UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

Civil Action No.: 1:20-cv-08390-RA

| | |
|---|---|
| BOJA KRAGULJ,<br>Plaintiff,<br>v.<br><br>MARTHA CORTES, D.D.S, STEVE GALELLA, D.D.S., ORTHOMATRIX CORP., INC., FACIAL BEAUTY INSTITUTE<br><br>and<br><br>JOHN'S DENTAL LABORATORY, INC.<br><br>Defendants. | **THIRD AMENDED COMPLAINT** |

Plaintiff Boja Kragulj ("plaintiff"), by counsel, for her Third Amended Complaint, states as follows:

**Jurisdiction**

1. The amount in controversy in regard to the claim that is the basis of this Third Amended Complaint is in excess of $75,000.00, exclusive of interest and costs.

2. This action is brought pursuant to 28 U.S.C. §1332(a)(1), so-called diversity of citizenship jurisdiction.

**Venue**

3. Venue is proper in the Southern District of New York pursuant to 28 U.S.C. §1391(b)(2), as that is where a substantial part of the events or omissions giving rise to the claim occurred.

**Nature of the Action**

4. This is an action for money damages for personal injury suffered by plaintiff Boja Kragulj as the result of the installation of a dental appliance and the failure to timely remove it. The claims are in the nature of dental malpractice (negligence), lack of informed consent, product liability (negligence, failure to warn, breach of warranty, strict liability) and consumer protection (NY

General Business Law §349). The appliance, known as an "Anterior Growth Guidance Appliance" ("AGGA") was manufactured, designed, and marketed as a means of correcting dental, facial and airway abnormalities in lieu of complex jaw surgery. The product designer, and an organization that promoted AGGA, taught dentists how it allegedly functioned and prepared AGGA treatment plans for dentists, and claimed that AGGA causes can cause three-dimensional changes in the nasomaxillary complex including causing the maxilla to move forward over time while causing new bone to grow, and that it was a reasonable alternative to jaw surgery. Plaintiff alleges that these claims, in regard to adults, are false, and are contrary to medical science; that instead AGGA works in adults, *inter alia*, to push the upper teeth out of their housing in the alveolar bone, that it causes no new bone growth or dimensional changes in the nasomaxillary complex of adults (whose nasomaxillary complex, unlike children, have stopped growing naturally), that it is not a reasonable alternative to jaw surgery for adults, and that it presents a risk of serious and permanent harm for adults. As a result of the fact that, for adults, AGGA as designed and manufactured was not reasonably safe and was unreasonably dangerous; of the promotion and teaching of AGGA involving false representations to dentists including plaintiff's dentist; of the creation of a treatment plan for plaintiff utilizing a product whose risk to adults is substantially outweighed by its utility, of the failure to warn plaintiff and/or her dentist about the actual utility and risks to adults of AGGA, and of the installation of AGGA in plaintiff and failure to timely remove it when damage should have become apparent to a dental professional, plaintiff has sustained significant and permanent damage to her teeth and face, economic loss, disfigurement, embarrassment, loss of enjoyment of life, and physical and mental pain and suffering, among other injury and damages.

## The Parties

5. Plaintiff Boja Kragulj is an individual residing at 4186 Highwood Drive, Jacksonville, FL

32216, and is a citizen of the State of Florida.

6. Defendant Martha Cortes, D.D.S. ("defendant Cortes") is an individual residing at 33 Greenwich Avenue, Apt. 10C, New York, New York 10014, and is a citizen of the State of New York.

7. Defendant Steve Galella, D.D.S. ("defendant Galella) is an individual residing at 997 Eastwood Terrace, Collierville, Tennessee 38017, and is a citizen of the State of Tennessee.

8. Defendant OrthoMatrix Corp., Inc. ("defendant OrthoMatrix") is a foreign corporation organized under the laws of the State of Tennessee, with a principal place of business at 875 West Poplar Avenue, Suite 16, Collierville, Tennessee 38017, and is a citizen of the State of Tennessee.

9. Defendant Facial Beauty Institute ("defendant FBI") is an entity that, on information and belief, is a wholly owned division and/or tradename of defendant OrthoMatrix, is not formally organized as a corporation or other legal entity separate from said defendant OrthoMatrix, has a principal place of business at 875 West Poplar Ave., Suite 16, Collierville, TN 38017, and is not a citizen of the State of Florida.

10. Defendant John's Dental Laboratories, Inc. ("defendant John's Dental") is a foreign corporation organized under the laws of the State of Indiana, with a principal place of business at 423 South 13th Street, Terre Haute, Indiana 47808.

**Facts Alleged**

11. Plaintiff, at all times relevant to the Third Amended Complaint, is an adult and is a talented professional clarinetist with a doctorate in clarinet performance who has played with the Philadelphia Orchestra, the Orpheus Chamber Orchestra, and other orchestras and ensembles.

12. As a child, in order to correct a poor bite relationship between her upper and lower teeth, plaintiff underwent a number of dental procedures/orthodontic techniques including use of an orthodontic expander, braces, and removal of four bicuspid teeth.

