity appears to suggest that claims 5, 6, 10-12 of the ‘693 patent and claims 20-25 of the ‘063 patent are invalid, but does not directly address this issue. Therefore, the validity of these claims will not be addressed in this opinion, and the parties shall file briefs on this issue within thirty days.

963 F.2d 520, 523 (2d Cir.) (quoting Anderson, 477 U.S. at 248), cert. denied, 506 U.S. 965 (1992). After discovery, if the nonmoving party “has failed to make a sufficient showing on an essential element of [its] case with respect to which [it] has the burden of proof,” then summary judgment is appropriate. Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986).

The Court resolves “all ambiguities and draw[s] all inferences in favor of the nonmoving party in order to determine how a reasonable jury would decide.” Aldrich, 963 F.2d at 523. “Only when reasonable minds could not differ as to the import of the evidence is summary judgment proper.” Bryant v. Maffucci, 923 F.2d 979, 982 (2d Cir.), cert. denied, 502 U.S. 849 (1991); see also Suburban Propane v. Proctor Gas, Inc., 953 F.2d 780, 788 (2d Cir. 1992).

III. Claim Construction

The first step in analyzing the validity and infringement issues raised by the motions for summary judgment is claim construction, that is, the determination of the ordinary and customary meaning that would be attributed to the claim terms by those skilled in the art. See Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed. Cir. 1995) (en banc) (Markman I), aff’d, 517 U.S. 370 (1996) (Markman II). In construing a claim, a court initially looks to intrinsic evidence, which includes “the patent itself, including the claims, the specification, and, if in evidence, the prosecution history.” Vitronics Corp. v. Conceptoronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996). In examining the intrinsic evidence, the court first considers “the words of the claims themselves, both asserted and nonasserted, to define the scope of the patented invention.” Id. These words are to be given their ordinary and customary meaning, which is presumed to be correct unless a different meaning is clearly and deliberately set forth in the intrinsic materials or unless the ordinary and accustomed meaning would

deprive the claim of clarity. See K-2 Corp. v. Salomon S.A., 191 F.3d 1356, 1362-63 (Fed. Cir. 1999).

The court also may reference other intrinsic evidence, including the specification and prosecution history. Prosecution history contains the record of proceedings before the Patent and Trademark Office and the prior art cited therein. See id; Vitronics, 90 F.3d at 1583; Markman I, 52 F.3d at 980. While an analysis of the intrinsic evidence generally will resolve ambiguity in a disputed term, the court may look to extrinsic evidence when this is not the case. See Vitronics 90 F.3d at 1583-84; Lacks Industries Inc. v. McKechnie Vehicle Components USA Inc., 322 F.3d 1335 (Fed. Cir. 2003). Extrinsic evidence includes expert testimony, inventor testimony, dictionaries, technical treatises and articles, and prior art not cited in the specification or file history. See Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1308 (Fed. Cir. 1999); Vitronics, 90 F.3d at 1584. This evidence, and in particular expert testimony, may be used only to assist the court in arriving at the proper understanding of the claims; it may not be used to vary or contradict the claim language or other parts of the specification. See Vitronics, 90 F.3d at 1584. However, “it is entirely appropriate, perhaps even preferable, for a court to consult trustworthy extrinsic evidence to ensure that the claim construction it is tending to from the patent file is not inconsistent with clearly expressed, plainly apposite and widely held technical understandings in the pertinent technical field.” Pitney Bowes, Inc., 182 F.3d at 1309.

The construction of the relevant claims of the ‘693 and ‘063 patents appears to be undisputed, with the exception of the issue of whether the ‘693 patent covers skin depigmenters. Accordingly, with the exception of that issue, the claim construction set forth below is based on Perricone’s claim

construction contained in his memorandum in support of his motion for summary judgment of infringement.⁷

A. Claims of the '693 Patent

The '693 patent contains thirteen claims. Claims 1 and 8 are its independent claims.⁸ They read:

1. A method for treating skin sunburn comprising topically applying to the skin sunburn a fatty acid ester of ascorbic acid effective to solubilize in the lipid-rich layers of the skin an amount effective to scavenge therefrom free radicals present as a result of transfer of energy to the skin from the ultraviolet radiation which produced said sunburn.

8. A method for preventing sunburn damage to exposed skin surfaces, comprising topically applying to said skin surfaces a fatty acid ester of ascorbic acid effective to solubilize in the lipid-rich layers of the skin in an amount effective to scavenge therefrom free radicals generated by reason of transfer of energy to the exposed skin surfaces from the ultraviolet radiation of sunlight.

U.S. Patent No. 5,409,693. The other, dependent, claims of the '693 patent specify that the fatty acid esters of ascorbic acid be delivered in an "dermatologically acceptable carrier" (Claims 2 and 9), that a specific fatty acid ester of ascorbic acid be used (Claims 3, 4, 11, and 12), that a particular amount of fatty acid ester of ascorbic acid be used (Claims 5, 6, and 10), and that Vitamin E be added to the

⁷The Court notes that the parties have not requested a Markman hearing on the issue of whether the '693 patent covers skin depigmenters. Additionally, the Court need not reach this issue, or Medicis's estoppel argument, in light of its findings on double patenting and anticipation infra.

⁸Pursuant to 35 U.S.C. § 112, "[a] claim may be written in independent, or if the nature of the case admits, in dependent or multiple dependent form." A dependent claim is one that contains "a reference to a claim previously set forth" and specifies "a further limitation of the subject matter claims." Id. Dependent claims are "construed to incorporate by reference all the limitations of the claim to which [they] refer[]." Id.

composition (Claims 7 and 13).

“Skin sunburn,” as disclosed in claim 1, is a type of skin damage caused by ultraviolet radiation. The cause of sunburn is believed to be the generation of oxygen species resulting from the transfer of energy from ultraviolet radiation to the skin. Those oxygen species are referred to as “free radicals” and can cause damage to the DNA of the cells. Skin sunburn covers a spectrum of clinical symptoms from mild increased sensitivity of the skin to severe pain. In addition, inflammatory redness of the skin, referred to as “erythema,” may accompany the sensitivity of the skin. Sunburn damage, as described in claim 8, includes damage to the skin membranes, skin cells, DNA, erythema, premature aging of the skin, cancerous growths of the skin, and diminished collagen content. Collagen is a protein that serves as the support structure for the skin and other connective tissues.

