UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

NICHOLAS V. PERRICONE, M.D. Plaintiff	: :	
v.	:	3:99-cv-1820 (CFD)
MEDICIS PHARMACEUTICAL CORPORATION 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 (filed Mar 1, 1993) entitled "Method for Treating and Preventing Sunburn and Sunburn Damage to the Skin" (the "'693 Patent") and U.S. Patent No. 5,574,063 (filed mar. 17, 1995), entitled "Method and Compositions for Topical Application of Ascorbic Acid Fatty Acid Esters for Treatment and/ or Prevention of Skin Damage" (the "'063 Patent").

In December 2005, the United States Court of Appeals for the Federal Circuit affirmed this Court's ruling that claims 1 through 19 of the '063 patent, and claims 8, 9 and 13 of the '693 patent were invalid. Perricone v. Medicis Pharmaceutical, Corp., 432 F.3d 1368 (Fed. Cir. 2005). However, the Federal Circuit reversed this Court's ruling that claims 1 through 4 and 7 of the '693 patent were invalid and remanded for further proceedings on these claims.

I. The '693 Patent

Dr. Perricone's '693 patent claims a method of treating and preventing sunburn through

the topical application of ascorbic acid (Vitamin C) in a fat soluble form. See '693 patent, col.2, ll.26-34. Specifically, the patent discloses the topical application of an ascorbyl fatty acid ester (e.g., ascorbyl palmitate, ascorbyl laurate, ascorbyl myristate, ascorbyl stearate) with a dermatologically acceptable carrier. See '693 patent, col.2, ll.26-34. Because the carrier, as well as the ascorbyl fatty acid ester, is fat soluble, it can "effectively penetrate skin layers and deliver the active ascorbyl fatty acid ester to the lipid-rich layers of the skin." '693 patent, col.4, ll.4-6. Upon reaching the lipid-rich layers of skin, the ascorbyl fatty acid ester produces a number of beneficial effects ranging from the acceleration of collagen synthesis to the scavenging of oxygen-containing radicals caused by exposure to damaging ultraviolet radiation. See '693 patent, col.5, ll.30-35, col.6, ll.35-50.

A. The Remaining Claims of the '693 Patent

Currently at issue are five of the remaining claims of the '693 patent. Claim One, the only remaining independent claim, reads:

> 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.

The other, dependent, claims at issue specify that the ascorbyl fatty acid ester be delivered in a "dermatologically acceptable carrier" (Claim Two), that a specific ascorbyl fatty acid ester be used (Claims 3 and 4) and that Vitamin E be added to the composition (Claim Seven).

As set forth in this Court's previous summary judgment ruling:

> "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.

Perricone v. Medicis Pharmaceutical Corp., 267 F. Supp.2d 229, 235-36 (D. Conn. 2003).

Dr. Perricone alleges that Medicis infringed the '693 patent with its LUSTRA® line of prescription skin depigmenters. LUSTRA® is a cream that, with hydroquinone as its active ingredient, reduces the production of melanin, i.e., the pigment in skin. LUSTRA® also includes ascorbyl palmitate and Vitamin E.

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, 106 S.Ct. 2505, 91 L.Ed.2d 202 (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. Glens 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., 963 F.2d 520, 523 (2d Cir. 1992) (quoting Anderson, 477 U.S. at 248, 106 S.Ct. 2505). 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, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986).

III. Validity

A patent is presumed to be valid under 35 U.S.C. § 282. Thus, an accused infringer must prove invalidity by clear and convincing evidence. Geneva Pharm., Inc. v. Glaxosmithkline PLC, 349 F.3d 1373, 1377 (Fed. Cir. 2003). Medicis argues that Claims One through Four and Seven of the '693 patent are invalid because they were anticipated and rendered obvious by the prior art.

A. Anticipation

Under Section 102 of the Patent Act a person is not entitled to a patent if "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." 35 U.S.C. § 102(b).

According to the Federal Circuit:

> A single prior art reference that discloses, either expressly or inherently, each limitation of a claim invalidates that claim by anticipation. Minn. Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc., 976 F.2d 1559, 1565 (Fed. Cir.1992). Thus, a prior art reference without express reference to a claim limitation may nonetheless anticipate by inherency. See In re Cruciferous Sprout Litig., 301 F.3d 1343, 1349 (Fed. Cir. 2002). "Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claims limitations, it anticipates." Id. (quoting MEHL/Biophile Int'l Corp. v. Milgraum, 192 F.3d 1362, 1365 (Fed. Cir. 1999)). Moreover, "[i]nherency is not necessarily coterminous with 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." Id.; see also Schering Corp. v. Geneva Pharms., 339 F.3d 1373, 1377 (Fed. Cir. 2003) (rejecting the contention that inherent anticipation requires recognition in the prior art) (citing In re Cruciferous Sprout Litig., 301 F.3d at 1351; MEHL/Biophile, 192 F.3d at 1366).

Perricone, 432 F.3d at 1375 -1376.

"A century-old axiom of patent law holds that a product which would literally infringe if later in time anticipates if earlier." Upsher-Smith Laboratories, Inc. v. Pamlab, L.L.C., 412 F.3d 1319, 1322 (Fed. Cir. 2005) (internal citations and quotation marks omitted). Thus, "if granting patent protection on the disputed claim would allow the patentee to exclude the public from practicing the prior art, then that claim is anticipated, regardless of whether it also covers subject matter not in the prior art." Atlas Powder Co. v. Ireco, Inc., 190 F.3d 1342, 1346 (Fed. Cir. 1999); see also Titanium Metals Corp. v. Banner, 778 F.2d 775, 780-82 (Fed. Cir.1985) ("It is also an elementary principle of patent law that when, as by a recitation of ranges or otherwise, a claim covers several compositions, the claim is 'anticipated' if one of them is in the prior art.")