13. After the aforementioned procedures/techniques, plaintiff developed breathing and posture issues for which she has sought solutions ever since.

14. At some point in her early 20's, plaintiff underwent a surgical procedure known as

distraction osteogenesis, which procedure was designed to improve her still-existent poor bite relationship between her upper and lower teeth by expanding her upper jaw, as well as improve her breathing/airway issues.

15. The distraction osteogenesis did little to alleviate her condition or symptoms, and plaintiff then underwent another course of orthodontics as well as the removal of her lower lateral incisor tooth.

16. Prior to 2013, plaintiff came under the care of Dr. Ira Shapira, a dentist who gave her a custom orthotic to wear. This device caused her mandible to come downward and forward, while making her jaw muscles relax and her jaw feel better. However, her airway/breathing difficulties were not improved, and her teeth were in an increased position of malocclusion.

17. Prior to May 2013, plaintiff consulted with an eminent oral surgeon, Dr. Michael Gunson, who recommended maxilla-mandibular advancement surgery, sometimes called "double jaw surgery", in which the bones of the upper and lower jaw are repositioned forward to increase the size of the airway, and, in combination with additional orthodontic work, would realign her teeth.

18. Before embarking on Dr. Gunson's prescribed surgical/orthodontic course, and in an effort to avoid surgery, plaintiff consulted with defendant Cortes on May 22, 2013 on referral from Dr. Shapira.

19. In May of 2013, Defendant Cortes, a general dentist duly licensed by the State of New York, with an office at 120 Central Park South, New York, New York, claimed on the website of her office, Cortes Advanced Dentistry, to have expertise in general dentistry as well as in the fields of "holistic dentistry", "aesthetic dentistry", "laser dentistry", "neuromuscular dentistry", "periodontal dentistry, "porcelain dentistry", "cerec restorations", "laser and high-tech equipment", "DNA appliance", "sleep apnea" and TMD treatment". Her website touted her credential, among others, as Fellow and Master of the International College of Cranio-Mandibular Orthopedics.

20. At all times relevant to the case, defendant Cortes and plaintiff were in a dentist-patient relationship, and said defendant provided dental care and treatment to plaintiff.

21. Dr. Cortes informed plaintiff that she could produce an equivalent result to the surgical

intervention by utilization of a dental appliance known as the "Daytime Nighttime Appliance", or "DNA". Based on defendant Cortes' representations as to the expected efficacy of DNA, plaintiff was fitted with a DNA appliance. After wearing that appliance for more than four years, there was no appreciable improvement in her condition or symptoms. The DNA was removed, and Dr. Cortes then inserted an "Advanced Lightwire Functional" or "ALF" device in her mouth to hold her teeth in place.

22. In January 2018, in a further attempt to successfully treat plaintiff, Dr. Cortes prescribed a device known as an "Anterior Growth Guided Appliance", or "AGGA" and, later, "Controlled Arch Braces" ("CAB").

23. At all times relevant to the case, defendant Galella was a general dentist duly licensed by the State of Tennessee and a diplomate of an organization called the International Board of Orthodontics.

24. Prior to January 2018, defendant Galella designed the dental appliances AGGA and CAB.

25. Prior to January 2018, defendant Galella founded defendant FBI, and at all times relevant to the Third Amended Complaint defendant Galella and defendant FBI shared office space in Tennessee, along with defendant OrthoMatrix.

26. Prior to January 28, 2018, defendant FBI became an unincorporated division and/or trade name of defendant OrthoMatrix.

27. At all times relevant to the case, the actions and omissions of defendant FBI referenced in this Third Amended Complaint are equivalent to acts and omissions of defendant OrthoMatrix, as said defendant is a division and/or trade name of defendant OrthoMatrix.

28. At all times relevant to the Third Amended Complaint, defendant FBI and therefore defendant OrthoMatrix, and defendant Galella, offered and taught courses to dentists on the use and alleged safety and efficacy of AGGA and CAB, with the expectation that said dentists, including New York dentists, would in turn promote AGGA and CAB to consumers including New York consumers, as a safe and efficacious alternative treatment to jaw surgery for patients,

including children and adults, and would install AGGA and CAB on consumers including adult New York consumers.

29. At all times relevant to the Third Amended Complaint, defendant FBI and therefore defendant OrthoMatrix claimed to be, *inter alia*, a research organization conducting research in various fields including biological mechanisms that cause craniofacial growth in adults.

30. At all times relevant to the case, and while performing any acts or making any omissions referenced in this Third Amended Complaint, defendant Galella was employed by and working in furtherance of the business of, and/or acted as agent of, defendant FBI and, therefore of defendant OrthoMatrix.