“Topically applying” refers to applying a substance directly to the surface of the skin, in contrast to oral, intravenous, or other administration.

A “fatty acid ester of ascorbic acid” is a form of Vitamin C that is fat-soluble. “Soluble” means capable of being dissolved. “Fatty acid” refers to any acid derived from fats by a chemical reaction with water. “Ester” refers to an organic compound that is usually formed by the reaction between an acid and an alcohol with elimination of water. A “fatty acid ester of ascorbic acid” is also referred to as an “ascorbyl fatty acid ester.” The class of chemical compounds known as ascorbyl fatty acid esters includes ascorbyl palmitate, ascorbyl laurate, ascorbyl myristate and ascorbyl stearate.

“Effective to solubilize” refers to the ability of the ascorbyl fatty acid ester to be dissolved and readily absorbed through the skin’s surface and delivered to its intended target.

“Lipid-rich layers of the skin” are layers of the skin which contain abundant amounts of lipids.

“Lipids” are fat-containing organic compounds. The epidermis and dermis layers are lipid-rich layers of the skin. The epidermis is the outermost layer of the skin, functions as a protective barrier, and consists primarily of cells named keratinocytes, which produce the protein known as keratin, and melanocytes, which produce pigment in the skin. The dermis is the middle layer and is a tough, supportive connective tissue matrix connected to the epidermis. The dermis principally consists of collagen, but also contains fibroblasts, a type of cell that synthesizes collagen, among other functions.

“Effective to solubilize in the lipid-rich layers of the skin” therefore means that the ascorbyl fatty acid ester is capable of penetrating the skin’s surface and is available to the epidermis and dermis layers of the skin.

“Free radicals” are atoms or molecules having at least one unpaired electron. They are created during an energy transfer that takes place when ultraviolet radiation hits the skin. Because free radicals have an unpaired electron, they naturally seek to normalize (or stabilize) themselves by attacking neighboring molecules and capturing their free electrons. When they attack lipid cell membranes in the skin, free radicals produce a host of dangerous chemicals which can injure cell membranes and impair the proper function of cells. Free radicals may be neutralized or “scavenged” by certain substances that capture the free electron to render the free radical harmless. An ascorbyl fatty acid ester is capable of “scavenging” free radicals when it solubilizes in the lipid-rich layers of the skin.

The amount of ascorbyl fatty acid ester “effective” to scavenge free radicals depends upon the particular disorder, its severity and extent, the particular ascorbyl fatty acid ester employed, and its concentration.

A “dermatologically acceptable carrier” means that the carrier should resist washing off and

should aid in delivery and penetration of the ingredient ascorbyl fatty acid ester into the lipid-rich layers of the skin.

B. Claims of the '063 Patent

The '063 patent has twenty-five claims. Claims 1, 9, and 16 are the relevant independent claims of the '063 patent. They read:

1. A method for the treatment of skin disorders which arise because of depleted or inhibited collagen synthesis which comprises topically applying to the affected skin areas a composition containing ascorbyl fatty acid in a dermatologically acceptable, fat-penetrating carrier such that the ester is percutaneously delivered to the lipid-rich layers of the skin in amounts effective to accelerate collagen synthesis.

9. A method for the treatment of skin damaged or aged by oxygen- containing free radicals or oxidative generation of biologically active metabolites which comprises topically applying to affected skin areas a composition containing an effective amount of an ascorbyl fatty acid ester in a dermatologically acceptable, fat-penetrating carrier such that the ester is percutaneously delivered to the lipid rich layers of the skin.

16. A method for the treatment of damaged or aging skin and epithelial tissue disorders which are directly or indirectly caused or mediated by collagen deficiency, oxygen-containing free radicals, oxidative generation of biologically active metabolites, or mixtures of these, said treatment comprising topically applying to the affected tissue areas, the combination of

- A. an effective amount of a fat-soluble fatty acid ester of ascorbic acid selected from the group consisting of ascorbyl palmitate, ascorbyl laurate, ascorbyl myristate, ascorbyl stearate, and mixtures thereof, and
- B. a compound selected from the group consisting of [alpha]-, [beta]-, [gamma]-, and [delta]-tocotrienols, desmethyl-tocotrienol, didesmethyl-tocotrienol, their derivatives having methylated or demethylated chroman rings, acylated derivatives and alpha-hydroxy acids, and mixtures thereof,

all in a carrier composition that solubilizes and dispenses the above active ingredients.

U.S. Patent No. 5,574,063. Claims 2 to 8, 10 to 15, and 17 to 19 are the relevant dependent claims of the '063 patent. These claims require that the topical skin compositions described in the '063 patent contain a certain weight of ascorbyl fatty acid ester (Claims 2, 3, and 11), that lecithin be used as a carrier (Claims 4, 10, and 17), that ascorbyl palmitate, ascorbyl laurate, ascorbyl myristate and/or ascorbyl stearate be used as the ascorbyl fatty acid ester (Claims 5-6, 12-13, and 19), and that the composition further contain an alpha-hydroxy acid (Claims 7, 14 and Claims 8, 15, and 18, specifying glycolic acid).

Disorders arising from “depleted or inhibited collagen synthesis,” as disclosed in claim 1, may be caused by chronic exposure to sunlight as well as the natural aging process. “Skin disorders which arise because of depleted or inhibited collagen synthesis” include photoaging, also known as dermatoheliosis, photodamage, and psoriasis. Photoaging is the clinical appearance of leathery, inelastic, sallow skin with dilated blood vessels, and may include wrinkling, dyspigmentation, rough texture, pre-skin cancer, and skin cancer. Psoriasis is a chronic, recurrent, scaling skin disease of unknown etiology.

“Skin damaged or aged by oxygen-containing free radicals or oxidative generation of biologically active metabolites,” as disclosed in claim 9, also refers to the effects of skin sunburn, psoriasis, and natural aging.

“Damaged or aging skin and epithelial tissue disorders which are directly or indirectly caused or mediated by collagen deficiency, oxygen-containing free radicals, oxidative generation of biologically

active metabolites, or mixtures of these” also refers to the effects of skin sunburn, psoriasis, and natural aging. “Epithelial tissue” refers to a group of cells tightly bound together in coherent sheets or layers.

“Epithelial tissue disorders” are conditions or malfunctions of the epithelial tissue.