Anticipation is a question of fact. Elan Pharm., Inc. v. Mayo Found. for Med. Educ. & Research, 346 F.3d 1051, 1054 (Fed. Cir. 2003).

1. The Federal Circuit's Anticipation Analysis

In its prior summary judgment ruling, this Court found that claims 1 through 4, 7 through 9, and 13 of the '693 patent and claims 1 through 19 of the '063 patent were anticipated by U.S. Patent No. 4,981,845 ("Pereira").

Pereira was filed on August 25, 1989 and addresses problems associated with the shelf life and storage stability of compositions that deliver "skin benefit ingredients" to the subcutaneous regions of the skin. Pereira, col.1, ll.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, ll.11-34. Among the "skin benefit ingredients" mentioned by Pereira are ascorbyl palmitate and tocopherol (Vitamin E). Id., col.1, ll.60-62; col.2, ll.43-46. Among the compositions disclosed by Pereira are skin creams and lotions. Id., col.6, ll.64-70; col.7, ll.1-6. See Perricone v. Medicis Pharmaceutical Corp., 267 F. Supp.2d 229, 236 (D. Conn. 2003).

The Federal Circuit found that claims 1 through 4 and 7 of the '693 patent were not anticipated by Pereira because "there is an important distinction between topical application to skin for the purpose of avoiding sunburn, and the much narrower topical application to skin sunburn." Perricone, 432 F.3d at 1379.

Conversely, the Federal Circuit found that claim 8 of the '693 patent, which "merely requires application of the composition to exposed skin surfaces" was anticipated. Id.. The Federal Circuit reasoned that "[b]ecause all skin surfaces are susceptible to sunburn damage, and because one can only realistically apply a composition to a skin surface when that surface is exposed, Pereira's 'topical application' encompasses the application step of claim 8." Id. The Federal Circuit also ruled that claims 1 and 9 of the '063 patent were anticipated by Pereira.

Claim 1 of the '063 patent is a "method for the treatment of skin disorders which arise because of depleted or inhibited collagen synthesis." Claim 9 of the '063 patent is "a method for the treatment of skin damaged or aged by oxygen-containing free radicals or oxidative generation of biologically active metabolites."

2. Medicis' Renewed Motion for Summary Judgment

Medicis now argues that it is entitled to summary judgment of invalidity based on anticipation by five prior patents. Perricone argues that it is entitled to summary judgment of validity based on its prior motion and the Federal Circuit's ruling. As set forth below, the Court finds that the prior art identified by Medicis anticipates claims 1, 2 and 7 of the '693 patent. However, the Court finds that there are genuine issues of material fact about whether the prior art anticipates claims 3 and 4.

a. Prior Art Anticipating Certain Claims

(1) Bissett[1]

U.S. Patent No. 4,847,071 (Bissett) entitled "Photoprotection Compositions Comprising Tocopherol Sorbate and an Anti-Inflammatory Agent" was filed October 22, 1987. One of the objects of Bissett is "to provide a photoprotection composition which can be applied to the skin prior to or following UV exposure without significant loss of efficacy." Bissett col.4, ll.15-18.

Bissett "relates to the topical use of compositions containing a radical scavenging

[1] Perricone argues that it would be inappropriate to consider at this time whether Bissett and Voyt '325 anticipate, because, in its 2001 motion for summary judgment of invalidity, Medicis only argued that this prior art anticipated Perricone's sunburn prevention claims. Because it would be futile to proceed to trial on claims that are invalid as a matter of law, the Court will consider this prior art. Perricone addressed whether Bissett and Voyt '325 anticipate in response to Medicis' new motion for summary judgment. See Dkt. # 417.

compound, selected from the group consisting of . . . tocopherol (Vitamin E), tocopherol sorbate, other esters of tocopherol . . . [and] the ascorbyl esters of fatty acids." Id. col.4, l.60 - col.5, l.5. According to Bissett, "[e]ach of these compounds has photoprotecting capability, however, of these, tocopherol sorbate is preferred to prevent the deleterious effects of UV exposure." Id. at col.5, ll.5-8. In addition to the active ingredients, compositions according to Bissett "contain a safe and effective amount of an acceptable carrier . . . [encompassing] both pharmaceutically-acceptable carriers and cosmetically-acceptable carriers. . . which are suitable for delivering the active components to the skin." Id. at col.8, ll.20-29.

Bissett describes application of the composition "4 hours prior to UV exposure, [and] up to about 30 minutes after exposure."[2] Id. at col. 25, lines 28-31 (noting that "[f]or protection against acute damage from UV-radiation, application of tocopherol sorbate and the anti-inflammatory agent just prior to exposure, or immediately following exposure, is sufficient"). While Perricone argues that Bissett teaches only sunburn prevention and not treatment, if an ascorbyl fatty acid ester were applied to skin following UV exposure it would inherently both prevent the development of further sunburn and treat any sunburn that had already developed.[3]

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[2] Bissett also discloses that the invention protects against "damage resulting from chronic UV exposure, e.g., photoaging." Bissett at col. 24, lines 19-22.

[3] Perricone admits that "histologic changes [associated with skin sunburn] are present within 30 minutes of UV radiation exposure." [Plaintiff's Memorandum of Law in Support of Motion for Summary Judgment of Infringement Dkt. # 269, at p. 20, citing Richard W. Gagne, Acute Effects of Ultraviolet Radiation in the Skin, in Dermatology in General Medicine (McGraw Hill Cook Company, 3rd ed. 1987) ("Longer wavelength radiation (UVA) may result in immediate erythema, already present and maximal at the end of the irradiation period . . . . Microscopic changes are visible within 30 min of irradiation, and precede erythema. . . UVB and UVC radiation characteristically induce "sunburn cells" in the epidermis. These occur within 30 min of exposure and are maximal at 24 h later.")

Further, ascorbyl fatty acid esters will inherently solubilize in the lipid rich layers of the skin and scavenge free radicals found therein. Thus, Bissett anticipates claims 1 and 2 of the '693 patent.