31. Prior to January 28, 2018, defendant Galella, defendant FBI and therefore defendant OrthoMatrix made certain representations ("the representations") to dentists throughout the world, including to dentists who practiced in New York State, that:

a. AGGA is a device that mechanically causes three-dimensional changes in the nasomaxillary complex over time, including causing the maxilla to move forward, for patients including adults;

b. by touching and thereby stimulating a nerve in the upper palate, AGGA causes new bone to grow at the maxillary tuberosity (the most distal aspect of the upper jaw) and other places, which in turn causes the maxilla to move forward, effectively lengthening the upper jaw, including in adults ;

c. as the maxilla moves forward, upper teeth move with it, including in adults;

d. by adhering bite plates to the lower molars, the lower jaw moves forward as the upper jaw moves forward, including in adults;

e. the movement of the jaws has the effect of opening the airway, and moving the jaws into a position more natural for the user's face, including in adults;

f. AGGA is reasonably safe for installation into dental patients' mouths, including in adults;

g. AGGA can be utilized as a substitute for jaw surgery, including in adults.

32. Prior to January 28, 2018, defendant Galella, defendant FBI and therefore defendant OrthoMatrix, made additional representations to dentists throughout the world, including to dentists who practiced in New York State, that, once AGGA causes the desired maxilla and mandible position to be obtained, and AGGA was then removed, CAB could be used to make relatively minor adjustments in order to guide all teeth to their proper positions, as well as to widen the dental arches, including in adults.

33. The representations, made prior to January 28, 2018 by defendant Galella, defendant FBI and therefore defendant OrthoMatrix, were made for the purpose of, *inter alia*, causing dentists to promote AGGA and CAB to consumers, including adult consumers in New York State, as being a safe and efficacious alternative for them to jaw surgery.

34. Representations concerning AGGA as being safe and efficacious for adults were also made by defendant Galella directly to plaintiff.

35. Neither AGGA nor CAB have ever been submitted to the Federal Drug Administration, or any other government agency, for approval, and they have never been approved by any governmental agency for use in the United States.

36. At all times relevant to the Third Amended Complaint, defendant Galella, defendant FBI and therefore defendant OrthoMatrix, knew or should have known that, while the representations may have been true in regard to use of AGGA by children (who are still growing naturally), the representations as to adults were unproven, not supported by medical knowledge or science, and were false and materially misleading, and that:

a. in adults, AGGA cannot mechanically or in any other way cause three-dimensional changes in the nasomaxillary complex over time, including causing the maxilla to move forward;

b. AGGA cannot mechanically or in any other way cause the maxilla to move forward in an adult;

c. AGGA does not stimulate new bone growth at the maxillary tuberosity, or anywhere else, in an adult;

d. AGGA does not move or grow the maxilla in an adult; instead, *inter alia*, it pushes certain of the upper teeth in an adult forward over time within the alveolar bone which is attached to the maxilla;

e. AGGA pushes the upper anterior teeth forward in an adult, and when those teeth are pushed past a certain limited point in the course of a futile attempt to make dimensional changes in the nasomaxillary complex, they move beyond a safe position within the alveolar bone, causing the teeth to flare out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth.

f. AGGA does not open an adult user's airway;

g. Any utility of AGGA in moving teeth through bone is far outweighed by the risks it presents to adults as aforesaid, and such utility can be accomplished with other dental appliances of different design that pose significantly less risk;

h. AGGA is not reasonably safe and is unreasonably dangerous, when used in adult patients in an attempt to make dimensional changes in the nasomaxillary complex of adult patients; and,

i. AGGA is not a substitute for jaw surgery performed on an adult.

37. Prior to January 28, 2018, in a particular course taught by defendant Galella, defendant FBI and therefore by defendant OrthoMatrix ("the course"), these defendants made the representations concerning AGGA to defendant Cortes, a New York State dentist, and to other dental professionals, including for the purpose of their informing consumers including New York State consumers as to the alleged safety and efficacy of AGGA as an alternative to jaw surgery for adults.

38. On information and belief, the course, which lasted approximately 2.5 days, largely or completely comprised the extent of defendant Cortes' training concerning AGGA and CAB.

39. At no time did defendant Galella, defendant FBI nor therefore defendant OrthoMatrix, ever warn defendant Cortes or plaintiff that AGGA was unproven for use on adults for the purpose of making three-dimensional changes in the nasomaxillary complex including advancement of the maxilla, that such claims for use on adults were not supported by scientific or medical

knowledge, and that AGGA was not reasonably safe and was unreasonably dangerous for use on adults, was not efficacious for adults in making dimensional changes in the nasomaxillary complex, that the risk to adults is substantially outweighed by its utility and it presented a risk of serious and permanent injury to adult consumers when used in an attempt to make dimensional changes in the nasomaxillary complex.

40. Prior to January 28, 2018, defendant Galella approved the use of an AGGA device for plaintiff, whom he knew or should have known was an adult, and had a doliocephalic skeletal pattern.

41. Prior to January 28, 2018, defendant Cortes, defendant Galella, defendant FBI and therefore defendant OrthoMatrix knew or should have known that plaintiff was an adult and had a doliocephalic skeletal pattern, and they also knew or should have known that the consequent thin bone support to her teeth made it particularly likely that AGGA would push the upper teeth roots outside of the supporting bone.

42. At all times relevant to the Third Amended Complaint, plaintiff and defendant Galella were in a dentist-patient relationship.

