

PLAINTIFF

4. The FTC is an independent agency of the United States Government created by statute. 15 U.S.C. §§ 41-58. The FTC enforces Section 5(a) of the FTC Act, 15 U.S.C. § 45(a), which prohibits unfair or deceptive acts or practices in or affecting commerce. The FTC also enforces Section 12 of the FTC Act, 15 U.S.C. § 52, which prohibits false advertisements for food, drugs, devices, services, or cosmetics in or affecting commerce.

5. The FTC is authorized to initiate federal district court proceedings, by its own attorneys, to enjoin violations of the FTC Act and to secure such equitable relief as may be appropriate in each case, including rescission or reformation of contracts, restitution, the refund of monies paid, and the disgorgement of ill-gotten monies. 15 U.S.C. § 53(b).

DEFENDANTS

6. Defendant DERMAdoctor, Inc. is a Missouri corporation with its principal place of business at 1901 McGee Street, Kansas City, MO 64108. DERMAdoctor, Inc. transacts or has transacted business in this district and throughout the United States. At all times material to this Complaint, acting alone or in concert with others, DERMAdoctor, Inc. has labeled, advertised, marketed, distributed, or sold cosmetics and/or drugs to consumers throughout the United States.

7. Defendant Audrey Kunin, M.D., is the President and majority owner of DERMAdoctor, Inc. At all times material to this Complaint, acting alone or in concert with others, she has formulated, directed, controlled, has the authority of control, or participated in the acts and practices set forth in this Complaint. Defendant Kunin has, in connection with the matters alleged herein, transacted business in this district and throughout the United States.

COMMERCE

8. At all times material to this Complaint, Defendants have maintained a substantial course of trade in or affecting commerce, as “commerce” is defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

DEFENDANTS’ BUSINESS ACTIVITIES

9. Defendants advertise, market, distribute, and sell the DERMAdoctor brand line of cosmetic products. Defendants sell these products directly to consumers at the DERMAdoctor flagship store in Kansas City, MO, and via Defendants’ website, www.dermadoctor.com. Consumers also may purchase DERMAdoctor products in stores or online from retailers including Nordstrom, Sephora, and Ulta; at various times some DERMAdoctor products have been offered for sale via shopping channels and their associated websites, including HSN and QVC.

Photodynamic Therapy Facial Lotion

10. Since October 2010, Defendants have marketed and sold a product called Photodynamic Therapy Liquid Red Light Anti-Aging Lotion with Broad Spectrum SPF 30, or Photodynamic Therapy Sunlight-Activated Laser Lotion with SPF 30 (collectively, “Photodynamic Therapy”). Photodynamic Therapy has a suggested retail price of \$85 for a one-ounce bottle. Photodynamic Therapy contains extract of noni fruit (*Morinda citrifolia*), and was promoted to capture ultraviolet light and transform it into visible red light that has anti-aging effects on the skin. The results are claimed to be equivalent to those obtained from a laser or intense pulsed light treatment available in a physician’s office.

11. Defendants have disseminated or caused to be disseminated advertisements, packaging, and promotional materials for Photodynamic Therapy, including, but not limited to the attached Exhibits A-D. These materials contain the following statements:

A. Exhibit A: Excerpt of QVC “Beauty Prescription” Program, May 5, 2011

QVC Host Jill Bauer: I am so excited about our next product.... It is from our DERMAdoctor line, which is a line of outstanding products developed by dermatologist Dr. Audrey Kunin, who is with us for the show tonight....

Audrey Kunin: I am thrilled to be here and share this brand new technology. You're – Jill, you're correct, you w

worried about dryness, and roughness of your skin, if you want to restore the brilliance, even out your skin tone.

Bauer: Wow.

Kunin: Photodynamic Therapy contains that brand new, cutting edge red light therapy to give you these amazing results.

Bauer: What do they mean it's red light? I don't get it.

Kunin: Exactly. A picture is worth a thousand words. And so on the top you have 100 percent raw active powder. It's the noni fruit, which is tropical. But under a controlled lab situation, you can see that the powder is actually capturing light around it and emitting that red glow. It is that red light that is helping improve the appearance of your lines and wrinkles. That's – and it is clinically proven, in just four weeks....

