

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF CONNECTICUT**

SENSATIONAL SMILES LLC,
D/B/A SMILE BRIGHT,

Plaintiff,

Civil Action No.
3:11-CV-01787-MPS

v.

Date: April 8, 2013

DR. JEWEL MULLEN, ET AL.,

Defendants.

LOCAL RULE 56(a)(1) STATEMENT OF UNDISPUTED FACTS

As required by Local Civil Rule 56(a)(1), Plaintiff submits the following statement of material facts as to which Plaintiff contends there is no genuine issue to be tried.

Introduction

1. Before the Dental Commission sent them a cease-and-desist order, Plaintiff Smile Bright provided teeth-whitening services to customers in Connecticut. Decl. of Stephen Barraco in Supp. of Pl.'s Mot. for Summ. J. (Barraco Decl.) ¶¶ 2, 4.

2. Teeth whitening is a popular cosmetic procedure that temporarily lightens the color of stains on a person's teeth. Decl. of Martin Giniger in Supp. of Pl.'s Mot. for Summ. J. (Giniger Decl.) ¶¶ 27, 42-44.

3. Although there are multiple ways to remove tooth stains or reduce their appearance, this case concerns teeth whitening performed with peroxide-based gels that customers apply to their own teeth. Giniger Decl. ¶ 19; Barraco Decl. ¶¶ 5-22.

Peroxide-based Teeth Whitening

4. Peroxide-based teeth-whitening products temporarily reduce the appearance of "extrinsic stains," which are defined as stains on the surface of teeth. Giniger Decl. ¶¶ 31, 44.

5. Extrinsic stains are caused when chemicals present in certain foods or beverages, like coffee or red wine, or produced by certain bacteria, bind with the surface of the teeth and cause discoloration. Giniger Decl. ¶ 31.

6. These stains can be physically removed by polishing the surface of the tooth. It is also possible, however, to temporarily lighten the stains through the use of peroxide-based teeth-whitening products. Giniger Decl. ¶¶ 33-35, 37-44.

7. These products do not physically remove the stain particles from the surface of the tooth. Rather, they cause the stain particles to temporarily decolorize. Giniger Decl. ¶ 44.

8. The ability of hydrogen peroxide to whiten teeth was discovered by chance in 1989 when a dentist “observed that when a hydrogen peroxide oral antiseptic was administered by dental tray to address gingival irritation and inflammation, vital teeth also became whiter.” This quickly led to the development of commercial whitening products. Giniger Decl. ¶ 29.

9. These products are now widely available for purchase from drug stores, on the Internet, from dentists, or from entrepreneurs like Plaintiff Smile Bright. Giniger Decl. ¶¶ 42-43, 45, 49.

10. Literally millions of people worldwide have whitened their teeth using peroxide-based products. Giniger Decl. ¶¶ 20, 115.

11. The active ingredient in peroxide-based teeth-whitening products is either hydrogen peroxide or a related chemical called carbamide peroxide, which breaks down into hydrogen peroxide in the presence of water and salivary enzymes. Giniger Decl. ¶ 45.

12. Carbamide peroxide breaks down into hydrogen peroxide in a ratio of approximately 3:1. Thus, a teeth-whitening product with a 30% concentration of carbamide peroxide is approximately equivalent in strength to a product with a 10% concentration of hydrogen peroxide. Giniger Decl. ¶ 45.

13. Carbamide peroxide is preferred by some manufacturers of teeth-whitening products because it is more shelf-stable than hydrogen peroxide. Regardless of which of these chemicals is used as an active ingredient, however, the whitening process is the same. Giniger Decl. ¶¶ 45-46.

14. Hydrogen peroxide is commonly used in the production of food and cosmetics. Teeth-whitening products containing hydrogen peroxide or carbamide peroxide are both regulated by the FDA as cosmetics, which means that they are available for sale, without a prescription, to any person. Giniger Decl. ¶¶ 54-58.

15. Many peroxide-based teeth-whitening products are used in conjunction with LED “enhancing lights.” These lights consist of a multitude of light-emitting diodes mounted side by side so that they can illuminate all of a person’s visible teeth. Giniger Decl. ¶¶ 74-75.