However, Bissett does not disclose use of ascorbyl palmitate, ascorbyl laurate, ascorbyl myristate, or ascorbyl stearate, but rather only discloses a broad genus without any suggestion for selecting one of these four species of ascorbyl fatty acid ester. "When a reference discloses a class of compounds, i.e., a genus, a person of ordinary skill in the art should be able to 'at once envisage each member of th[e] ... class' for the individual compounds, i.e., species, to be enabled. If the members cannot be envisioned, the reference does not disclose the species and the reference is not enabling." Impax Laboratories, Inc. v. Aventis Pharmaceuticals Inc., 468 F.3d 1366, 1383 (Fed. Cir. 2006) (internal citation omitted, alterations in original). However, one skilled in the art need not be able to "at once define in his mind the formal boundaries of the class." In re Petering, 49 C.C.P.A. 993, 1000, 301 F.2d 676, 681 (1962).

The '693 patent was itself originally denied by the patent office as indefinite because "[t]he term 'a fatty acid ester of ascorbic acid' is indefinite and insufficiently disclosed since it is not clear what specific esters are intended." Perricone responded that "Fatty acid esters of ascorbic acid are known in the art," and the patent was issued. Accordingly, there is a genuine issue of material fact concerning whether the genus of ascorbyl fatty acid esters was narrow enough to disclose specific esters. Thus, Bissett is not a sufficient basis for granting summary judgment of invalidity as to claims 3 and 4.

Further, Bissett only discloses use of ascorbyl palmitate as an alternative to tocopherol or tocopherol sorbate, rather than in conjunction with tocopherol. Thus, Bissett does not anticipate claim 7.

(2) Voyt '325

U.S. Patent No. 4,144,325 (Voyt '325), entitled "Method and Composition for Preventing Sunburn while Affording Tanning" was filed on November 10, 1976. Voyt '325 teaches a cosmetic composition for topical application to the skin to prevent sunburn. Voyt '325, col.18, ll.12-20. The active photoprotective ingredient in Voyt '325 is tocopherol (Vitamin E).[4] The composition also includes an inert carrier vehicle consisting of water, mineral oil, vegetable oil, petrolatum, silicone oil, alcohol, and mixtures thereof, and an ascorbyl fatty acid ester as a stabilizer. Voyt '325 teaches that application of the composition "to previously sunburned skin . . . provide[s] a chemical oxygen barrier on the skin . . . which enhances the healing of the burn." Id. at col.7, ll.46-54.

Perricone argues that Voyt '325 does not anticipate because it does not disclose application of an ascorbyl fatty acid ester to skin sunburn.

Voyt '325 anticipates each element of claims 1-2 and 7. Voyt '325 expressly discloses topical application of a composition including a tocopherol, an ascorbyl fatty acid ester and a dermatologically acceptable carrier to skin sunburn. In this composition, the fat-soluble ascorbyl fatty acid ester will inherently solubilize in the lipid-rich layers of the skin. Further, while Voyt '325 does not disclose a particular concentration of ascorbyl fatty acid ester, any amount of ascorbyl fatty acid ester will scavenge free radicals, providing some degree of benefit. Thus, Voyt '325 inherently functions in accordance with claims 1, 2 and 7.

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[4] Specifically, in its preferred form Voyt '325 teaches use of one of fourteen listed tocopherols. According to Voyt '325, four of these demonstrate Vitamin E activity and three other are expected to. Voyt '325 also distinguishes between "pure tocopherols are other related compounds which exhibit Vitamin E activity" and teaches away from Vitamin E compounds that lack antioxidant properties. Voyt '325, col. 5, lines 56-67.

Like Bissett, Voyt '325 does not disclose the selection of a particular ascorbyl fatty acid ester**.** Accordingly, Voyt '325 is also not a sufficient basis for granting summary judgment of invalidity as to Perricone '693, claims 3 and 4.

b. Other Prior Art

(1) N'Guyen '235 and '716

U.S. Patent 5,023,235 (N'Guyen '235) entitled "Antioxidant System Based on an Ascorbyl Ester in Combination with a Complexing Agent and a Thiol and to Compositions Containing the Same" was filed on February 8, 1988. N'Guyen '235 suggests that cosmetic compositions be prepared containing .05 to .5 percent tocopherol,[5] and .45 to 1.6 percent ascorbyl ester. According to N'Guyen '235, such cosmetic compositions can be prepared "in the form of . . . anti-sun creams . . . [and] anti-sun milks." N'Guyen '235, col.3, l.39-50. Further, "[i]n accordance with a preferred embodiment, the cosmetic compositions are provided in the form of creams intended for the protection of skin lipids against oxidation." Id. col.3, ll.51-54. N'Guyen '235 also discloses that ascorbyl fatty acid esters such as ascorbyl palmitate, ascorbyl stearate, and ascorbyl laurate solubilize in a fatty material. Id. col.1, ll.30-35, 65-68.

U.S. Patent 5,114,716 (N'Guyen '716) is similar to N'Guyen '235. It is entitled "Anti-oxidant System Containing Stabilized Ascorbyl Ester, Tocopherol or Cafeic Acid or a Derivative Thereof, a Complexing Agent and a Polypeptide, and Compositions Containing the Anti-Oxidant System" and was filed July 28, 1989. N'Guyen '716 suggests that cosmetic compositions be prepared containing .05 to .5 percent tocopherol, and .45 to 1.6 percent ascorbyl

[5] According to N'guyen "By 'tocopherols' is meant not only α- tocopherol but also β-, γ-, or δ-tocopherol as well as mixtures thereof."

ester. N'Guyen '716, col.3, ll.54-64. According to N'Guyen '716, such cosmetic compositions include "anti-solar creams" and "anti-solar milks." Id. col.3, ll.40-49. N'Guyen '716 also provides that "[i]n accordance with a preferred embodiment of the present invention, the cosmetic compositions are provided in the form of creams intended for the protection against the oxidation of the lipids of the skin." Id., col.3, ll.50-54.