A “dermatologically acceptable, fat-penetrating carrier” means an ingredient that is capable of dissolving other active ingredients and may include water, alcohol, and oil. As noted above, “dermatologically acceptable” means that the carrier should resist washing off and should aid in delivery and penetration of the ingredient ascorbyl fatty acid ester into the lipid-rich layers of the skin. “Fat-penetrating” means fat-soluble such that it facilitates the passage of the ascorbyl fatty acid ester into the lipid-rich layers of the skin. Examples of the carrier include lotion, cream, ointment and soap.

“Percutaneously” means the passage of substances through unbroken skin. To “percutaneously deliver” an ascorbyl fatty acid ester to the skin means to administer it through the skin. This limitation is synonymous with “effective to solubilize,” previously construed for claims 1 and 8 of the ‘693 patent.

Similar to the effective amounts of claim 1 of the ‘693 patent for scavenging free radicals resulting from sun exposure, the amount that is “effective” to accelerate collagen synthesis and “an effective amount of an ascorbyl fatty acid ester in a dermatologically acceptable, fat-penetrating carrier such that the ester is percutaneously delivered to the lipid rich layers of the skin” varies, depending upon factors such as the particular disorder being treated, its severity and extent, the particular ascorbyl fatty acid ester used, and its concentration. The limitation of “amounts effective to accelerate collagen synthesis” refers to the concentration of ascorbyl fatty acid ester necessary to stimulate the skin into increasing collagen production.

“[Alpha]-, [beta]-, [gamma]-, and [delta]-tocotrienols, desmethyl-tocotrienol, didesmethyl-

tocotrienol, their derivatives having methylated or demethylated chroman rings, acylated derivatives and alpha-hydroxy acids, and mixtures thereof,” as disclosed in claim 16, refers to certain forms of tocopherols, or Vitamin E. “[Alpha]-hydroxy acids” include glycolic acid and can further enhance the efficacy of the compositions.

“Lecithin,” as disclosed in claims 4, 10, and 17, is a wetting, emulsifying, and penetrating agent.

The terms contained in the relevant claims of the ‘063 patent that overlap with terms contained in the relevant claims of the ‘693 patent are hereby incorporated by reference.

IV. Validity

Under the patent statutes, a patent enjoys a presumption of validity, which can be overcome only through clear and convincing evidence. See 35 U.S.C. § 282; United States Surgical Corp. v. Ethicon, Inc., 103 F.3d 1554, 1563 (Fed.Cir.1997). “Thus, a moving party seeking to invalidate a patent at summary judgment must submit such clear and convincing evidence of invalidity so that no reasonable jury could find otherwise. Alternatively, a moving party seeking to have a patent held not invalid at summary judgment must show that the nonmoving party, who bears the burden of proof at trial, failed to produce clear and convincing evidence on an essential element of a defense upon which a reasonable jury could invalidate the patent. In determining whether a genuine issue of material fact exists, the court views the evidence in the light most favorable to the nonmoving party and resolves all doubts in its favor.” Eli Lilly and Co. v. Barr Laboratories, Inc., 251 F.3d 955, 962 (Fed. Cir. 2001) (citing Anderson, 477 U.S. at 255, and Transmatic, Inc. v. Gulton Indus., Inc., 53 F.3d 1270, 1274 (Fed. Cir.1995)).

As noted above, Medicis has filed a motion for partial summary judgment of invalidity of claims

9, 11-13, 16, 18, and 19 of the '063 patent on the basis of double patenting and of claims 1-4, 7-9, and 13 of the '693 patent and claims 1-19 of the '063 patent on the basis of anticipation. Each issue will be examined below.

A. Double Patenting

“The basic concept of double patenting is that the *same* invention cannot be patented more than once, which, if it happened, would result in a second patent which would expire some time after the original patent and extend the protection timewise.” General Foods Corp. v. Studiengesellschaft Kohl mbH, 972 F.2d 1272, 1279-80 (Fed. Cir. 1992) (emphasis in original). Double patenting precludes a person from obtaining more than one patent for either the “same invention” or an “obvious” modification of the same invention. In re Longi, 759 F.2d 887, 892 (Fed. Cir. 1985). “Same invention” double patenting is where a patentee obtains two patents for the identical subject matter. See id.

“Obviousness-type” double patenting, on the other hand, “is a judicially created doctrine grounded in public policy” and prohibits “the issuance of the claims in a second patent not patentably distinct from the claims of the second patent.” Id. at 892. This type of double patenting occurs when a patent’s claim(s) are “merely an obvious variation” of the other patent claim. See In re Goodman, 11 F.3d 1046, 1052 (Fed. Cir. 1993); Georgia-Pacific Corp. v. United States Gypsum Co., 195 F.3d 1322, 1326 (Fed. Cir. 1999) (“Under obviousness-type double patenting, a patent is invalid when it is merely an obvious variation of an invention disclosed and claimed in an earlier patent by the same inventor”). Obviousness-type double patenting can be overcome by filing a “terminal disclaimer” with the PTO before the second patent issues, in which the patentee disclaims the portion of the second patent which would extend beyond the expiration of the first and thus “gives up any extension of the patent protection

that might have resulted.”⁹ Goodman, 11 F.3d at 1052.

As noted above, Medicis argues that certain claims of the ‘063 patent are double patented over claim 1 of the ‘693 patent and certain of the ‘693 patent’s dependent claims. Specifically, Medicis argues that Perricone engaged in obviousness-type double patenting by first obtaining a narrow, “species” patent, and then later obtaining a broader, “genus” patent that encompasses the same invention claimed in the species patent. Medicis argues that the cited ‘693 patent claims regard inventions that are merely subsets of broader inventions encompassed in the ‘063 patent claims.

“Generally, an obviousness-type double patenting analysis entails two steps. First, as a matter of law, a court construes the claim in the earlier patent and the claim in the later patent and determines the differences. Second, the court determines whether the differences in subject matter between the two claims render the claims patentably distinct.” Lilly, 251 F.2d at 968 (internal citations omitted). In accordance with that standard, using the Court’s claims construction above, the Court determines the differences in subject matter between the claims. As noted above, Medicis argues that claims 9, 11-13, 16, 18, and 19 of the ‘063 patent are double patented over claim 1 of the ‘693 patent and certain of the ‘693 patent’s dependent claims.