16. The LED lights emit blue light that is distributed across a band of 420–480nm with a power that is equivalent to an 8-watt light bulb, or less. There are no legal limits on who may purchase LED enhancing lights. The lights are available for purchase directly by consumers, and some at-home teeth-whitening products are packaged with LED enhancing lights. Giniger Decl. ¶¶ 21, 75, 88.

Smile Bright’s Whitening Procedure

17. Sensational Smiles LLC d/b/a Smile Bright is a Connecticut limited-liability corporation formed in 2007 by entrepreneurs Steve Barraco and Tasos Kariofyllis to offer peroxide-based teeth-whitening services. At various times, Smile Bright has offered teeth-whitening services at home shows, in shopping malls, and in salons. Regardless of the location, however, the whitening process was the same. Barraco Decl. ¶¶ 2, 4.

18. A complete description of the whitening process that Smile Bright previously offered is given below. A video demonstrating the process is also available at http://www.youtube.com/watch?v=IjZ_8qbzsGI. Barraco Decl. ¶ 5.

19. Smile Bright's services begin with an explanation of the product they sell and the process of teeth whitening. Barraco Decl. ¶ 6.

20. Customers are asked to review and sign an information sheet indicating that they will follow all of the instructions supplied with the product and affirming that they do not have any condition that would contraindicate whitening, such as difficulty breathing comfortably through their nose during the 20-minute procedure, gum disease, or a recent oral piercing or surgery. Barraco Decl. ¶ 7.

21. Customers are told that not all causes of tooth discoloration will respond to peroxide-based whitening and that they should only whiten their teeth if they have healthy teeth, but Smile Bright employees never attempt to diagnose the underlying cause of any tooth discoloration or whether a customer's teeth are actually healthy. Barraco Decl. ¶ 8.

22. Smile Bright does not offer teeth whitening services to minors or to women who indicate that they are nursing or pregnant. Smile Bright has no basis for believing that teeth whitening is dangerous for such people; they simply take this step out of an abundance of caution. Barraco Decl. ¶ 9.

23. After the customer has reviewed the form and consented to the whitening process, they are invited to sit in a reclining chair like those used in salons. Barraco Decl. ¶ 10.

24. A Smile Bright employee then measures the color of the customer's teeth using a device known as a shade guide. The shade guide is simply a device that holds a row of artificial teeth of varying shades, arranged from lightest to darkest. Barraco Decl. ¶ 11.

25. To measure the shade of the customer's teeth, the employee visually compares the color of the customer's teeth to the shade guide and selects the shade that is closest to the customer's natural shade. This comparison is purely visual and the employee makes no effort to diagnose the cause of any tooth discoloration the customer might have. Barraco Decl. ¶ 12.

26. Using a handheld mirror, the customer is also allowed to look at the shade guide, so that the customer can decide for herself whether the employee has accurately judged the shade of the customer's teeth. The purpose of using the shade guide is so that the customers can evaluate the results of the whitening process and see how much whiter their teeth have become. Barraco Decl. ¶ 13.

27. Next, the Smile Bright employee dons disposable gloves and hands the customer a pre-packaged "brush up," a disposable tooth-cleaner that fits over the index finger like the finger of a glove. The customer is instructed to open the brush up, slide it over her finger, and gently rub the surface of her visible teeth to ensure that they are free of any debris before the whitening. Barraco Decl. ¶ 14.

28. The employee then opens a prepackaged teeth-whitening mouth tray containing a 30% carbamide peroxide gel. These one-size-fits-all trays are disposed of immediately after use. Barraco Decl. ¶ 15.

29. The employee inspects the tray to ensure that it has shipped with whitening gel in it and that the gel is evenly distributed across the tray. If the tray does not have sufficient gel, the employee adds gel to the tray from a sterile, disposable, prepackaged plastic syringe. If the gel has settled unevenly during transport, the employee uses a disposable wooden stick, similar to a tongue depressor, to spread the gel evenly across the tray. The employee then places the tray into a disposable plastic bowl and hands it to the customer. Barraco Decl. ¶¶ 16-17.