Bauer: It's my moisturizer, it's my sun protection, and I'm getting the benefits of this red light therapy.

Kunin: This is the future now in lotion form.

Bauer: Now we talk about this being, quote, unquote "solar powered"?

Kunin: That's right.

Bauer: But we don't want you to think

Bauer: That's any type of light. Yeah.

Kunin: – you're driving to a soccer game, you – I'm a dermatologist, I don't want you going to seek extra sun.

Bauer: Right.

Kunin: It's normal, everyday activity. It's going to allow this light emitting laser lotion to –

Bauer: Wow.

Kunin: – deliver the impact of improving the fine lines and wrinkles, and clinically proven to firm the skin, restore elasticity, in just four weeks' time.

Bauer: And remember, this technology has never been made available before. It's never been available so that you can get the benefits of red light at home. So, this is going to be part of your skincare regimen. Frankly, Dr. Kunin has made your morning routine so much easier. You're going to wash your face and you're going to put on your Photodynamic Therapy Lotion. Because it's your moisturizer, it's going to be your SPF. You're going to be getting the benefits of that red light technology.

Kunin: That's right. That anti-aging light.

Bauer: All in one product.

Kunin: That's right.

Kunin: You won't find this anywhere in the world. It is a red light emitting laser lotion we call it.

Bauer: And, again, what is red light used for in skin care?

Kunin: Red light is used because it's a proven known method of rejuvenation and anti-aging. But prior to DERMAdoctor's Photodynamic Therapy –

Bauer: You couldn't get it at home.

Kunin: – you couldn't have a lotion at home –

Bauer: Yeah, mm-hmm.

Kunin: – that did this type of simplicity.

Bauer: Mm-hmm.

Innovative lotion technology that supplies the skin with a precise skin-firming, wrinkle busting red wavelength of light. Simply apply this lotion for all day anti-aging benefits, including a more radiant appearance, minimized appearance of fine lines and wrinkles, evened out skin tone and improved elasticity.

How Does It Work?

Morinda Citrifolia Extract (Noni Fruit) contains a special polyphenol that specifically captures UV rays then converts and emits this energy as a highly focused visible red wavelength of light (648 nm).

D. Exhibit D: PDT product packaging

PHOTO
DYNAMIC
therapy[™]

liquid red light
anti-aging lotion with
broad spectrum spf 30

Just what the skin doctor ordered.[®]

Ground-breaking, patent-pending solar powered technology *in lotion form* captures UV light transforming it into visible *red* light, a proven energy source for eliciting anti-aging effects on the skin.

In-office lasers, IPL (intense pulsed light) and other light treatments, used to help build collagen and elastin, are expensive and inconvenient, requiring a series of doctor's visits and maintenance sessions.

At-home red light devices are costly, difficult to remember to use as well as time consuming.

Imagine a new reality in skin rejuvenation where skin can experience continuous exposure to anti-aging red light through the mere daily application of a lotion.

DERMAdoctor[®] Photodynamic Therapy

How Does It Work?

Morinda Citrifolia Extract (Noni Fruit) contains a special polyphenol that specifically captures light then converts and emits this energy as a highly focused visible red wavelength of light (648 nm) equivalent to that of a red LED.

Binding of this polyphenol to an inert tricalcium phosphate particle creates a complex capable of transmitting the visible red light to the skin where it works to encourage the production of collagen and elastin fibers within the dermis.

DERMAdoctor[®] Photodynamic Therapy[™]

- Utilizes UV light to revitalize the skin

- Improves skin elasticity

- Reduces the appearance of fine lines and wrinkles

- Improves skin tone and texture

applied a placebo lotion, or women who applied a lotion with a lower concentration of the compound. However, the subjects who used the compound at the same concentration as that contained in Photodynamic Therapy were required to spend at least two hours a day in natural sunlight, and they wore sunscreen with an SPF of only 8 throughout the course of the study.

14. In addition, Defendants commissioned an eight-week clinical study of Photodynamic Therapy, with the goal of assessing the product's efficacy on improving the appearance of wrinkles and hyper-pigmented spots. This study was not designed to, and did not, assess the purported mechanism by which Photodynamic Therapy could transform UV light into visible red light with anti-aging effects.