1. Differences Between Claim 9 of the ‘063 Patent and Claim 1 of the ‘693 Patent

As noted above, Claim 1 of the ‘693 patent teaches “a method for treating skin sunburn comprising topically applying to the skin sunburn a fatty acid ester of ascorbic acid effective to solubilize in the lipid-rich layers of the skin an amount effective to scavenge therefrom free radicals present as a

⁹It is undisputed that Perricone did not file a terminal disclaimer before the ‘063 patent issued.

result of transfer of energy to the skin from the ultraviolet radiation which produced said sunburn.” U.S. Patent No. 5,409,693, claim 1. Claim 9 of the ‘063 patent teaches “a method for the treatment of skin damaged or aged by oxygen-containing free radicals or oxidative generation of biologically active metabolites” comprising the topical application of an effective amount of an ascorbyl fatty acid ester in a carrier such that the ester is “percutaneously delivered to the lipid-rich layers of the skin.” U.S. Patent No. 5,574,063, claim 9. Dependent claims 12 and 13 of the ‘063 patent teach specific variations of the method taught in claim 9.

The parties do not dispute that ascorbyl fatty acid ester is another name for a fatty acid ester of ascorbic acid. Nor do they dispute that the methods taught in both claim 1 of the ‘693 patent and claim 9 of the ‘063 patent involve the application of ascorbyl fatty acid ester to the skin. The only differences between claim 9 of the ‘063 patent and claim 1 of the ‘693 patent are the following: (1) claim 9 of the ‘063 patent teaches a method for treatment of certain skin disorders, while claim 1 of the ‘693 patent teaches a method for treatment of sunburn; (2) claim 9 of the ‘063 patent recites the use of “an effective amount of an ascorbyl fatty acid ester . . . ,” while claim 1 of the ‘693 patent teaches applying an ascorbyl fatty acid ester “effective to solubilize in the lipid-rich layers of the skin an amount effective to scavenge free radicals present as a result of the transfer of energy to the skin from the ultraviolet radiation which produced [the] sunburn”; and (3) claim 9 of the ‘063 patent recites the use of “a dermatologically acceptable, fat-penetrating carrier such that the ester is percutaneously delivered to lipid-rich layers of the skin,” while the ‘693 patent does not explicitly recite the use of a carrier.

These differences do not render claim 9 of the ‘063 patent patentably distinct from claim 1 of the ‘693 patent. First, a person of ordinary skill in the art would have recognized that “skin sunburn” is

one type of “skin damaged or aged by oxygen-containing free radicals or oxidative generation of biologically active metabolites.” Though Perricone argues that these two claims aim at achieving different objectives—one to treat skin damaged by free radicals or metabolites from any source or cause and the other to scavenge free radicals resulting only from sunburn-producing ultraviolet radiation—the latter objective is merely a subset of the first. Said differently, sunburn is a species of the genus of skin disorders mentioned in the ‘063 patent. See Lilly, 251 F.3d at 971 (“Our case law firmly establishes that a later genus claim limitation is anticipated by, and therefore not patentably distinct from, an earlier species claim.”). It is “well settled that a generic claim cannot be allowed to an applicant if the prior art discloses a species falling within the claimed genus.” 1 Donald Chisum, *Chisum on Patents*, § 3.02[2] (2001) (quoting In re Slayter, 276 F.2d 408, 411 (C.C.P.A. 1960)); see also In re Berg, 140 F.3d at 1437 (Fed. Cir.1998); In re Goodman, 11 F.3d 1046, 1053 (Fed. Cir.1993); In re Van Ornum, 686 F.2d 937, 944 (C.C.P.A.1982).

Additionally, though the “effective” amounts claimed in the ‘693 patent may be different from those in the ‘063 patent, again, those amounts are subsumed within the broader range of “effective” amounts claimed in the ‘063 patent. The specifications of the ‘693 patent indicate that the ascorbyl fatty acid ester compositions should “contain at least about 0.5% by weight, more preferably at least about 2% by weight, and most preferably at least about 10% by weight.” U.S. Patent No. 5,409,693, col. 3, lines 30-42, while the specifications of the ‘063 patent indicate that the ascorbyl fatty acid ester compositions should “contain from about 0.025% to about 10%” by weight, ascorbyl fatty acid esters. U.S. Patent No. 5,574,063, col. 4, lines 36-49. Accordingly, the range of “effective amount[s] of an ascorbyl fatty acid ester in a dermatologically acceptable, fat-penetrating carrier such that the ester is

percutaneously delivered to the lipid rich layers of the skin,” as disclosed in claim 9 of the ‘063 patent, encompasses the narrower range of “amount[s] effective to scavenge therefrom free radicals present as a result of transfer of energy to the skin from the ultraviolet radiation which produced said sunburn,” as disclosed in claim 1 of the ‘693 patent.

Finally, though claim 1 of the ‘693 patent does not expressly recite the use of a fat-penetrating carrier, “deliver[y]” by a “dermatologically acceptable, fat-penetrating carrier such that the ester is percutaneously delivered to the lipid rich layers of the skin” as discussed in the ‘063 patent, is the same as delivery “effective to solubilize” the fatty acid ester in the “lipid-rich layers of the skin,” as disclosed in claim 9 of the ‘693 patent. This is evidenced by the specifications of both patents, which indicate that the ascorbyl fatty acid ester composition is to be used with a “dermatologically acceptable carrier” and that the “most preferred” carrier is “fat-soluble, i.e., th[at] which can effectively penetrate skin layers and deliver the active ascorbyl fatty acid ester to the lipid-rich layers of the skin.” U.S. Patent No. 5,409,693, col 4, lines 1-6, and U.S. Patent No. 5,574,063, lines 7-12.

Accordingly, claim 9 of the ‘063 patent is invalid as double patented over claim 1 of the ‘693 patent.

2. Differences Between Claims 12 and 13 of the ‘063 Patent and Claim 1 of the ‘693 Patent

Claims 12 and 13 of the ‘063 patent teach specific variations of the method taught in claim 9 of the ‘063 patent. They read:

12. A method according to claim 9 wherein the ascorbyl fatty acid ester is selected from the group consisting of ascorbyl palmitate, ascorbyl laurate, ascorbyl myristate, ascorbyl stearate and mixtures thereof.

13. A method according to claim 12 wherein said fatty acid ester of ascorbic acid is ascorbyl palmitate.

U.S. Patent No. 5,574,063. Claims 3 and 4 of the '693 patent read:

3. A method according to claim 2 wherein said fatty acid ester of ascorbic acid is selected from the group consisting of ascorbyl palmitate, ascorbyl laurate, ascorbyl myristate, ascorbyl stearate and mixtures thereof.