30. After handing the tray to the customer, the employee instructs the customer to insert the tray into her mouth and to wiggle the tray slightly to ensure that the gel is evenly distributed over the surface of her teeth. The employee then gives the customer a pair of tinted glasses, activates a blue LED light, and positions the light in front of the customer's mouth. Barraco Decl. ¶ 18.

31. After 20 minutes the light automatically shuts off. The customer removes the tray and places it back into the disposable plastic bowl. The employee hands the customer a small cup of water so that the customer can rinse her mouth. After rinsing, the customer spits the water into the disposable plastic bowl and the gloved employee discards the bowl. Barraco Decl. ¶ 19.

32. Finally, the employee and the customer use the shade guide to measure the change in the color of the customer's teeth. Barraco Decl. ¶ 19.

33. After each customer, a Smile Bright employee disinfects the glasses, chair, and light. Barraco Decl. ¶ 20.

34. Each time an employee leaves a customer and returns, or goes to work with a new customer, the employee dons new, clean gloves. Barraco Decl. ¶ 21.

35. At no time during the whitening procedure does the employee put her hands, or anything else, into the customer's mouth. The application of the teeth-whitening product itself is performed entirely by the customer, just as they would at home. Barraco Decl. ¶ 22.

Expert Qualifications of Dr. Martin Giniger

36. Dr. Martin Giniger is a licensed dentist and an expert on the history, practice, and safety of peroxide-based teeth whitening. He holds a DMD from Fairleigh Dickinson University School of Dental Medicine (1984), an MSD in Oral Medicine from the University of Connecticut (1993), and Ph.D. in Biomedical Science with a concentration in oral biology, also from the University of Connecticut (1993). Giniger Decl. ¶¶ 2-4, 11-12.

37. Dr. Giniger has taught basic and advanced courses in oral diagnosis, diagnostic sciences, and treatment planning at the Louisiana State University Medical Center School of Dentistry and the University of Medicine and Dentistry of New Jersey. Giniger Decl. ¶ 5.

38. Dr. Giniger also has extensive experience developing and testing the safety and effectiveness of a variety of oral-care products, including teeth-whitening products. Giniger Decl. ¶¶ 8-9.

39. Dr. Giniger previously provided expert testimony in *FTC v. North Carolina Board of Dental Examiners*, No. 9343, in which he was retained by the United States Federal Trade Commission to testify regarding the safety of peroxide-based teeth-whitening services like those offered by Plaintiff. Giniger Decl. ¶ 10.

Dr. Giniger’s testimony on the safety of peroxide-based teeth whitening

40. All of the possible side effects of peroxide-based teeth whitening are mild and invariably temporary. Despite the fact that millions of people worldwide have whitened their teeth using peroxide-based products, the published literature does not reveal a single instance of anyone suffering permanent or serious harm as a result. Instead, the most common side effects are temporary tooth and gum sensitivity, which the reported literature finds resolve on their own within days of the whitening. Giniger Decl. ¶¶ 20, 22, 59-61, 64.

41. There is no evidence that the temporary side effects of teeth whitening are more prevalent or severe with non-dentist-provided teeth whitening as compared to teeth whitening accomplished with drugstore preparations or those found on-line, and there is no conceivable mechanism by which applying products at the mall can be more dangerous than applying them at home, since the products and lights that are available from either source are materially indistinguishable. Indeed, these side effects may be “most frequent and pronounced with dentist-

provided chairside bleaching owing to the greater concentration of hydrogen peroxide and more intense light/heat activation often used in dental offices.” Giniger Decl. ¶¶ 22, 59, 90-91.

42. There is no evidence—“[e]ven in conditions of plainly excessive use”—that peroxide-based whitening could cause anything beyond minor and reversible surface change in the tooth enamel. Even these changes are “no different from those that occur after drinking a glass of orange juice” and are “quickly reversed when teeth are exposed to saliva.” Giniger Decl. ¶¶ 48, 63, 70.