Photodynamic Therapy Eye Lotion

15. Since September 2012, Defendants have marketed and sold a product called Photodynamic Therapy Liquid Red Light Eye Lift Lotion ("PDT Eye"). PDT Eye has a suggested retail price of \$65 for a one-half ounce bottle. Like Photodynamic Therapy, PDT Eye also contains noni fruit extract and was claimed to have the same ability to capture and transform UV light into visible red light with anti-aging effects.

16. Defendants have disseminated or caused to be disseminated advertisements, packaging, and promotional materials for PDT Eye, including, but not limited to the attached Exhibits E-G. These materials contain the following statements:

A. Exhibit E: Print Ad from *Shape Magazine*, December 2012

[Depiction: bottles of Photodynamic Therapy liquid red light eye lift lotion and Photodynamic Therapy liquid red light anti-aging lotion with broad spectrum spf 30]

Dear Doctor,
Red light anti-aging skin care treatments sound amazing. My friends are doing it, yet I can't commit to expensive and time-consuming in-office

C. Exhibit G: PDT Eye product packaging

PHOTO
DYNAMIC
therapy[™]

19. The second study was designed and conducted by employees of DERMAdoctor who did not have relevant scientific training or expertise to undertake such a study. The DERMAdoctor, Inc. study included four test subjects who were directed to use PDT Eye twice daily for ten weeks. Participants were given a questionnaire after eight weeks of using PDT Eye. Two out of the four participants reported that their skin was firmer. The questionnaire did not ask whether the participants saw less sagging skin. The “before” and “after” photos in Exhibit F are from one of the four participants in this study.

Shrinking Beauty

20. Since December 2012, Defendants have marketed and sold a product called

**B. Exhibit I: Shrinking Beauty product description from
DERMAdoctor.com website**

Shrinking Beauty

firming, sculpting & toning lotion with lobster weight loss
inspired technology

This vegan formulation smoothes, firms, tones & improves the appearance of
cellulite. Leaves skin sleek contoured and dimple free. Clinically proven to
lose up to an inch within 2 weeks of use.

Directions

Apply to mid-section (belly and muffin top area), buttocks, thighs and right above knee area. Massage into area for 20-30 seconds until absorbed. Apply twice daily....

Just what the skin doctor ordered.[®]

Learn from the lobster. This sea creature knows exactly how to shrink a size effortlessly without going on a diet. Our slimming and toning formula mirrors the ecdysteroid hormone lobsters produce to get skinny and wiggle free of their shells.

Clinical Results

Clinically proven to lose up to an inch within 2 weeks of use.

75% of panelists felt skin was less dimpled.

100% of panelists felt skin was smoother.

22. At the time that the advertisements in Paragraph 21 were disseminated, Defendants possessed information relating to two clinical studies potentially relevant to the performance of Shrinking Beauty on the thigh or buttock area.

23. One of the studies was provided to Defendants by the supplier of an ingredient in Shrinking Beauty. In that placebo-controlled study, ultrasound was used to measure the thickness of fat tissue in the thighs and calculate changes in thigh circumference after daily application of the ingredient. After two months of use, none of the 27 subjects in the study had a decrease in thigh circumference as large as one inch.

24. The second study was designed and conducted by employees of DERMAdoctor who did not have relevant scientific training or expertise to undertake such a study. The DERMAdoctor uncontrolled study included five test subjects who were instructed to apply

Shrinking Beauty to their thigh and buttock region on both legs daily for ten weeks. One study participant took her own weekly measurements of thigh diameter at home during the study. The other four participants had their thighs measured weekly by a DERMAdoctor employee; each of these subjects missed two or more weekly measurements for various reasons. Each week, the DERMAdoctor employee took three measurements of right and left thigh circumference for each subject, to the nearest eighth of an inch. These three measurements were averaged together and used to calculate whether or not a subject's thigh circumference had decreased since the beginning of the study. The three measurements of an individual thigh on a particular date routinely varied, with differences of up to three-quarters of an inch.

VIOLATIONS OF THE FTC ACT

25. Section 5(a) of the FTC Act, 15 U.S.C. § 45(a), prohibits “unfair or deceptive acts or practices in or affecting commerce.”