4. A method according to claim 3 wherein said fatty acid ester of ascorbic acid is ascorbyl palmitate.

U.S. Patent No. 5,409,693. Because claim 9 of the '063 patent is invalid for double patenting, claim 12 is dependent on claim 9, and claim 12 adds no limitations over claim 3 of the '693 patent, claim 12 of the '063 patent is invalid for double patenting. Similarly, because claim 9 of the '063 patent is invalid for double patenting, claim 13 is dependent on claim 9, and claim 13 adds no limitations over claim 4 of the '693 patent, claim 13 of the '063 patent is invalid for double patenting.

3. Differences Between Claims 16, 18, and 19 of the '063 Patent and Claims 4 and 7 of the '693 Patent

Claim 16 of the '063 patent teaches a method for the treatment of damaged skin through application of an ascorbyl fatty acid ester. Claims 18 and 19 of the '063 patent are dependent on claim 16 and teach a specific variation of the method taught in claim 16. Claim 7 of the '693 patent teaches a method for the treatment of skin sunburn by the application of a fatty acid ester of ascorbic acid composition containing Vitamin E. As noted above, the differences regarding "damaged skin" versus "skin sunburn" and "a composition containing an effective amount" of ascorbyl fatty acid ester "in a dermatologically acceptable, fat-penetrating carrier such that the ester is percutaneously delivered to lipid-rich layers of the skin," versus "effective to solubilize in the lipid-rich layers of the skin an amount

effective” to scavenge free radicals therefrom do not render claim 16 of the ‘063 patent and claim 7 of the ‘693 patent patentably distinct. Additionally, the limitation in claim 16 regarding the types of fatty acid esters of ascorbic acid (e.g., ascorbyl palmitate) is subject to the same comparison as claim 12 of that patent and is thus rendered obvious for the reasons previously stated.

The only other difference between claim 16 of the ‘063 patent and claim 7 of the ‘693 patent is the mention of Vitamin E versus the mention of specific “tocotrienols.” However, Perricone admits that tocotrienols are forms of tocopherol or Vitamin E. Accordingly, this is not a patentable difference. Further, part (B) of claim 16 recites a Markush group, an artificial grouping within a single claim of materials having common characteristics in which what is claimed is “an item selected from the group consisting of A, B, C and D.” Ex parte Markush, 340 O.G. 839 (Comm’r Pat. 1925). So long as any one of the items in the group is not patentably distinct over an earlier issued patent, the entire Markush group is invalid as a matter of law. See In re Skoll, 523 F.2d 1392, 1397 (C.C.P.A. 1975). As the tocotrienols are invalid for obviousness-type double patenting, the entirety Markush group of claim 16, and therefore claim 16 in its entirety, is invalid as a matter of law.

Claim 18 of the ‘063 patent is dependent on claim 16. Claim 18 merely limits the alpha-hydroxy acid in claim 16 part (B) to one particular type of alpha hydroxy acid, known as glycolic acid. As previously mentioned, because the tocotrienol element of claim 16 is obvious in light of claim 7 of the ‘693 patent, claim 18 is also obvious and thus, invalid.

Like claim 18, claim 19 of the ‘063 patent is dependent on claim 16. Claim 19 merely reads that the ascorbyl fatty acid ester referenced in claim 16 is ascorbyl palmitate. Claim 4 of the ‘693 patent, when read together with claim 7 of that patent, specifies that the ascorbyl fatty acid ester is

ascorbyl palmitate. Thus, claim 19 is also invalid for obviousness-type double patenting.

4. Differences Between Claim 11 of the '063 Patent and Claim 5 of the '693 Patent

Claim 11 of the '063 patent is dependent on claim 9 of that patent and specifies ranges by weight of the ascorbyl fatty acid ester to be included in the claimed composition. It teaches “[a] method according to claim 9 wherein the composition contains from about 0.025% to about 5% by weight ester.” Claim 5 of the '693 patent teaches “[a] method according to claim 4 wherein said composition comprises at least about 2% ascorbyl palmitate by weight.” Patent claims that specify a particular range may be rendered invalid for obviousness if any part of the claimed range is disclosed in a previously-issued patent. See, e.g., Van Ornum, 686 F.2d at 943. Thus, claim 11 of the '063 patent is invalid because it claims a weight range for ascorbyl fatty acid ester that is obvious in light of the weight ranges for ascorbyl palmitate claimed in the '693 patent.

In sum, the Court concludes that the defendant has satisfied its burden on summary judgment of the invalidity of claims 9, 11-13, 16, 18, and 19 of the '063 patent. Those claims are invalid for double-patenting, as a matter of law.

B. Anticipation by the Prior Art

Medicis also claims that there are no genuine issues of material fact as to whether claims 1-4, and 7-9, and 13 of the '693 patent and claims 1-19 of the '063 patent are anticipated by the prior art. Medicis asserts that the prior art anticipates Perricone’s patented method for treating and preventing skin damage and disorders by applying to the skin fatty acid esters of ascorbic acid which scavenge harmful “free radicals” resulting from sun exposure. In response, Perricone argues that the prior art

references fail to disclose each and every limitation of the relevant claims of the '693 and '063 patents. Accordingly, he argues that his patents are novel and valid despite the prior art.

According to 35 U.S.C. § 102(b),¹⁰ a patent is invalid for anticipation when a single prior art reference discloses, either expressly or inherently, every element or limitation of a claim. See Electro Med. Sys. S.A. v. Cooper Life Servs., 34 F.3d 1048, 1052 (Fed. Cir. 1994); Continental Can Co., USA, Inc. v. Monsanto Co., 948 F.2d 1264, 1268 (Fed. Cir. 1991). “There must be no difference between the claimed invention and the referenced disclosure, as viewed by a person of ordinary skill in the field of the invention.” Scripps Clinic & Research Found. v. Genentech, Inc., 927 F.2d 1565, 1576 (Fed. Cir. 1991). Anticipation, therefore, is an issue of fact. See id.

“[A] prior art reference may anticipate when the claim limitation or limitations not expressly found in the reference are nonetheless inherent in it.” Mehl/Biophile Int’l Corp. v. Milgraum, 192 F.3d 1362, 1364 (Fed. Cir. 1999). “Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claims limitations, it anticipates.” Id.; see also In re King, 801 F.2d 1324, 1326-28 (Fed. Cir. 1986).