43. Prior to January 28, 2018, defendant Cortes, on information and belief in reliance on advice, guidance, instruction and the representations provided by defendant Galella, defendant FBI and therefore defendant OrthoMatrix, provided information and/or specifications to defendant John's Dental concerning plaintiff and did place an order for an AGGA appliance to be manufactured by defendant John's Dental for the specific use of plaintiff in order to make dimensional changes in her nasomaxillary complex.

44. At all times relevant to the Third Amended Complaint, defendant John's Dental was in the business of, *inter alia*, manufacturing, selling and putting into the stream of commerce, dental appliances including but not limited to AGGA and CAB, and were bound to anticipate and they are charged with the knowledge that their products would be, through dental professionals,

presented to the general public for their use, including by consumers within the State of New York.

45. Prior to January 28, 2018, defendant John's Dental did manufacture an AGGA appliance for use by defendant Cortes for installation in plaintiff's mouth, did place it in the stream of commerce and did sell that appliance to defendant Cortes, who was then within the State of New York, and said defendant John's Dental knew at the time it was placed into the stream of commerce that it would be installed in an adult member of the public, and specifically that defendant Cortes would install it in plaintiff.

46. At the time of sale of the AGGA to defendant Cortes as aforesaid, defendant John's Dental impliedly warranted and represented that the AGGA was fit, capable and suitable for the ordinary purposes for which it was intended, that it was fit for the specific purpose for which it was sold to defendant Cortes, that it had no design defects, that it was of merchantable quality, and that it was safe and not unreasonably dangerous.

47. Plaintiff reasonably relied upon the aforementioned implied warranties of defendant John's Dental, as well as on its skill and judgment.

48. At the time of sale of the AGGA to defendant Cortes as aforementioned, the AGGA was inherently defective by virtue of its design, was not fit for its intended purpose nor for the specific purpose for which it was sold for installation in plaintiff's mouth, it was not of merchantable quality, was not reasonably safe, was unreasonably dangerous and defective, all at the time it left the possession, custody and control of defendant John's Dental, for reasons that include but are not limited to:

a. AGGA as designed, manufactured and sold was not based on valid scientific principles in regard to adults, does not stimulate new bone growth in adults, does not make three-dimensional

changes in the adult nasomaxillary complex including that it does not move or grow the maxilla, does not open an adult user's airway, and is in no way a substitute for jaw surgery in an adult;

b. AGGA is unreasonably dangerous in that, rather than move or grow the maxilla or make any three-dimensional changes in the adult nasomaxillary complex, it pushes the upper anterior teeth forward and, after moving more than a limited amount, out of their safe position within the alveolar bone, causing the teeth to flare out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth; and,

c. While AGGA may have additional utility for children, the utility of AGGA in an adult is in its moving teeth a limited amount within the bone (a function that can be performed by other, standard orthodontic appliances), which utility is far outweighed by the risks AGGA creates; and,

d. defendant John's Dental failed to warn defendant Cortes or anyone else:

(i) of the limitations of AGGA's utility for adults in that it would move teeth through bone, but could not make three-dimensional changes in the adult nasomaxillary complex including that it cannot move or grow the maxilla, cannot open an adult user's airway, and is in no way a substitute for jaw surgery in an adult;

(ii) that AGGA should not be used for the purpose of attempting to make dimensional changes in the adult nasomaxillary complex including attempting to move the maxilla;

(iii) that using AGGA for the purpose of attempting to make dimensional changes in the adult nasomaxillary complex including attempting to move or grow the maxilla, could result in serious injury including causing teeth to flare out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth;

(iv) that claims made about AGGA making three-dimensional changes in the nasomaxillary complex of adults were contrary to medical science and unproven; and,

(v) if AGGA were used in an adult, the patient should be closely monitored to ensure it was not causing gum recession, root resorption or other injury indicative of excessive movement of teeth through bone.

49. At the time that defendant John's Dental manufactured, placed into the stream of commerce and sold to defendant Cortes the AGGA appliance for use on plaintiff as aforesaid, that appliance was not reasonably safe for use on adults, was not minimally safe for its expected purpose, and was dangerous to the extent beyond which would be contemplated by the ordinary dentist or consumer who purchases or uses it, with the ordinary knowledge common to such dentists or users.

50. At all times relevant to the Third Amended Complaint, had plaintiff or defendant Cortes been warned of the defects and deficiencies of AGGA as described above, she would not have embarked on any course of treatment using AGGA.

51. At all times relevant to the Third Amended Complaint, had defendant Cortes been warned by any of her co-defendants of the defects and deficiencies of AGGA as described above, she would not, on information and belief, have embarked on any course of treatment of plaintiff using AGGA.

52. At all times relevant to the Third Amended Complaint, plaintiff would not by exercise of ordinary and reasonable care have discovered the defects and deficiencies of AGGA as described above nor perceived its danger.

53. On January 28, 2018, defendant Cortes did install the AGGA appliance sold to her as aforesaid, in plaintiff's mouth.

54. At some point prior to January 28, 2018, defendant Cortes knew or should have known

through her education, training and experience as a dentist that the representations referenced in Paragraph 31 above, as pertaining to adults, did not comport with the known histology/physiology of tooth movement and the nasomaxillary complex.