43. There are “no literature reports that suggest that bleaching in lay-operated bleaching facilities results in any more ‘surface changes’ than are found with dentist-provided bleaching or bleaching through self-application of products available from drugstores or on-line.” Giniger Decl. ¶ 63.

44. The possibility of systemic side effects from exposure to hydrogen peroxide is not a realistic concern. The level of systemic exposure to hydrogen peroxide during teeth whitening is “quite low.” Dr. Giniger “very conservatively” estimated that a 70 kg (154 lbs.) person would have to be exposed to two grams of hydrogen peroxide before any systemic side effects were plausible, and that a teeth-whitening customer could expect to be exposed to between 5 and 11.25 mg (i.e., between .005 and .01125 grams) of hydrogen peroxide for services provided by non-dentists and dentists, respectively. By comparison, a recent independent review of the safety profile of Crest WhiteStrips concluded that the maximum daily exposure to hydrogen peroxide from use of its products is between 42 and 49 mg. Even this exposure, which is significantly higher than the exposure that would occur in “chairside” whitening, is “well below any known risk level for humans.” Giniger Decl. ¶¶ 65-69.

45. Non-dentist teeth whitening as practiced by Plaintiff Smile Bright provides “little opportunity for cross contamination between bleaching center personnel and the consumer,” and

Dr. Giniger is “aware of no incidence of such cross-contamination being reported in the scholarly literature.” Giniger Decl. ¶ 71.

46. “[H]ydrogen peroxide is itself a potent antimicrobial agent and likely helps prevent any possible cross contamination.” Giniger Decl. ¶ 71.

47. Although “[t]here may be periodic breaches of proper sanitation and infection control in lay-operated bleaching facilities . . . that will be true in dental offices as well.” A recent study found ““a lack of understanding of the basics of infection control and the prevention of transmission of communicable infectious diseases not only in large percentages of dental and dental hygiene students, but also in graduate students and among the dentists and dental hygienists who responded to this survey.”” Giniger Decl. ¶ 72.

48. While breaches of “proper sanitation and infection control practices might warrant action against the specific dentist or non-dentist teeth bleaching facility involved,” the inevitability of such breaches “hardly seems to warrant exclusion of all non-dentist providers from the market, any more than occasional breaches of sanitation by make-up artists warrants exclusion of everyone but licensed dermatologists from the practice of make-up artistry.” Giniger Decl. ¶ 72.

Dr. Giniger’s testimony on the safety of LED enhancing lights

49. The LED lights used in teeth whitening are very low energy and emit light over a narrow band of the visible spectrum. They generate little heat and no collateral UV B or C radiation, making them no more harmful than a typical consumer flashlight. Giniger Decl. ¶ 75.

50. There is no published literature showing that any person has ever been harmed as a result of being exposed to the type of low-powered LED bleaching lights used by non-dentists. Giniger Decl. ¶ 75.

51. Dr. Giniger has conducted first-hand scientific experiments with several of the LED bleaching lights available to non-dentists and found none of them able to generate additional

external heat energy change above 1°C (1.8°F). This is significant because it is necessary to cause at least a 5.5°C (9.9°F) increase in the temperature of the tooth pulp to cause any possible transient tooth harm. Giniger Decl. ¶ 76.

52. “[I]t would be scientifically and practically impossible for these lights to cause any more harm than a household flashlight (in other words, no chance).” Giniger Decl. ¶ 77.

Dr. Giniger’s testimony regarding Smile Bright’s whitening products and LED lights

53. The teeth-whitening gel and LED lights that Smile Bright uses are safe. Giniger Decl. ¶ 78.

54. The carbamide peroxide gel used in Smile Bright’s teeth-whitening trays is equivalent to 10 to 12% hydrogen peroxide, which is less concentrated than the gel found in the over-the-counter product Crest WhiteStrips Supreme, which utilizes 14% hydrogen peroxide and has been safely used by millions of consumers. Giniger Decl. ¶ 80.

55. The hydrogen peroxide ampules Smile Bright uses for filling trays shipped with insufficient gel are even less concentrated at only 6% hydrogen peroxide. Giniger Decl. ¶ 86.