The Court concludes that, as a matter of law, the prior art anticipates claims 1-4, and 7-9, and 13 of the '693 patent and claims 1-19 of the '063 patent. The claim constructions contained in Section III.A.1 and 2 are hereby incorporated by reference.

¹⁰35 U.S.C. § 102(b) provides, “[a] person shall be entitled to a patent unless . . .

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or

U.S. Patent No. 4,981,845 (“Pereira”), entitled “Cosmetic Composition,” was filed on August 25, 1989 and assigned to Chesebrough Pond’s U.S.A. Company. Pereira addresses problems associated with the shelf life and storage stability of compositions that deliver “skin benefit ingredients” to the subcutaneous regions of the skin. U.S. Patent No. 4,981,845, col. 1, lines 6-49. To that end, Pereira discloses cosmetic compositions containing “special emulsifiers” in combination with “skin benefit ingredients” and an “emollient oil” for topical application to the skin. *Id.*, col. 2, lines 11-34. Among the “skin benefit ingredients” mentioned by Pereira are ascorbyl palmitate and tocopherol (Vitamin E). *Id.*, col. 1, lines 60-62; col. 2, lines 43-46. Ascorbyl palmitate may be present in the compositions in an amount ranging from .01% to 20%. *Id.*, col. 1, lines 55-60. Among the compositions disclosed by Pereira are skin creams and lotions. *Id.*, col. 6, lines 64-70; col. 7, lines 1-6.

1. Anticipation of Claims 1-4, 7-9, and 13 of the ‘693 Patent

Pereira’s disclosures anticipate each element of claims 1-4, 7-9, and 13 of the ‘693 patent. Pereira discloses a composition containing ascorbyl fatty acid esters for the topical application to human skin. Pereira describes ascorbyl palmitate as a “skin benefit ingredient.” Though Pereira does not expressly disclose the use of an ascorbyl fatty acid ester for treating or preventing skin sunburn, the topical application of a cream or lotion containing an amount of ascorbyl fatty acid ester disclosed in Pereira—up to 20%—will in its “normal and usual operation” treat and prevent sunburn. See *In re King*, 801 F.2d at 1327.

As noted above, “a prior art reference may anticipate when the claim limitation or limitations not expressly found in the reference are nonetheless inherent in it.” *Id.* An inventor may not obtain a patent

on a method of using that patented composition unless that method is “useful and nonobvious.” Catalina Marketing Int’l. Inc. v. Coolsavings.com, Inc., 289 F.3d 801, 809 (Fed. Cir. 2002). Said differently, ““if a previously patented [composition], in its normal and usual operation, will perform the function which an appellant claims in a subsequent application for process patent, then such application for process patent will be considered to have been anticipated by the former patented [composition].”” In re King, 801 F.2d at 1326 (quoting In re Ackenbach, 45 F.2d 437, 439 (C.C.P.A. 1930)).

The following hypothetical set forth by the Federal Circuit in Catalina illustrates this concept well:

Inventor A invents a shoe polish for shining shoes (which, for the sake of example, is novel, useful, and nonobvious). Inventor A receives a patent having composition claims for shoe polish. Indeed, the preamble of these hypothetical claims recites "a composition for polishing shoes." Clearly, Inventor B could not later secure a patent with composition claims on the same composition because it would not be novel. Likewise, Inventor B could not secure claims on the method of using the composition for shining shoes because the use is not a "new use" of the composition but, rather, the same use shining shoes.

Suppose Inventor B discovers that the polish also repels water when rubbed onto shoes. Inventor B could not likely claim a method of using the polish to repel water on shoes because repelling water is inherent in the normal use of the polish to shine shoes. In other words, Inventor B has not invented a "new" use by rubbing polish on shoes to repel water. Upon discovering, however, that the polish composition grows hair when rubbed on bare human skin, Inventor B can likely obtain method claims directed to the new use of the composition to grow hair. Hence, while Inventor B may obtain a blocking patent on the use of Inventor A's composition to grow hair, this method patent does not bestow on Inventor B any right with respect to the patented composition. Even though Inventor A's claim recites "a composition for polishing shoes," Inventor B cannot invoke this use limitation to limit Inventor A's composition claim because that preamble phrase states a use or purpose of the composition and does not impose a limit on Inventor A's claim.

Catalina, 289 F.3d at 809 (internal citations omitted).

Here, Pereira discloses a composition containing up to 20 percent ascorbyl palmitate for topical

application to the skin for the purpose of conferring certain benefits on the skin. U.S. Patent No. 4,981,845, col. 1, lines 55-60. Perricone claims to have discovered that one of the benefits of such a composition is the treatment and prevention of sunburn. However, like Inventor B in the hypothetical above, Perricone cannot claim a method of using the composition to treat or prevent sunburn because treating and preventing sunburn is inherent in the normal use of the ascorbyl palmitate composition to benefit the skin. In other words, Perricone has not invented a "new" use of the ascorbyl palmitate composition. See Catalina, 289 F.3d at 809.

“Newly discovered results of known processes directed to the same purpose are not patentable because such results are inherent.” Bristol-Myers Squibb Co. v. Ben Venue Labs. Inc., 246 F.3d 1368, 1376 (Fed. Cir. 2001) (citing In re May, 574 F.2d 1082, 1090 (C.C.P.A. 1978)). In May, cited by the Federal Circuit in Bristol-Myers as exemplifying this principle, a patentee claimed a method of treating pain through the use of certain painkillers without producing the side-effect of physical dependency on those painkillers. The patent disclosed the administration of a genus of non-addictive analgesic compounds to achieve that result. The court in May found that such method was anticipated by a prior art reference that disclosed a species of the genus that was used as an analgesic. In re May, 574 F.2d at 1090. Though the prior art was silent as to the addictiveness of the prior art analgesic, the patent-in-suit’s claims “merely recited a newly discovered result—non-addictiveness—of a known method directed to the same use, i.e., treating pain with an analgesic.” Bristol-Myers, 246 F.3d at 1377 (citing In re May, 574 F.2d at 1090). Accordingly, the court found that such claims were anticipated by the prior art. See In re May, 574 F.2d at 1090; U-Fuel, Inc. v. Highland Tank & Mfg. Co. Inc., 228 F. Supp. 2d 597, 609-611 (E.D. Pa. 2002).