Although N'Guyen '235 and '716 do not describe the function or purpose of anti-sun or anti-solar products, Medicis claims that these products and other similar lotions have long been used to treat sunburned skin. According to Dr. Ronald Marks, a clinical dermatologist and emeritus professor of dermatology, "it is common for persons who suffer sunburn and sunburn damage to often use topical products such as skin lotions, skin creams, and skin ointments to treat these conditions. Any topical product . . . is attractive to sunburned persons as a way to soothe, treat and prevent the pain experienced in sunburned skin." Further, according to Lester Packer, Ph.D., a biochemist, physiologist and emeritus professor of molecular and cell biology, "[a] 'solar cream' or an 'anti-sun cream' is without any doubt a product for the treatment and prevention of sunburn."

Perricone has not presented evidence suggesting a contrary interpretation of the N'Guyen patents, but argues that Dr. Marks' declaration is not clear and convincing evidence about the purpose of "solar cream." The Court concurs; a reasonable jury might conclude that anti-solar creams and milks were meant to be applied to sunburned skin, but would not be required to reach this conclusion. Accordingly, there is a genuine issue of material fact concerning whether N'Guyen '235 and '716 anticipate.

(2) Shinomiya

Japanese Patent 62-72605 ("Shinomiya") teaches a cosmetic composition including a chemically altered ascorbyl fatty acid ester and a form of Vitamin E for skin beautification. Shinomiya also disclosed that ascorbyl fatty acid esters have long been used to treat suntan. Shinomiya describes a "skin fairness recovery test" in which 2% ascorbyl stearate was applied to skin for three months, beginning one week after the skin had been exposed to two times the minimum erythema dose. The test demonstrated that ascorbyl stearate improved the skin's recovery from UV exposure.

Medicis claims that the "skin fairness recovery test" describes application of ascorbyl stearate to sunburned skin. Perricone concedes that Shinomiya precludes summary judgment of validity. The Court finds that a reasonable jury would not be required to conclude that the skin in Shinomiya remained sunburned at the time ascorbyl stearate was applied.[6] Thus, there is a genuine issue of material fact as to whether Shinomiya anticipates claim 3 of Perricone '693.

Because there are genuine issues of material fact concerning the validity of claims 3 and 4, summary judgment of invalidity based on anticipation cannot be granted.

B. Obviousness

Section 103 forbids issuance of a patent when "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

[6] Richard W. Gagne, Acute Effects of Ultraviolet Radiation in the Skin, in Dermatology in General Medicine (McGraw Hill Cook Company, 3rd ed. 1987) ("Erythema fades over several days, to be followed by other visible changes such as desquamation and tanning. In some fair-skinned individuals, erythema may be very persistent and last for a period of weeks.")

which said subject matter pertains." 35 U.S.C. § 103. A patent is obvious if it is merely "predictable use of prior art elements according to their established functions." KSR Intern. Co. v. Teleflex Inc., —U.S.—, 127 S.Ct. 1727, 1740 (2007).

> The analysis to determine obviousness is objective:
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> > Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.

KSR Intern. Co. v. Teleflex Inc., —U.S.—, 127 S.Ct. at 1734 (quoting Graham v. John Deere Co. of Kansas City, 383 U.S. 1, 17-18, 86 S.Ct. 684, 15 L.Ed.2d 545 (1966).). "The ultimate judgment of obviousness is a legal determination" based on these underlying facts. Graham, 383 U.S. at 17, 86 S.Ct. 684.

The party seeking to invalidate a patent is also required to articulate an "apparent reason" for altering the prior art to achieve the claimed invention. KSR, 127 S.Ct. at 1741. Historically this was through the "teaching, suggestion, or motivation" test. In re Rouffet, 149 F.3d 1350, 1355 (Fed. Cir.1998) (citing In re Geiger, 815 F.2d 686, 688 (Fed. Cir. 1987)); see also ACS Hosp. Sys., Inc. v. Montefiore Hosp., 732 F.2d 1572, 1577 (Fed. Cir. 1984). In KSR the Supreme Court cautioned that "[t]he obviousness analysis cannot be confined by a formalistic conception of the words, teaching, suggestion, and motivation." KSR, 127 S.Ct. at 1741. Courts must avoid a "rigid approach" in determining whether an invention would have been obvious to a skilled artisan. KSR, 127 S. Ct. at 1739-40. An "expansive and flexible approach" must instead be applied, and the courts may utilize "common sense" in addressing a question of obviousness

under § 103. KSR, 127 S. Ct. at 1739-40, 1741-42; see also DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co., 464 F.3d 1356, 1367-71 (Fed. Cir. 2006) cert. denied 127 S.Ct. 2937, 168 L.Ed.2d 262 (2007) (holding that common knowledge and common sense of one skilled in the art must be considered in determining obviousness); Alza Corp. v. Mylan Labs., Inc., 464 F.3d 1286, 1291 (Fed. Cir. 2006) (noting that flexibility exists within the "teaching, suggestion, or motivation test" because a motivation may be found implicitly in the prior art).

As the Supreme Court explained in KSR:

> In determining whether the subject matter of a patent claim is obvious, neither the particular motivation nor the avowed purpose of the patentee controls. What matters is the objective reach of the claim. If the claim extends to what is obvious, it is invalid under § 103. One of the ways in which a patent's subject matter can be proved obvious is by noting that there existed at the time of invention a known problem for which there was an obvious solution encompassed by the patent's claims.

KSR Intern. Co. v. Teleflex Inc., 127 S.Ct. 1741-42.