56. All of the inactive ingredients used in the trays and ampules, including glycerine, propylene glycol, alcohol and flavorings are recognized as safe and are commonly used in medicine, food, and cosmetics. Giniger Decl. ¶¶ 80-86.

57. The specific formulation used in the trays Smile Bright sells is sold to about 50% of all non-dentist teeth-whitening clinics throughout the world. Dr. Giniger is unaware of any complaints regarding its safety. Giniger Decl. ¶ 80.

58. The specific light Smile Bright uses is “extremely safe” and has “no potential for human harm when used as directed.” The light is “equivalent in strength to many home LED flashlights sold in drugstores and retail chains.” Even more powerful lights are sold for home use. Giniger Decl. ¶ 88.

Dr. Giniger's testimony regarding the safety of teeth whitening compared to other oral procedures that are not considered to be the practice of dentistry.

59. The risk of injury associated with teeth-whitening services like Smile Bright's is "far lower than the risks associated with the practice of tongue piercing, which is commonly performed in lay establishments with no oversight by a licensed dentist." Giniger Decl. ¶ 100.

60. Potential complications of oral piercings are numerous and include:

- increased salivary flow;
- gingival injury or recession;
- damage to teeth, restorations, and fixed porcelain prostheses;
- interference with speech, chewing or swallowing;
- scar-tissue formation;
- development of metal hypersensitivities;
- prolonged bleeding;
- airway obstruction; and
- infection.

Giniger Decl. ¶¶ 100-105.

61. "Secondary infection from oral piercing can be serious. A recent article in the British Dental Journal reported a case of Ludwig's angina, a rapidly spreading cellulitis . . . that manifested four days after the 25-year-old patient had her tongue pierced. Intubation was necessary to secure the airway. When antibiotic therapy failed to resolve the condition, surgical intervention was required to remove the barbell-shaped jewelry and decompress the swelling in the floor of the mouth." Giniger Decl. ¶ 105.

62. Dr. Giniger is unaware of any facts that would justify treating the comparatively harmless practice of teeth-whitening as dentistry while allowing laypeople to perform tongue piercing.

The presence of a non-dentist who is familiar with the use of teeth-whitening products directing the application of those products can only enhance the safety of teeth whitening. Giniger Decl.

¶¶ 86, 106.

63. Unlike teeth-whitening services, dentists typically do not offer piercing services. Giniger Decl. ¶ 106.

Dr. Giniger's testimony regarding teeth whitening as a component of dental-school curricula.

64. Teeth whitening is rarely, if ever taught in dental schools. Not one of the 65 dental schools in North America has any clinical requirement for teeth whitening. In other words, to graduate from dental school it is not necessary to have performed even a single teeth-whitening procedure. Giniger Decl. ¶¶ 107-111.

65. In Dr. Giniger's experience, the absence of teeth-whitening from dental-school curricula is attributable to the lack of available time in an already crowded curriculum and the fact that the techniques are so simple that no training is necessary. Giniger Decl. ¶ 108.

66. Dr. Giniger analogized requiring dental students to learn about teeth whitening to requiring dermatology students to learn about make-up application. Indeed, he considers it even more irrational because—while there are no documented incidents of any person anywhere ever suffering permanent injury as a result of teeth whitening—there are documented instances of people suffering permanent damage to their skin from the use of cosmetics. Giniger Decl. ¶ 110.

67. These facts lead Dr. Giniger to conclude that the Dental Commission, “in excluding non-dentists from the market for teeth whitening services, has injured consumers and teeth whitening entrepreneurs needlessly.” Giniger Decl. ¶ 26.

Connecticut's Regulation of Teeth Whitening

68. Under Connecticut's Dental Practice Act, no person may engage in the "practice of dentistry or dental medicine" unless that person is a fully licensed dentist. Conn. Gen. Stat. §§ 20-106, -123.

69. "The practice of dentistry or dental medicine" is defined as "the diagnosis, evaluation, prevention or treatment by surgical or other means, of an injury, deformity, disease or condition of the oral cavity or its contents, or the jaws or the associated structures of the jaws." Conn. Gen. Stat. § 20-123(a).