55. Prior to the installation of the AGGA in plaintiff, and at no time, did defendant Cortes provide plaintiff information either orally or in writing about the risks of AGGA treatment for adults, including the limitations of AGGA's utility for adults in that it would move teeth through bone, but could not make three-dimensional changes in the adult nasomaxillary complex including that it cannot move or grow the maxilla, cannot open an adult user's airway, and is in no way a substitute for jaw surgery in an adult; that AGGA should not be used for the purpose of attempting to make dimensional changes in the adult nasomaxillary complex including attempting to move or grow the maxilla, and that using AGGA for the purpose of attempting to make dimensional changes in the adult nasomaxillary complex including attempting to move or grow the maxilla, could result in serious injury including causing teeth to flare out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth; that AGGA was unproven in regard to making dimensional changes in an adult nasomaxillary complex and such claim was contrary to science and medicine; nor did defendant Cortes inform plaintiff as to risks specific to plaintiff, including that her doliocephalic skeletal pattern was a contraindication for use of AGGA.

56. Plaintiff continued to be a patient of and treated by defendant Cortes through at least February 2020.

57. Through at least May 2020, plaintiff continued to be a patient of defendant Galella, and said defendant continued consulting with defendant Cortes concerning her care and treatment of plaintiff with AGGA and then with CAB, including but not limited to an examination of plaintiff in defendant Galella's Tennessee office in March 2020.

58. At some point after January 28, 2018, defendant Cortes knew or should have known that

plaintiff was exhibiting gingival, or gum, recession, and that where such recession was occurring was a direct indication that the teeth at those locations were moving through the alveolar bone housing, and not moving with the bone.

59. Had defendant Cortes removed the AGGA appliance when she first knew or should have known of the gingival recession as aforesaid, any further damage to plaintiff caused by the device would have been prevented and any damage that had occurred by that point would have more probably than not been reversible.

60. On information and belief, defendant Cortes kept defendant Galella regularly apprised of plaintiff's condition throughout her AGGA treatment, that defendant Galella knew or should have known that the AGGA appliance was causing plaintiff's teeth to move out of the alveolar bone rather than her teeth moving with the maxilla as aforesaid, and that the AGGA should be removed before it did permanent damage to plaintiff, yet defendant Galella failed to recommend the removal of AGGA.

61. Had defendant Galella instructed defendant Cortes to remove the AGGA appliance when he first knew or should have known of the gingival recession as aforesaid, any further damage to plaintiff caused by the device would have been prevented and any damage that had occurred by that point would have more probably than not been reversible.

62. Sometime before October 23, 2018, a portion of the AGGA appliance in plaintiff's mouth debonded or broke loose, a fact of which defendant Cortes was aware by at least October 23, 2018.

63. Defendant Cortes knew or should have known, at least from the time that she first installed the AGGA device in plaintiff, that debonding of the device was an unwanted and dangerous development, and that, in general, with any active orthodontic appliance, if it breaks, it needs to be properly reattached to prevent uncontrolled tooth movement.

64. Instead of fixing the loosened AGGA appliance in a timely manner, defendant Cortes waited

for approximately another month before removing the AGGA device.

65. In November 2018, due to debonding of the appliance, the AGGA appliance was removed by defendant Cortes.

66. By October 2018, defendant Cortes and defendant Galella knew or should have known that AGGA was causing tooth flaring, tipping, root dehiscence, gum recession and tissue blanching – all signs that there was alveolar bone damage and loss occurring, and that the AGGA should be immediately removed.

67. Unfortunately, despite the signs referenced in Paragraph 58 and Paragraph 66, as well as the fact that the AGGA device had already been worn for more than 10 months, defendant Cortes, after consulting in October 2018 with defendant Galella in regard to further treatment for plaintiff, decided to install a second AGGA appliance in plaintiff on or about November 27, 2018.

68. Prior to January 28, 2018, defendant OrthoMatrix, through its unincorporated division or trade name defendant FBI and/or through another unincorporated division or tradename of defendant OrthoMatrix called OrthoLogic, maintained a program that purported to analyze patients' dental/cranio maxillofacial condition using "radiologists" and "experts" to determine whether said patients were appropriate candidates for AGGA/CAB treatment, and prepare AGGA and CAB treatment plans for such patients with comprehensive instructions that were alleged to be specific and customized for each patient ("the program").

69. In October or November 2018, for the first time in regard to plaintiff, defendant Cortes submitted a questionnaire and dental records to the program, and thereafter and as a result, in November 2018, defendant Galella, defendant FBI and (through FBI's participation and/or that of another division or trade name of OrthoMatrix called OrthoLogic) defendant OrthoMatrix, represented to defendant Cortes and to plaintiff that AGGA and CAB were appropriate treatments for plaintiff, and said defendants FBI, Galella and OrthoMatrix produced an AGGA/CAB treatment plan for plaintiff ("the treatment plan").

70. The treatment plan was unsigned, and was provided on plain white paper with no letterhead or other identifying marking.