Medicis now claims that the sunburn treatment claims in Perricone '693 are obvious in light of Voyt, Bissett, N'Guyen '235, N'Guyen '716 and Shinomiya.[7]

1. Scope and Content of Prior Art

In determining the content of prior art, references should be considered as a whole to

[7] Perricone argues that Medicis is precluded from arguing for summary judgment of obviousness because (1) Medicis failed to provide adequate discovery concerning the basis for this defense; and (2) Medicis never sought leave of the Court to file its 2006 motion for summary judgment of obviousness. However, Perricone did move for summary judgment of nonobviousness in 2001. See Dkt. # 216. The issue of obviousness being fully briefed by the parties (see Dkt. ## 417, 419, 421) the Court finds that it is appropriate to consider the issue on summary judgment, rather than conducting a trial in the absence of a genuine issue of material fact. The Court further finds that Medicis' motion relies only on prior art otherwise disclosed to Perricone during discovery, and that there is no prejudice to Perricone from the nature of Medicis' discovery responses. Thus, the Court grants leave to file the 2006 motion for summary judgment, and renews the 2001 motions for summary judgment.

determine their teachings. Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc., 796 F.2d 443, 448-49 (Fed. Cir. 1986). Thus, all of the disclosures of a reference are considered, including unpreferred embodiments. See, e.g., Merck & Co. V. Biocraft Labs, Inc., 874 F.2d 804, 807 (Fed. Cir. 1989).

Perricone argues that Medicis' obviousness argument should be rejected because it failed to present expert evidence on the scope and content of the prior art. However, Perricone does not dispute that the patents described above – all of which relate to the use of ascorbyl fatty acids and/or tocopherols in dermatological products designed to control the effects of UV radiation on the skin – are within the scope of the prior art for the '693 patent.

Further, the Court finds that expert testimony is not necessary to establish that the prior art disclosed at least the following[8]:

Tocopherols Alone

Tocopherols are useful as topically applied skin benefit ingredients. See, e.g, Bissett, col.3, ll.23-53, col.4, ll.60-64, Shinomiya at 4 ("The skin stimulating ingredient could be those conventionally known as . . . vitamin E acetate, vitamin E nicotinate, [or] vitamin E orotate"); Voyt, col.7, ll.43-45 ("Studies have shown that the tocopherols prevent degradation of sebum and cellular fats by oxidation."); Pereira col.1, ll.50-62 ("a skin benefit ingredient chosen from . . .

[8] See e.g., Monaplastics, Inc. v. Caldor, Inc., 378 F.2d 20, 21 (2d Cir. 1967) (holding that summary judgment of obviousness was appropriately granted despite lack of expert testimony because "device would have been obvious to persons having ordinary skill in the plastics molding industry, and would even have been obvious to ordinary laymen of modest intelligence.") Further, the Court notes that Perricone has not presented evidence, expert or otherwise, suggesting a contrary view of the prior art. In particular, Perricone has not presented evidence suggesting that, to one skilled in the art, superficially straightforward prior art would be more complicated or would present unanswered questions.

tocopherol") see generally, N'Guyen '235, N'Guyen '716.

One benefit provided by the tocopherols is protection of the skin against sunburn. See, e.g., Bissett, col.3, ll.23-28 ("Tocopherol works to protect the skin from deleterious effects of UV-irradiation without interfering with the tanning response"); see generally Voyt. Tocopherols can prevent sunburn from forming even when applied after UV exposure by scavenging free radicals in the skin. See, e.g., Bissett, col.4, ll.15-18 ("It is still further object of the invention to provide a photoprotection composition which can be applied to the skin prior to or following UV exposure without significant loss of efficacy.") Tocopherols also treat sunburn by preventing further oxidation of the skin. Voyt, col.7, ll.37-54 ("The composition of this invention also provides an additional function where applied to previously sunburned skin. Due to their antioxidant properties, the tocopherols when applied in a thin film will . . . enhance[] the healing of the burn.")

Ascorbyl Fatty Acid Esters Alone

Ascorbyl fatty acid esters are useful as topically applied skin benefit ingredients. See, e.g., Shinomiya at 2 ("many skin-beautifying cosmetics have been proposed, containing L-ascorbic acid esters of various higher fatty acids."); Bissett, col.4, ll.60-col.5, ll.8; see generally N'Guyen 235; N'Guyen '716. Among the class of ascorbyl fatty acids, ascorbyl palmitate, ascorbyl stearate, and ascorbyl laurate may be selected as skin benefit ingredients. N'Guyen '235 col.1, l.68; N'Guyen '716, col.2, l.8; Shinomiya (selecting ascorbyl stearate only). Ascorbyl fatty acids function as antioxidants in fatty bodies. N'Guyen '235, N'Guyen '716, col.1, ll.19-40. Ascorbyl fatty acid esters can prevent sunburn from forming even when applied after UV exposure by scavenging free radicals in the skin. See, e.g., Bissett, col.4, ll.15-18. Ascorbyl fatty

acid esters can be used to treat or prevent skin pigmentation associated with suntan. Shinomiya.

Ascorbyl Fatty Acid in Combination with Tocopherols

The use of ascorbyl esters in combination with other antioxidant agents such as the tocopherols enhances the antioxidant effects of the other agents. N'Guyen '235; N'Guyen '716, col.1, ll.41-46 ("apart from their own anti-oxidant properties, that ascorbic derivatives also have the property of improving the activity of anti-oxidant agents such as tocopherols . . . by favoring the regeneration of these anti-oxidant agents.") An "antioxidant system" including an ascorbyl fatty acid ester and a tocopherol is useful to protect the lipids of the skin against oxidation. N'Guyen '235, col.3, ll.51-54 ("the cosmetic compositions are provided in the form of creams intended for the protection of skin lipids against oxidation"); N'Guyen '716. Such an "antioxidant system" is also useful to protect the skin from the effects of the sun. N'Guyen '235, col.3, ll.42-50 ("cosmetic compositions according to the present invention are provided in the form of . . .anti-sun creams . . . anti-sun milks"); N'Guyen '716.