70. "No person, except a licensed and registered dentist, and no corporation, except a professional service corporation organized and existing under chapter 594a for the purpose of rendering professional dental services, and no institution shall own or operate a dental office, or an office, laboratory or operation or consultation room in which dental medicine, dental surgery or dental hygiene is carried on as a portion of its regular business." Conn. Gen. Stat. § 20-122(a).

71. Violation of any of these provisions is a felony offense punishable by a fine of \$500, five years in jail, or both. Further, "each instance of patient contact or consultation" that is in violation of the prohibition on the unlicensed practice of dentistry "shall constitute a separate offense." Conn. Gen. Stat. § 20-126.

72. The Connecticut Dental Commission is a nine-member body with the authority to issue declaratory rulings interpreting the Dental Practice Act and to impose civil penalties for violations of the Dental Practice Act. Conn. Gen. Stat. §§ 20-103a, -114.

73. By statute, six of the nine members of the Commission must be practicing dentists. Conn. Gen. Stat. § 20-103a(a).

74. The Connecticut Dental Commission has authority to impose civil penalties of up to \$25,000 for any violation of the Dental Practice Act or for "the aiding or abetting in the practice

of dentistry, dental medicine or dental hygiene of a person not licensed to practice dentistry, dental medicine or dental hygiene in this state.” Conn. Gen. Stat. §§ 19a-17(6), 20-114(a).

75. On September 8, 2010, the Connecticut State Dental Commission began a declaratory ruling proceeding to determine under what circumstances teeth-whitening services constituted the “practice of dentistry” as set forth in Conn. Gen. Stat. § 20-123. Decl. of Paul Sherman in Supp. of Pl.’s Mot. for Summ. J. (Sherman Decl.) Ex. 1, at 1.

76. On June 8, 2011, the Dental Commission issued a declaratory ruling concluding that teeth-whitening services constitute the practice of dentistry when they include:

(1) assessing and diagnosing the causes of discoloration; (2) making recommendations of how to perform teeth whitening; (3) customizing treatment; (4) utilizing instruments and apparatus such as enhancing lights; (5) selecting or advising individuals on the use of trays; (6) preparing or making customized trays for individuals; (7) applying teeth whitening products to the teeth of a customer; (8) instructing a customer on teeth whitening procedures or methods; or, (9) other activities as discussed in [the] declaratory ruling.

Sherman Decl. Ex. 1, at 6.

77. At the time the Dental Commission issued its declaratory ruling, two of the public seats on the Commission were vacant. Sherman Decl. Ex. 1, at 1 (listing Barbara Ulrich as the only sitting public member).

78. The Commission has subsequently clarified that it is not the practice of dentistry for an individual to:

- “merely sell a self-administered teeth-whitening product for use at the place of purchase”;
- “[p]rovid[e] a client with the instructions that are provided by the manufacturer of the product”;
- “provide the purchaser of a self-administered teeth-whitening product with a place to use and dispose of the product”; or

- “use a shade guide to demonstrate to a customer the shade of their teeth either before or after the use of a teeth-whitening product.”

Sherman Decl. Ex. 4, at 2-3 (Reqs. 8-11).

79. Defendants have stated that it is not the practice of dentistry to make an LED enhancing light available for use by a teeth-whitening customer, but that it *is* the practice of dentistry to position that light for the customer. Sherman Decl. Ex. 3, at 30:13-22, 31:7-10; Ex. 4, at 3 (Req. 13).

80. The Commission has also stated that it is the practice of dentistry to “provid[e] personalized instruction to a consumer and instruct[] a person based on an assessment or supervis[e] the use and application of tooth bleaching or lightening fluids or other agents to that person’s teeth to improve or change the color of the teeth.” Sherman Decl. Ex. 4, at 2 (Req. 9).

81. Neither the Department of Public Health nor the Connecticut Dental Commission requires aspiring dentists to demonstrate any experience with or proficiency in teeth whitening. Sherman Decl. Ex. 5, at 2-3 (Reqs. 20, 22); Ex. 6, at 2-3 (Reqs. 25-30); Ex. 7, at 1.