Here, the claimed process is not directed to a new use of ascorbyl palmitate, but rather, the same use disclosed in *Pereira*—the topical application of ascorbyl palmitate to benefit the skin. See id. Moreover, it is apparent that the specific benefit of the treatment and prevention of sunburn is naturally realized by the topical application of the compositions disclosed in *Pereira*. As noted above, the specifications of the ‘693 patent indicate that an ascorbyl fatty acid ester composition “contain[ing] at least about 0.5% by weight, more preferably at least about 2% by weight, and most preferably at least about 10% by weight” will treat and prevent sunburn. U.S. Patent No. 5,409,693, col. 3, lines 30-42. Accordingly, the topical application of a composition disclosed in *Pereira* containing up to 20% ascorbyl palmitate will inherently perform the method claimed in the ‘693 patent. Additionally, though *Pereira* fails to explicitly disclose that the ascorbyl fatty acid ester be “effective to solubilize in the lipid-rich layers of the skin,” as required by independent claims 1 and 8 of the ‘693 patent, for the same reasons noted above, the amount of ascorbyl fatty acid ester disclosed in *Pereira* will inherently function in such a manner when topically applied to the skin.

As in *May*, the fact that the prior disclosure was silent as to the particular “newly discovered result” of treating and preventing sunburn is irrelevant because one who is topically applying the amount of ascorbyl palmitate disclosed in *Pereira* in order to “benefit” their skin will naturally and consequentially treat and prevent sunburn. “[R]ules of natural law that are recited in a claim. . . do not need to be recognized by one of ordinary skill in the art for a finding of inherency.” *EMI Group N. Amer. Inc. v. Cypress Semiconductor Corp.*, 268 F.3d 1342, 1351 (Fed. Cir. 2001); see also *Mehl/Biophile*, 192 F.3d at 1365 (“Inherency is not necessarily coterminous with the knowledge of those of ordinary skill in the art. Artisans of ordinary skill may not recognize the inherent characteristics

or functioning of the prior art.”).

The Federal Circuit reached this issue in In re Cruciferous Sprout Litigation, 301 F.3d 1343 (Fed. Cir. 2002). That case involved three patents describing methods of harvesting and preparing food products containing certain vegetable sprouts. The inventors of the patents had recognized that some kinds of vegetable sprouts, when harvested before a certain stage in their development, are rich in glucosinates and help protect against cancer. The inventors obtained three patents directed to various methods of preparing and administering food products comprised of the selected glucosinate-rich sprouts they had identified, harvested at an early stage in their development.

While acknowledging that the inventors may have discovered a significant property of certain types of sprouts, the district court invalidated the patents on the grounds of inherent anticipation, holding that “one skilled in the art could, by following the teachings of the prior art, germinate broccoli seeds, harvest the sprouts, and sell them as a food product.” Cruciferous Sprout, 301 F.3d at 1346. The Federal Circuit affirmed, stating that a “plant (broccoli sprouts), long well known in nature and cultivated and eaten by humans for decades, [cannot] be patented merely on the basis of a recent realization that the plant has always had some heretofore unknown but naturally occurring beneficial feature.” Id. at 1350.

Here, as in Cruciferous Sprout, ascorbyl fatty acid esters have long been identified. Also, as evidenced by Pereira, the skin benefit nature of ascorbyl fatty acid esters was known before Perricone’s inventions were patented. Thus, while it is true that Perricone may have discovered that ascorbyl fatty acid esters treat and prevent sunburn, this “recent realization that [ascorbyl fatty acid esters] ha[ve] always had some heretofore unknown but naturally occurring beneficial feature,” is

insufficient to make the patent novel over the prior art. Id. at 1350. Perricone cannot patent the discovery of the skin benefit traits of ascorbyl fatty acid esters that are inherent in those esters. See id.

Perricone argues, however, that Pereira's disclosure of numerous possible "skin benefit ingredients" that may be present in a broad range of weight percentages "involves such a high degree of selectivity as to preclude the determination that Pereira identically describes the claimed invention within the meaning of 35 U.S.C. § 102." Pl.'s Mem. Supp. Mtn. Summ. J. of Validity at 41 (citing Air Products & Chemicals, Inc. v. Charles S. Tanner Co., 219 U.S.P.Q. 223 (D.S.C. 1983)). Because a person of ordinary skill in the art would be required to "pick and choose" ascorbyl palmitate from the plethora of "skin benefit ingredients" disclosed in Pereira in the specific percentage required to treat or prevent sunburn, argues Perricone, Pereira does not anticipate the '693 patent.

In Air Products, the district court stated that "a prior art reference which contains a broad general disclosure requiring guessing, testing, speculation or 'picking and choosing' from an encyclopedic disclosure will not anticipate." 219 U.S.P.Q. at 231 (citing In re Arkley, 455 F.2d 586 (C.C.P.A. 1972) (in order to anticipate, a piece of prior art "must clearly and unequivocally disclose the claimed compound or direct those skilled in the art to the compound without any need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference"); In re Samour, 571 F.2d 559, 562 (C.C.P.A. 1972); and General Battery Corp. v. Gould, Inc., 545 F. Supp. 731, 740 (D. Del. 1982)). In Arkley, 455 F.2d 586 (Cust. & Pat. App.1972), the Court of Customs and Patent Appeals held that the disclosures of the cited prior art must be sufficiently clear that a person of ordinary skill in the art would understand their full implication without resorting to speculation or guesswork. 455 F.2d at 587. Because that was not the case in

Arkley, the court declined to sustain the patent office’s rejection of the patent application on the basis of anticipation. See id.

In General Battery, the court noted that a prior art reference “must contain within its four corners, adequate directions for the practice of the patent claim sought to be invalidated.” 5454 F. Supp. at 744 (internal quotation marks and citation omitted). “Unless all of the same elements are found in exactly the same situation and united in the same way to perform the identical function in a single prior art reference, there is no anticipation.” Id. (internal quotation marks and citation omitted).

In analyzing the prior art reference cited by the defendant, the court found that:

the references which in combination allegedly anticipate the [patent-in-suit] are scattered throughout the work. One would have to pick and choose among various pages in Vinal ([the prior art]) to piece together a battery such as that claimed in the patents in suit. This process of selection would require some inventive skills to determine by simply reading Vinal's book that adding sodium sulfate in a conditioning amount to a moist battery would enhance the shelf life of that battery. The elements of the invention are not in the same location nor are adequate directions provided to manufacture the invention.

Id.