2. Differences between Prior Art and Perricone '693

"In making the assessment of the differences between the prior art and the claimed subject matter, section 103 specifically requires consideration of the claimed subject matter 'as a whole,'" rather than part by part. Princeton Biochemicals, Inc. V. Beckman Coulter, Inc., 411 F.3d 1332; see also Ruiz v. A.B. Chance Co., 357 F.3d 1270 (Fed. Cir. 2004).

Perricone argues that Medicis' obviousness argument should be rejected because it failed to present expert evidence assessing the difference between the prior art and the claimed material.

However, even drawing all inferences from the undisputed facts in Perricone's favor, the

most that is missing from the prior art is an explicit instruction to apply the known combination of ascorbyl palmitate and Vitamin E to treat skin sunburn.

3. Level of Skill in the Art

The parties do not dispute that the level of skill in the art is an undergraduate degree in chemistry and two to five years of experience in the formulation of skin care products. Indeed, the '693 patent would have been obvious even to a layperson familiar with the prior art.

4. Apparent Reason to Combine

Perricone claims that Medicis has failed to provide "articulated reasoning" for modifying or combining the known elements in the prior art in the fashion claimed.

However, the Court finds that the prior art provides abundant motivation for combining ascorbyl palmitate with a tocopherol and applying the composition to sunburned skin. Further, the Court finds that the prior art provided abundant reason to expect that using ascorbyl palmitate and a tocopherol in this manner would treat sunburned skin.

The N'Guyen patents' teaching that ascorbyl fatty acids enhance the efficacy of the tocopherols, and that ascorbyl palmitate is a good selection to make from the genus of ascorbyl fatty acid esters is ample motivation to alter the Voyt patent – which already included an ascorbyl fatty acid as a stabilizer – by selecting ascorbyl palmitate as an additional active ingredient and applying the resulting composition, as suggested in Voyt, to sunburned skin.

Similarly, the N'Guyen patents supply an obvious motivation to alter the Bissett patent by combining ascorbyl palmitate and tocopherol – instead of merely using them as an alternatives – and applying that new composition to skin following UV exposure as already taught in Bissett.

Voyt and Shinomiya[9] then provide a sufficient basis to expect that following this method would enhance the healing of skin sunburn – rather than merely preventing exacerbation of the sunburn – even if the composition is not applied immediately after exposure.[10]

Together, the N'Guyen, Bissett, Voyt and Shinomiya patents provide enough information about how ascorbyl fatty acids and tocopherols work when applied to the skin, and about the nature of sunburn to lead to a reasonable expectation that a combination of ascorbyl palmitate and a tocopherol will treat sunburn.

Accordingly, based on the unrefuted evidence construed in the light most favorable to Perricone, Medicis has established that claims 1-4, and 7 of the '693 patent are obvious as a matter of law.

5. Secondary Considerations

"Secondary considerations" provide an important check against hindsight analysis. Ruiz v. A.B. Chance Co., 234 F.3d 654, 662-63, 667 (Fed. Cir. 2000); Gambro Lundia AB v. Baxter Healthcare Corp., 110 F.3d 1573, 1579 (Fed. Cir. 1997). These considerations include evidence of commercial success, unexpected results and long felt but unmet need. Dann v. Johnston, 425 U.S. 219, 230 n. 4, 96 S.Ct. 1393, 47 L.Ed.2d 692 (1976); Graham, 383 U.S. at 17-18, 86 S.Ct. 684. "Evidence of secondary considerations ... are but a part of the totality of the evidence that is used to reach the ultimate conclusion of obviousness." Richardson-Vicks Inc. v. Upjohn Co.,

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[9] Although Shinomiya concerns ascorbyl stearate, according to Perricone ascorbyl stearate, palmitate, myristate and laurate are structurally similar and can be expected to function similarly.

[10] Similarly, the N'Guyen patents provide motivation to select ascorbyl palmitate from the genus of ascorbyl fatty acid esters and apply it as the sole active ingredient as suggested in Bissett.

122 F.3d 1476, 1483 (Fed. Cir. 1997) (quotations omitted).

Perricone argues that it has advanced sufficient evidence of commercial success and copying to prevent summary judgment of obviousness.

While it is clear that Perricone has been successful, the Court is unaware of – and Perricone has failed to reference – any evidence of the commercial success Perricone may have achieved in marketing products to treat sunburned skin. Further, as set forth below, the Court does not find that Perricone has presented evidence that Medicis copied Perricone's sunburn treatment claims, except through administration of Lustra to research subjects incidental to testing Lustra's effectiveness at sunburn prevention. "Evidence of commercial success, or other secondary considerations, is only significant if there is a nexus between the claimed invention and the commercial success." Ormco Corp. v. Align Technology, Inc., 463 F.3d 1299, 1311 -1312 (Fed. Cir. 2006) petition for cert. filed 76 USLW 3456 (Feb 14, 2008)(No. 07-1070).

Perricone has failed to rebut Medicis' overwhelming showing of obviousness by raising secondary considerations, or presenting other evidence of nonobviousness. Accordingly, summary judgment of invalidity based on the obviousness of claims 1-4 and 7 of the '693 patent is granted.

IV. Infringement

Finally, the Court finds that even if the remaining claims in the '693 patent were valid, Medicis would be entitled to summary judgment of noninfringement as to the majority of Perricone's infringement allegations.