82. Defendants do not require that applicants for dental licensure demonstrate that they studied teeth whitening in dental school. Nor is teeth whitening covered on any of the tests required for licensure as a dentist in Connecticut. Sherman Decl. Ex. 5, at 2-3 (Reqs. 20, 22); Ex. 6, at 2-3 (Reqs. 25-30); Ex. 7, at 1; Ex. 8, at 19-21; Ex. 9, at 21-25; Ex. 10, at 32-113; Ex. 11, at 5-86; Ex. 12, at 2-5; Ex. 13, at 2-3, 22-112.

83. Defendants do not write any of the tests accepted for licensure as a dentist in Connecticut and instead rely on tests designed by outside testing groups. Defendants have stated that they do not know whether those tests cover teeth whitening. Sherman Decl. Ex. 6, at 2-3 (Reqs. 25-30).

84. The Dental Commission’s website, directs aspiring dentists to the websites of the various testing agencies, all of which provide guides describing the content of their examinations.

Sherman Decl. Ex. 7, at 1; Ex. 8, at 19-21; Ex. 9, at 21-25; Ex. 10, at 32-113; Ex. 11, at 5-86; Ex. 12, at 2-5; Ex. 13, at 2-3, 22-112.

85. None of those exam-preparation guides indicate that teeth whitening is covered on any exam required for licensure as a dentist in Connecticut. Sherman Decl. Ex. 8, at 19-21; Ex. 9, at 21-25; Ex. 10, at 32-113; Ex. 11, at 5-86; Ex. 12, at 2-5; Ex. 13, at 2-3, 22-112.

Harm to Smile Bright and Consumers

86. In 2009, Smile Bright was a thriving small business. It had locations in two shopping malls and one salon. It had been featured repeatedly on local television news. And it was not only looking at renewing leases for its two shopping mall locations, it had begun negotiations to open in a third mall. Barraco Decl. ¶¶ 23-24.

87. Then its owners heard that the Dental Commission was considering issuing a declaratory ruling on teeth whitening. Mr. Barracco and Mr. Kariofyllis had seen the results of similar efforts in other states, and were unwilling to renew their leases at their existing mall locations or enter into new leases at additional malls if, as seemed likely, the Dental Commission was going to criminalize their method of doing business. Barraco Decl. ¶ 25.

88. Anticipating the outcome of the Dental Commission's declaratory ruling, Smile Bright wound up their operations at the West Farms and Enfield Square shopping malls. They released the four employees who were working for them and began limiting their services to a salon. Up to that point, Smile Bright had served hundreds of customers at their mall locations, averaging approximately 125-150 customers per week. Not one of these customers was ever injured by Smile Bright's services. Barraco Decl. ¶¶ 26-27.

89. Smile Bright kept open their salon location in the hopes that this would still be permitted following the declaratory ruling. Barraco Decl. ¶ 28.

90. Following the declaratory ruling the Connecticut Department of Public Health prepared a letter—dated July 11, 2011—instructing Stephen Barraco, co-owner of Smile Bright, to “voluntarily cease the practice of offering teeth whitening services” and threatening legal action if he did not. The letter cited as authority the Dental Commission’s declaratory ruling. Sherman Decl. Ex. 2.

91. The Department of Public Health sent the letter because it believed Mr. Barraco was positioning the LED enhancing light for his customers, and was concerned that he may have been making a determination about the health of his customers’ teeth. Sherman Decl. Ex. 3 at 30:13-31:10.

92. Mr. Barraco and his employees were positioning the LED enhancing light for their customers, but they were not making determinations about the health of their customers’ teeth. Barraco Decl. ¶¶ 8, 12, 18.

93. The cease-and-desist letter did not specify which component of Plaintiff’s business constituted the practice of dentistry, but merely restated the language of the declaratory ruling. Sherman Decl. Ex. 2.

94. Neither Mr. Barraco nor Mr. Kariofyllis is licensed as a dentist and neither is currently eligible to become licensed. Additionally, Smile Bright is not licensed as a professional-services corporation as required under Chapter 594a of the Connecticut Statutes for corporations that offer services that constitute the practice of dentistry, and is not eligible to become licensed as a professional-services corporation. Barraco Decl. ¶ 3.