71. The treatment plan, prepared in November 2018, as provided to defendant Cortes included a warning to the effect that AGGA treatment goals were usually met in four months for adults, that flaring of the teeth should not occur, that there was a risk of unwanted debonding of the appliance, and that gingival recession, root resorption, bone loss and the possibility of flaring were all risks of the use of AGGA ("the limited warnings"), none of which limited warnings were ever passed on to plaintiff by defendant Cortes or anyone else at any time relevant to the Third Amended Complaint.

72. Prior to November 27, 2018, defendant Cortes, on information and belief in reliance on advice, guidance, instructions and the representations provided by defendant Galella, defendant FBI and therefore defendant OrthoMatrix, provided information and/or specifications to defendant John's Dental concerning plaintiff, and placed an order for a second AGGA appliance to be manufactured by defendant John's Dental for the specific use of plaintiff.

73. Prior to November 27, 2018, the aforementioned second AGGA appliance was manufactured, placed into the stream of commerce and sold to defendant Cortes, by defendant John's Dental, based on specifications provided to it by defendant Cortes, defendant Galella, defendant FBI and therefore defendant OrthoMatrix.

74. On information and belief, the first AGGA appliance installed in plaintiff was identical to the second AGGA appliance installed in her, including in its defects and deficiencies as set forth in Paragraph 48.

75. On or about March 18, 2019, defendant Cortes finally removed the second AGGA device from plaintiff.

76. By August 19, 2019, and as demonstrated by a Cone Beam CT ordered and paid for by plaintiff and viewed on or around that date by defendant Cortes, it was apparent that plaintiff had sustained irreversible upper alveolar bone loss.

77. Subsequent to the removal of the second AGGA appliance, defendant Cortes installed CAB in plaintiff, which CAB was eventually removed by another dental professional.

78. At no time did defendant Cortes or defendant Galella warn plaintiff about the risks presented by failing to remove either AGGA or CAB in light of physical findings presented by plaintiff as aforesaid.

79. At all times relevant to the Third Amended Complaint, defendant Galella, defendant FBI and therefore defendant OrthoMatrix, engaged in consumer-related conduct that was materially misleading in that: 1) each of them made material misrepresentations to dentists through the course and other courses, and through website marketing to both dentists and consumers, to the effect that AGGA was safe and efficacious and was a reasonable and functionally effective alternative to jaw surgery that would create three-dimensional changes in the nasomaxillary complex including movement of the human maxilla, in adults; 2) such material misrepresentations were made with the knowledge and expectation that those dentists would advertise and otherwise offer AGGA as a safe and efficacious treatment alternative to consumers, including but not limited to consumers in the State of New York including plaintiff; and, 3) such material misrepresentations were made with the knowledge and expectation that members of the general public would ask dentists for AGGA and/or otherwise accept AGGA as a safe and efficacious treatment alternative to jaw surgery, and were made to consumers, including but not limited to adult consumers in the State of New York including plaintiff.

80. As a result of the installation and use of the AGGA appliances as aforesaid, plaintiff has been caused to suffer significant and permanent injury and damage, including but not limited to: degradation and loss of alveolar bone; gum recession; exposure of tooth roots; pain; future loss of at least 4 to 6 upper anterior teeth, future need for bone grafts to support 4 to 6 anterior dental implants and two posterior implants for the space created by the AGGA's; embarrassment; disfigurement; substantial emotional distress; interference with her advancement as a professional clarinetist; and economic loss related to the cost of said worthless and harmful AGGA treatment and loss of income.

81. The aforementioned resulting injury and damage to plaintiff also includes: plaintiff's surgical treatment options to address her condition that caused her to originally treat with defendant Cortes are now limited due to changes in the bite and loss of bone support; she is likely to lose vertical dimension (distance between her nose and chin) over time; there is now compromised lip support which, in conjunction with the likely loss of vertical distance, will prematurely age her face over time; and she has suffered economic loss related to the cost of attempting to correct, to the extent it can be corrected, the damage to teeth and supporting structures; among other damages.

82. Plaintiff at all times relevant to the Third Amended Complaint acted reasonably, and nothing she reasonably did or failed to do caused or contributed to cause her aforementioned injuries.

**COUNT I (Dental malpractice/negligence against defendant Cortes)**

83. Plaintiff reaffirms and realleges Paragraphs 1 through 82 above as if specifically affirmed and alleged herein.

84. During the times hereinbefore mentioned, defendant Cortes failed to follow and did violate the standards of care for a dentist and was negligent in that, *inter alia* she: a) failed to timely remove the first AGGA appliance from plaintiff's mouth when she knew or should have known that the appliance was damaging plaintiff; b) allowed the first AGGA appliance installed in plaintiff's mouth to remain there in a debonded state for an unreasonably long period of time; c) failed to timely remove the first AGGA appliance from plaintiff's mouth when she knew or should have known that the appliance remained substantially longer than anticipated by the designer/seller of the appliance; d) installed the second AGGA appliance in plaintiff's mouth when she knew or should have known that the first AGGA appliance had caused damage to plaintiff; e) installed the second AGGA appliance in plaintiff's mouth when she knew or should have known that the first AGGA appliance had remained substantially longer than anticipated by the designer/seller of the appliance; f) failed to timely remove the second AGGA appliance when

she knew or should have known that it was damaging plaintiff; g) failed to recognize that the theory behind the use of AGGA on adults was contrary to medical science, was unproven and was false; h) failed to recognize that plaintiff, with her doliocephalic skeletal pattern, was not a candidate for the AGGA appliance and would likely suffer substantial damage from its use;) and, h) failed to reject AGGA as a course of treatment for plaintiff.