Perricone argues that it has presented evidence that Lustra was tested and marketed as a

method for treating skin sunburn, thus infringing claims 1 through 4 and 7 of the '693 patent. Medicis maintains that it only used and marketed LUSTRA to protect against, not treat, sunburn.[11]

Lustra is a prescription skin depigmenter, indicated for the treatment of skin discoloration. Sun exposure is one cause of skin discoloration. The active ingredient in Lustra is hydroquinone. According to Medicis, hydroquinone "interferes with the production of melanin, by inhibiting or blocking the action of tyrosinase." Lustra also includes ascorbyl palmitate and Vitamin E to "protect the skin cells from the damage of free radicals," glycolic acid "to soften the skin and increase[] the rate of shedding of the top layers of skin and helping to quickly remove over-pigmented cells," and moisturizers to "enhance the complexion by restoring the smooth surface [of the skin] and reducing the appearance of fine lines." Some versions of Lustra also include sunscreen "to help prevent re-pigmentation." Thus, Medicis is designed to treat some of the long-term effects of sun-exposure, while simultaneously protecting the skin against additional damage.

"Whoever without authority . . . uses . . . any patented invention, within the United States . . . during the term of the patent therefor, infringes the patent." 35 U.S.C. § 271(a). "Determination of the issue of infringement entails a two step analysis – construction of the claims, a matter of law; followed by application of the claims to the accused device, a question of fact." Voice Tech. Group, Inc. v. VMC, Inc., 164 F.3d 605, 612 (Fed. Cir. 1999). Infringement may be either literal, or under the doctrine of equivalents.

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[11] However, Lustra marketing materials also caution that "Sunscreens are recommended for use with products containing hydroquinone to prevent repigmentation . . . LUSTRA-AF is not intended to prevent sunburn."

To prove literal infringement the plaintiff must show that the accused product meets each element or limitation of a claim. Pennwalt Corp. V. Durand-Wyland, Inc., 833 F.2d 931, 934 (Fed. Cir. 1987) (en banc), abrogated on other grounds Cardinal Chemical Co. v. Morton Intern., Inc., 508 U.S. 83, 113 S.Ct. 1967, 124 L.Ed.2d 1 (1993).

"A finding of infringement under the doctrine of equivalents requires a showing that the difference between the claimed invention and the accused product or method was insubstantial or that the accused product or method performs the substantially same function in substantially the same way with substantially the same result as each claim limitation of the patented product or method." AquaTex Industries, Inc. v. Techniche Solutions, 479 F.3d 1320, 1326 (Fed. Cir. 2007).

A. Induced Infringement

Perricone claims that Medicis infringed the '693 patent by promoting Lustra as a method for treating skin sunburn. Medicis admits that it promoted Lustra for treating sun-damaged skin. However, Medicis maintains that its product is only intended to treat the long-term, chronic effects of sun exposure and not the acute symptoms of sunburn.

Under 35 U.S.C. § 271(b), "[w]hoever actively induces infringement of a patent shall be liable as an infringer." "Liability for either active inducement of infringement or for contributory infringement is dependent upon the existence of direct infringement. Thus, either form of 'dependent infringement' cannot occur without an act of direct infringement." Joy Technologies, Inc. v. Flakt, Inc., 6 F.3d 770, 774 (Fed. Cir. 1993) (internal citations omitted); see also, DSU Medical Corp. v. JMS Co., Ltd., 471 F.3d 1293, 1303 (Fed. Cir. 2006) ("the patentee always has

the burden to show direct infringement for each instance of indirect infringement.") Circumstantial evidence may be sufficient to establish direct infringement. Moleculon Research Corp. v. CBS, Inc., 793 F.2d 1261, 1272 (Fed. Cir. 1986) (holding that evidence that manufacturer included instructional booklet teaching infringing puzzle solution was adequate circumstantial evidence that users solved puzzle according to instructions, thus directly infringing patent). However, even for the purposes of summary judgment, evidence is insufficient if it requires "too speculative a leap to conclude that" direct infringement actually occurred. E-Pass Technologies, Inc. v. 3Com Corp, 473 F.3d 1213, 1222 (Fed. Cir. 2007) (distinguishing general-purpose devices from devices, such as that at issue in Moleculon Research, which could only be used to practice the infringing method).

Further, a plaintiff must also present evidence of "active steps taken to encourage direct infringement . . . such as advertising an infringing use or instructing how to engage in an infringing use. . . [to overcome] the law's reluctance to find liability when a defendant merely sells a commercial product suitable for some lawful use." Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd., 545 U.S. 913, 936, 125 S.Ct. 2764, 2779 - 2780 (2005) (internal alteration, citations and quotation marks omitted); Fromberg, Inc. v. Thornhill, 315 F.2d 407, 412-413 (5th Cir. 1963) (demonstrations by sales staff of infringing uses supported liability for inducement).

Lustra marketing materials (1) describe Lustra's ability to "increase the skin's tolerance to UV exposure" and to "protect against future photodamage"[12]; and (2) claim that Lustra can "counteract the cumulative effects of sun exposure" and treat "sun-damaged skin." Taken in

[12] The first category of marketing material includes descriptions of and claims based on efficacy studies showing that skin treated with Lustra is less likely to burn than untreated skin.

context, claims in the first category plainly indicate use to protect against future photodamage.[13] This material is outside the remaining scope of the '693 patent.

However, the second category of marketing material is clearly directed at treatment. This marketing material would be evidence of "active steps" taken to encourage direct infringement if the type of "sun-damaged skin" Lustra was advertised to treat could be understood to include active skin sunburn.

The Federal Circuit found that Claim 1 of the '693 patent was not anticipated by Pereira because it taught application of a fatty acid ester of ascorbic acid to "skin sunburn." However, the Federal Circuit found that claims teaching application to exposed skin surfaces, skin suffering from disorders which arise because of depleted or inhibited collagen synthesis, or skin damaged or aged by oxygen-containing free radicals or the oxidative generation of biologically active metabolites were anticipated and thus invalid.

This Court previously defined "skin sunburn" as disclosed in claim 1 as:

> a type of skin damage caused by ultraviolet radiation. . . 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.