95. Mr. Barraco and Mr. Kariofyllis feared civil or even criminal penalties because the declaratory ruling named several things that Plaintiff did as now the practice of dentistry, including “making recommendations of how to perform teeth whitening,” “utilizing instruments and apparatus such as enhancing lights,” “advising individuals on the use of trays,” and

“instructing a customer on teeth whitening procedures or methods,” all of which they reasonably believe describe their business model. Barraco Decl. ¶¶ 29-30.

96. Neither Mr. Barraco nor Mr. Kariofyllis has any intention of becoming licensed as a dentist. Among other reasons, doing so would be prohibitively time-consuming and would cost tens of thousands of dollars. Barraco Decl. ¶ 32.

97. Following the declaratory ruling, Smile Bright stopped offering teeth-whitening services entirely because Mr. Barraco and Mr. Kariofyllis did not want to risk fines or jail time. Smile Bright’s business is currently limited to selling teeth-whitening products for home use over the Internet—the same products they used to sell in their mall and salon locations. Barraco Decl. ¶¶ 30-31.

98. If it were lawful to do so, Smile Bright would immediately resume offering teeth-whitening services and begin searching out retail space in shopping malls for new locations. Barraco Decl. ¶ 32.

99. Dentists routinely charge more for teeth-whitening services than do businesses like Smile Bright. Sherman Decl. Ex. 5, at 5; Barraco Decl. 33

100. Five of the six dentists on the Dental Commission offer teeth-whitening services. The amount charged by each for these services is:

- Jeanne Strathearn—Zoom Treatment \$300. Zoom Treatment with additional trays \$350. Whitening trays with a set of tubes is \$200. Refill tubes are \$75.
- Peter Katz—Zoom in office whitening procedure with take home custom trays \$625 and take home bleaching kit with custom made trays \$325.
- Lance Banwell—Generally approximately \$200.
- Elliot Berman—Between approximately \$300-\$400.
- Steven Reiss—Between approximately \$75 and \$600.

Sherman Decl. Ex. 5, at 5 (Interrogatory No. 7).

101. Smile Bright, by contrast, charged between \$75 and \$100, depending on what specials they were offering. Barraco Decl. 33.

102. Complaints against non-dentists for offering teeth-whitening services came almost exclusively from dentists and the Connecticut State Dental Association. Sherman Decl. Ex. 3, at 26:8-28:1.

INSTITUTE FOR JUSTICE

/s/ Paul M. Sherman

William H. Mellor (DC Bar No. 462072)*

Dana Berliner (DC Bar No. 447686)*

Paul M. Sherman (DC Bar No. 978663)*

901 North Glebe Road, Suite 900

Arlington, VA 22203-1854

Tel: (703) 682-9320

Fax: (703) 682-9321

Email: wmellor@ij.org, psherman@ij.org,

dberliner@ij.org

Attorneys for Plaintiffs

**Admitted Pro Hac Vice*

SAWYER LAW FIRM, LLC

Scott W. Sawyer (CT Bar No. CT18441)

The Jill S. Sawyer Building

251 Williams Street

New London, CT 06320

Tel: (860) 442-8131

Fax: (860) 442-4131

Email: sawyerlawyer@ct.metrocast.net

Local Counsel for Plaintiffs

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on April 8, 2013, a true and correct copy of the foregoing
LOCAL RULE 56(a)(1) STATEMENT OF UNDISPUTED FACTS was sent via the Court's
CM/ECF to the following counsel of record:

GEORGE JEPSON
ATTORNEY GENERAL
Daniel Shapiro
Assistant Attorney General
Federal Bar No. ct20128
55 Elm Street
P.O. Box 120
Hartford, CT 06141-0120
Tel: (860) 808-5210
Fax: (860) 808-5385
Email: daniel.shapiro@ct.gov
Attorneys for Defendants

/s/ Paul M. Sherman
Paul M. Sherman
Attorney for Plaintiffs