85. Defendant Cortes acted with reckless disregard for the safety of plaintiff.

86. As a direct and proximate result of defendant Cortes' dental malpractice, negligence and reckless disregard for the safety of plaintiff as aforesaid, plaintiff has been substantially and permanently injured and damaged as outlined above.

87. This action falls within one or more exceptions to CPLR §1602.

**WHEREFORE, PLAINTIFF BOJA KRAGULJ DEMANDS JUDGMENT IN THE AMOUNT OF TEN MILLION DOLLARS ($10,000,000.00) AGAINST DEFENDANT MARTHA CORTES, D.D.S., PLUS INTEREST AND COSTS**

**COUNT II (Lack of informed consent against defendant Cortes)**

88. Plaintiff reaffirms and realleges Paragraphs 1 through 87 above as if specifically affirmed and alleged herein.

89. Defendant Cortes performed upon plaintiff dental treatment and procedures and/or failed to perform upon plaintiff necessary dental treatment and procedures, as aforesaid, without obtaining her informed consent.

90. Defendant Cortes failed to disclose all of the facts that a reasonable dentist under the circumstances would explain to a patient, including: a) failing to disclose certain risks of using the AGGA appliance including but not limited to the risk that the device would cause her upper teeth to be pushed forward and out of the alveolar bone rather than move her maxilla forward, and thereby could cause her substantial and permanent damage; b) failing to disclose the risk of leaving a debonded AGGA component in her mouth over time, which risk included substantial and permanent damage to her teeth and supporting structures; c) failing to disclose the risk of leaving an AGGA device in plaintiff's mouth for months beyond the time anticipated by the designer/seller, which risk included substantial and permanent damage to her teeth and supporting structures; d) failing to disclose the risk of leaving the first AGGA appliance in her

mouth when there was evidence of gum recession and/or tooth flaring, and/or other signs of alveolar bone loss or damage, which risk included substantial and permanent damage to her teeth and supporting structures; e) failing to disclose the risk of leaving the AGGA appliance in her mouth, and installing a second AGGA appliance, when there was evidence of tooth flaring, tipping, root dehiscence, gum recession and tissue blanching -all signs that there was alveolar bone damage and loss occurring- which risk included substantial and permanent damage to her teeth and supporting structures; f) failing to disclose that plaintiff, with her doliocephalic skeletal pattern, was not a candidate for the AGGA appliance and would likely suffer substantial damage from its use; and, g) failing to disclose to plaintiff that the theory behind AGGA regarding its use on adults and its alleged function of making three-dimensional changes in the nasomaxillary complex including forward movement of the maxilla, was contrary to her education and training, and to medical science, and was unproven,

91. A reasonably prudent person in plaintiff's position, had she been provided timely informed consent, would not have had the AGGA appliances installed; and/or would have demanded that the AGGA appliance be removed when she first demonstrated gum recession as aforesaid, and/or when it became debonded and/or when she demonstrated flared teeth and/or when the first AGGA device was in her mouth beyond four months and/or when there was evidence of tooth flaring, tipping, root dehiscence, gum recession and/or tissue blanching.

92. As a direct and proximate result of the lack of informed consent as aforesaid, plaintiff has been substantially and permanently injured and damaged as outlined above.

93. Defendant Cortes acted with reckless disregard for the safety of plaintiff.

94. This action falls within one or more exceptions to CPLR §1602.

**WHEREFORE, PLAINTIFF BOJA KRAGULJ DEMANDS JUDGMENT IN THE AMOUNT OF TEN MILLION DOLLARS ($10,000,000.00) AGAINST DEFENDANT MARTHA CORTES, D.D.S., PLUS INTEREST AND COSTS**

**COUNT III (Dental malpractice/negligence against defendant Galella)**

95. Plaintiff reaffirms and realleges Paragraphs 1 through 94 above as if specifically affirmed and alleged herein.

96. During the times hereinbefore mentioned, defendant Galella failed to follow and did violate

the standards of care for a dentist and was negligent in that, *inter alia*, a) he advised installation of a dental appliance in plaintiff, i.e. AGGA, when: (i) he knew or should have known that the safety and efficacy of such device was unproven for use on adults, and not supported by medical knowledge or by science; (ii) he knew or should have known that the device was likely to push the anterior upper teeth out of the alveolar bone and cause substantial and potentially permanent damage to plaintiff's teeth and supporting structures; (iii) he knew or should have known that plaintiff, with her doliocephalic skeletal pattern, was not a candidate for the AGGA appliance and would likely suffer substantial damage from its use; b) he failed to advise that the AGGA be removed from plaintiff when he was informed that it had been in use far beyond the expected four-month period; c) he failed to advise the removal of the AGGA appliances as soon as he became aware that there was evidence of gum recession and/or tooth flaring and/or other signs of alveolar bone loss or damage; d) he advised installation of the second AGGA appliance as aforesaid when he knew or should have known that plaintiff had sustained significant injury as a result of the installation of the first AGGA appliance; and, e) he failed to disclose and warn defendant Cortes or plaintiff that the theory behind AGGA regarding its use on adults and its alleged function of making three-dimensional changes in the nasomaxillary complex including forward movement of the maxilla, was contrary to his education and training, and to medical science, and was unproven.