This Court, however, finds the cases cited by Perricone to be distinguishable from the instant case. Here, unlike in Arkley and General Battery, Pereira contains within its four corners adequate directions for the topical application of ascorbyl palmitate to benefit the skin. Though Pereira discloses a range of “skin benefit ingredients” and a range of the effective amounts of those ingredients, it plainly discloses the topical application to the skin of ascorbyl palmitate to confer certain benefits on that skin. No speculation or guesswork is required for a person of ordinary skill in the art to understand as much.

Moreover, unlike in Samour, the Court’s finding of anticipation is not based on the combination

of several pieces of prior art, as would be impermissible in an anticipation inquiry, but permissible in an “obviousness” inquiry. Cf. Northern Telecom, Inc. v. Datapoint Corp., 908 F.2d 931, 934 (Fed. Cir. 1990) (proof of obviousness may rest upon the combination of pieces of prior art). Rather, Medicis argues, and the Court finds, that each and every element of the relevant claims are contained within one prior art reference.

Furthermore, as disclosed in claims 2 and 9 of the ‘693 patent, Pereira discloses the use of ascorbyl fatty acid esters with lecithin, a dermatologically acceptable carrier. U.S. Patent No. 4,981,845, col. 4, lines 67-68. As disclosed in claims 3 and 4 of the ‘693 patent, Pereira discloses the specific use of the ascorbyl fatty acid ester ascorbyl palmitate. Id., col. 1, line 60; col. 2, line 43. Finally, as disclosed in claims 7 and 13 of the ‘693 patent, Pereira discloses a method wherein the composition contains Vitamin E. Id., col. 1, lines 61-62; col. 2, lines 44-46.

Accordingly, the Court concludes that claims 1-4, 7-9, and 13 of the ‘693 patent are anticipated by Pereira.

2. Anticipation of Claims 1-19 of the ‘063 patent

Pereira’s disclosures also anticipate each element of claims 1-19 of the ‘063 patent of the ‘063 patent. As in claims 1, 9, and 16 of the ‘063 patent, Pereira discloses the topical use of ascorbyl fatty acid esters to benefit the skin.

Again, though Pereira does not expressly disclose the use of an ascorbyl fatty acid ester for the treatment of skin disorders which arise because of depleted or inhibited collagen synthesis, skin damaged or aged by oxygen containing free radicals or oxidative generation of biologically active metabolites, or damaged or aging skin and epithelial tissue disorders which are directly or indirectly

caused or mediated by collagen deficiency, oxygen-containing free radicals, oxidative generation of biologically active metabolites, or mixtures of these, the topical application of a Pereira cream or lotion containing the amount of ascorbyl fatty acid ester disclosed in Pereira will “in its normal and usual operation” function in such a manner.

The specifications of the ‘063 patent indicate that the ascorbyl fatty acid ester compositions should “contain from about 0.025% to about 10%” by weight, ascorbyl fatty acid esters.” Accordingly, the topical application of the composition disclosed in Pereira—which may contain up to 20% ascorbyl palmitate—will inherently perform the method claimed in the ‘063 patent. Furthermore, though Pereira fails to explicitly disclose that the ascorbyl fatty acid ester be “percutaneously delivered to the lipid-rich layers of the skin,” as required by independent claims 1 and 9 of the ‘063 patent, the amount of ascorbyl fatty acid ester disclosed in Pereira will inherently function in such a manner when topically applied to the skin.

As in claims 2, 3, and 11 of the ‘063 patent, Pereira discloses the use of ascorbyl fatty acid ester compositions containing between 0.01% to 20% by weight ascorbyl fatty acid ester. U.S. Patent No. 4,981,845, col. 1, lines 55-60. As in claims 1, 4, 9, 10, 16 and 17 of the ‘063 patent, those ascorbyl fatty acid esters may be used with lecithin, a fat-penetrating carrier. *Id.*, col. 4, lines 67-68. As in claims 5, 6, 12, 13, 16, and 19, Pereira discloses the specific use of the ascorbyl fatty acid ester ascorbyl palmitate. *Id.*, col. 1, line 60; col. 2, line 43. As in claims 7, 14 and 16 of the ‘063 patent, Pereira describes the additional use of alpha-hydroxy acids. *Id.*, col. 2, lines 1-3, 52-53. As disclosed in claims 8, 15, and 18 of the ‘063 patent, Pereira discloses ascorbyl fatty ester combinations that contain glycolic acid. *Id.*, col. 2, lines 1-3, 52-53. Finally, as disclosed in claim 16 of the ‘063 patent,

Pereira discloses the use of Vitamin E along with the ascorbyl fatty acid ester. Id., col. 1, lines 61-62; col. 2, lines 44-46.

Accordingly, the Court concludes that claims 1-19 of the '063 patent are anticipated by Pereira.¹¹

C. Conclusion as to Validity

For the foregoing reasons, the Court finds claims 9, 11-13, 16, 18, and 19 of the '063 patent invalid on the basis of double patenting and claims 1-4, 7-9, and 13 of the '693 patent and claims 1-19 of the '063 patent invalid on the basis of anticipation by the prior art, as a matter of law. Accordingly, Medicis's motion for partial summary judgment of invalidity is GRANTED, and Perricone's motion for summary judgment of validity is DENIED.

Moreover, because invalidity is an affirmative defense to infringement, see 35 U.S.C. § 282, Medicis's motion for summary judgment of non-infringement as to the '693 patent is GRANTED, and Perricone's motion for summary judgment of infringement is DENIED.

VI. Conclusion

For the foregoing reasons, the plaintiff's Motion for Summary Judgment of Validity of U.S. Patent No. 5,409,693 and U.S. Patent No. 5,574,063 [Doc. #216] is DENIED. The defendant's Motion for Partial Summary Judgment of Invalidity of Certain Claims of Plaintiff's U.S. Patent Nos. 5,574,063 and 5,409,693 on the Grounds of Double Patenting and Anticipation [Doc. #221] is GRANTED. The plaintiff's Motion for Summary Judgment of Infringement [Doc. #215] is DENIED,

¹¹The Court need not address the other pieces of prior art cited to by Medicis.

and the defendant's Motion for Partial Summary Judgment of Non-Infringement of Plaintiff's U.S.

Patent No. 5,409,693 [Doc. #226] is GRANTED.

SO ORDERED this ____ day of June 2003, at Hartford, Connecticut.

CHRISTOPHER F. DRONEY
UNITED STATES DISTRICT JUDGE