26. Misrepresentations or deceptive omissions of material fact constitute deceptive acts or practices prohibited by Section 5(a) of the FTC Act.

27. Section 12 of the FTC Act, 15 U.S.C. § 52, prohibits the dissemination of any false advertisement in or affecting commerce for the purpose of inducing, or which is likely to induce, the purchase of food, drugs, devices, services, or cosmetics. For the purposes of Section 12 of the FTC Act, 15 U.S.C. § 52, PDT, PDT Eye, and Shrinking Beauty are either a “cosmetic” or “drug” as defined in Section 15(b) and (c) of the FTC Act, 15 U.S.C. § 55(b), (c).

Count I

False or Unsubstantiated Mechanism Claims for Photodynamic Therapy

28. Through the means described in Paragraph 11, Defendants have represented, directly or indirectly, expressly or by implication, that Photodynamic Therapy:

A. Transforms UV light into visible red liA.

affecting commerce, in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52.

Count III

False Establishment Claims for Photodynamic Therapy Eye

34. Through the means described in Paragraph 16, Defendants have represented, directly or indirectly, expressly or by implication, that PDT Eye is clinically proven to:

- A. Lift and tighten sagging eyelids by 67%;
- B. Produce less sagging skin around the eye in 65% of users; and
- C. Produce firmer skin around the eye in 80% of users.

35. The representations set forth in Paragraph 34 are false.

36. Therefore, the making of the representations set forth in Paragraph 34 of this Complaint constitutes a deceptive act or practice and the making of false advertisements, in or affecting commerce, in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52.

Count IV

False or Unsubstantiated Efficacy Claims for Shrinking Beauty

37. Through the means described in Paragraph 21, Defendants have represented, directly or indirectly, expressly or by implication, that:

- A. Shrinking Beauty causes weight loss; and
- B. Shrinking Beauty reduces the size of thighs, buttocks, and the abdomen.

38. The representations set forth in Paragraph 37 are false or misleading, or were not substantiated at the time the representations were made.

39. Therefore, the making of the representations set forth in Paragraph 37 of this Complaint constitutes a deceptive act or practice and the making of false advertisements, in or affecting commerce, in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52.

Count V

False Establishment Claims for Shrinking Beauty

40. Through the means described in Paragraph 21, Defendants have represented, directly or indirectly, expressly or by implication, that Shrinking Beauty is clinically proven to:

- A. Cause loss of one inch in diameter on thighs, buttocks, and the abdomen in two weeks;
- B. Cause less dimpled skin in 75% of users; and
- C. Cause smoother skin in 100% of users.

41. The representations set forth in Paragraph 40 are false.

42. Therefore, the making of the representations set forth in Paragraph 40 of this Complaint constitutes a deceptive act or practice and the making of false advertisements, in or affecting commerce, in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52.

CONSUMER INJURY

43. Consumers have suffered and will continue to suffer substantial injury as a result of Defendants' violations of the FTC Act. In addition, Defendants have been unjustly enriched as a result of their unlawful acts or practices. Absent injunctive relief by this Court, Defendants are likely to continue to injure consumers, reap unjust enrichment, and harm the public interest.

THE COURT'S POWER TO GRANT RELIEF

44. Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), empowers this Court to grant injunctive and such other relief as the Court may deem appropriate to halt and redress violations of any provision of law enforced by the FTC. The Court, in the exercise of its equitable jurisdiction, may award ancillary relief, including rescission or reformation of contracts, restitution, the refund of monies paid, and the disgorgement of ill-gotten monies, to prevent and remedy any violation of any provision of law enforced by the FTC.

PRAYER FOR RELIEF

Wherefore, Plaintiff FTC, pursuant to Section 13(b) of the FTC Act, 15 U.S.C. §§ 53(b), and the Court's own equitable powers, requests that the Court:

- A. Enter a permanent injunction to prevent future violations of the FTC Act by Defendants;
- B. Award such relief as the Court finds necessary to redress injury to consumers resulting from Defendants' violations of the FTC Act, including but not limited to, rescission or reformation of contracts, restitution, the refund of monies paid, and the disgorgement of ill-gotten monies; and
- C. Award Plaintiff the costs of bringing this action, as well as such other and additional relief as the Court may determine to be just and proper.

Respectfully submitted,

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