Perricone v. Medicis Pharmaceutical Corp., 267 F. Supp.2d 229, 235 (D. Conn. 2003). Accordingly, "skin sunburn" refers to the acute phase of photodamaged skin marked by

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[13] See, e.g., Dkt. #271, exh. 3, excerpt from www.sunandskin.com ("The active antioxidants in LUSTRA . . .protect the skin cells from the damage of free radicals"; "LUSTRA's antioxidant protection was equivalent to the protection provided by sunscreen"); exh. 4, Lustra suggested presentation ("Lustra will . . .protect your patient against future photodamage"; "Lustra significantly increases skin's tolerance to UV"); exh. 19, deposition of Havens ("Q. Does Medicis promote the fact that the antioxidant system has a therapeutic and preventative effect on the skin when its exposed to free radicals? . . .A. It has a preventative effect. I don't know about the treatment effect.")

sensitivity, pain and inflamation, and not to the long-term, chronic effects of sun exposure such as wrinkles, fine-lines and blotchiness. Claim 1 teaches application to skin sunburn, and not to skin which was once sunburned.

An examination of Medicis' advertising and marketing materials reveals that treatment claims primarily promoted Lustra as a treatment for the long-term effects of sun exposure.[14] However, at least two statements in Lustra's marketing materials could be interpreted as claiming that Lustra is suitable for treating sunburn, rather preventing sunburn or treating the cumulative effects of sun exposure: First, a Medicis sales team memorandum dated December 30, 1998 indicates that "ascorbyl palmitate enhances the antioxidant efficacy of Vitamin E and published clinical reports indicate that it reduces erythema and inflammation." Second, a Lustra product monograph claims that the "Lustra antioxidant system has been shown to reduce cutaneous solar damage."[15]

However, even if a jury found that these ambiguous statements referred to reducing erythema and inflammation after UV exposure, through application to skin sunburn, Perricone has not presented evidence of any direct infringement by the general public. While evidence of advertising, promotions, or instruction sheets may be sufficient circumstantial evidence of direct infringement in some circumstances, Medicis has presented un-rebutted evidence that Lustra is

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[14] See, e.g., Dkt. #271, exh. 3, excerpt from www.sunandskin.com ("LUSTRA has an impressive ability to counteract the cumulative effects of sun exposure" (emphasis added); "LUSTRA is indicated for the gradual treatment of skin discoloration resulting from over-exposure to the sun"; defining photodamage as "[t]he cumulative effects of sun exposure")

[15] While these claims are similar to prevention claims appearing throughout Medicis' marketing materials, they lack context to indicate whether they reflect efficacy at prevention or treatment.

unsuitable for treating active sunburn.[16] The undisputed evidence is that hydroquinone, the active ingredient in Lustra is a skin irritant,[17] and that competent medical professionals are aware that it would be inappropriate to apply it to compromised skin.[18]

Because Perricone has not presented evidence from which a reasonable jury could find direct infringement by the general public, there is no genuine issue of material fact relevant to induced infringement. Accordingly, even if the remaining claims of the '693 patent were valid, Perricone would only be permitted to proceed to trial on the issue of whether Medicis itself

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[16] Perricone has not presented direct evidence that physicians prescribed Lustra to treat sunburn. A prescription is required to obtain Lustra.

[17] See, e.g., [Dkt. #271, exh 3, excerpt from www.sunandskin.com ("Occasional skin irritation may occur"; "If you experience any type of irritation, redness or a rash while using LUSTRA, discontinue using it and call your dermatologist"; "some patients experience temporary skin reddening and a mild burning sensation"; "[d]uring treatment and maintenance therapy, *sun exposure should be avoided on treated skin*"; exh. 13, Medicis sales memorandum ("you'll notice a spike in erythema after two weeks [using Lustra] . . . products containing hydroquinone can cause irritation but after two weeks the skin begins to adjust")

[18] During his deposition, Dr. Perricone was asked whether he knew any dermatologist who would prescribe Lustra for treating sunburn, and responded "No." Dr. Perricone also indicated that sunburned skin is sensitive to irritants and that hydroquinone is an irritant. While Dr. Perricone indicated that the antioxidants in Lustra could, in theory, counteract the irritation, he testified that he did not know whether the levels in Lustra would be sufficient to confer such an effect. Indeed, while the Court does not find it necessary to reach the parties' arguments concerning prosecution history estoppel, it is noted that Perricone previously maintained that skin whiteners are inconsistent with sunburn treatment.
In a declaration, Dr. Thomas Fitzpatrick, a dermatologist, indicated that "the hydroquinone in these products is well known to be a skin irritant. . . . As such, it should not be applied to sunburnt skin."
During his deposition, Dr. Ronald Marks testified that application of Lustra to sunburned skin is contraindicated and that "I certainly wouldn't want it applied to me, if I were sunburned."
During his deposition, Dr. Kays Kaidbey testified that it would be malpractice to use Lustra to treat sunburn, and that sunburn "is certainly not an indication for the use of Lustra or any hydroquinone."

infringed the '693 patent while testing Lustra.[19]

V. Conclusion

Medicis' motion for summary judgment of invalidity [Dkt. # 410] is GRANTED. Perricone's renewed motion for summary judgment of validity [Dkt. # 216] is DENIED. Perricone's renewed motion for summary judgment of infringement [Dkt. #215] is DENIED. The Clerk is directed to close this case.[20]

SO ORDERED this 20th day of March 2008 at Hartford, Connecticut.

/s Christopher F. Droney
CHRISTOPHER F. DRONEY
UNITED STATES DISTRICT JUDGE

[19] The Court finds that Perricone has presented evidence that Medicis applied Lustra to sunburned skin while testing Lustra's efficacy at sunburn prevention.

[20] On 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-infringement of these claims should be entered in the defendant's favor. See Dkt. # 197. The parties did not stipulate as to the validity or invalidity of these claims and in its 2003 Ruling, the Court directed the parties to file briefs on the status of these claims. Medicis and Perricone responded that the issue of validity was moot with respect to these claims. See Dkt. #328 (filed under seal), 329. Accordingly, there is no need to address these claims in this ruling.