97. Defendant Galella acted with reckless disregard for the safety of plaintiff and others.

98. As a direct and proximate result of the dental malpractice, negligence and reckless disregard for the safety of plaintiff by defendant Galella as aforesaid, plaintiff has been substantially and permanently injured and damaged as outlined above.

99. This action falls within one or more exceptions to CPLR §1602.

**WHEREFORE, PLAINTIFF BOJA KRAGULJ DEMANDS JUDGMENT IN THE AMOUNT OF TEN MILLION DOLLARS ($10,000,000.00) AGAINST DEFENDANT STEVE GALELLA, D.D.S., PLUS INTEREST AND COSTS**

**COUNT IV (Product liability-Negligence against defendant Galella)**

100. Plaintiff reaffirms and realleges Paragraphs 1 through 99 above as if specifically affirmed and alleged herein.

101. Defendant Galella was negligent in that, *inter alia,* he:

a. designed and marketed the AGGA devices that were installed in plaintiff for use by adults, when he knew or should have known that the theory behind AGGA regarding its use on adults and its alleged function of making three-dimensional changes in the nasomaxillary complex including forward movement of the maxilla of adults, was contrary to his education and training, and to medical science, and was unproven, that AGGA was neither safe nor efficacious in regard to making three-dimensional changes in the nasomaxillary complex including forward movement of the maxilla of adults, had limited utility for adults, that it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by plaintiff, all as aforesaid;

b. taught the course to defendant Cortes, informing her and others that the AGGA device was safe and efficacious for use by adults, when he knew or should have known that the theory behind AGGA regarding its use on adults and its alleged function of making three-dimensional changes in the nasomaxillary complex including forward movement of the maxilla of adults, was contrary to his education and training, and to medical science, and was unproven, that AGGA was neither safe nor efficacious in regard to making three-dimensional changes in the nasomaxillary complex including forward movement of the maxilla of adults, that it had limited utility for adults, that it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by plaintiff, all as aforesaid; and,

c. failed to warn purchasers of AGGA and dentists to whom he taught the course including defendant Cortes and other similar courses, or anyone else:

(i) of the limitations of AGGA's utility for adults in that it would move teeth through bone, but could not make three-dimensional changes in the adult

nasomaxillary complex including that it cannot move or grow the maxilla, cannot open an adult user's airway, and is in no way a substitute for jaw surgery in an adult;

(ii) that AGGA should not be used for the purpose of attempting to make dimensional changes in the adult nasomaxillary complex including attempting to move the maxilla;

(iii) that using AGGA for the purpose of attempting to make dimensional changes in the adult nasomaxillary complex including attempting to move or grow the maxilla, could result in serious injury including causing teeth to flare out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth.

(iv) that claims made about AGGA making three-dimensional changes in the nasomaxillary complex of adults were contrary to medical science and unproven; and, if AGGA were used in an adult, the patient should be closely monitored to ensure it was not causing gum recession, root resorption or other injury indicative of excessive movement of teeth through bone.

102. Defendant Galella acted with reckless disregard for the safety of others, including plaintiff.

103. As a direct and proximate result of the negligence of defendant Galella, and his reckless disregard for the safety of others including plaintiff as aforesaid, plaintiff has been substantially and permanently injured and damaged as outlined above.

104. This action falls within one or more exceptions to CPLR §1602.

**WHEREFORE, PLAINTIFF BOJA KRAGULJ DEMANDS JUDGMENT IN THE AMOUNT OF TEN MILLION DOLLARS ($10,000,000.00) AGAINST DEFENDANT STEVE GALELLA, D.D.S., PLUS INTEREST AND COSTS**

**COUNT V (Negligence against defendant FBI)**

105. Plaintiff reaffirms and realleges Paragraphs 1 through 104 above as if specifically affirmed and alleged herein.

106. Defendant FBI was negligent in that, *inter alia,* it:

a. taught the course to defendant Cortes, informing her and others that the AGGA device was safe and efficacious for use by adults, when it knew or should have known that the theory behind AGGA regarding its use on adults and its alleged function of making three- dimensional changes in the nasomaxillary complex including forward movement of the maxilla of adults, was contrary to Galella's education and training and to medical science, and was unproven, that AGGA was neither safe nor efficacious in regard to making three- dimensional changes in the nasomaxillary complex including forward movement of the maxilla of adults, that it had limited utility for adults, that it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by plaintiff, all as aforesaid;

b. marketed AGGA to defendant Cortes, to plaintiff and to dentists and consumers throughout the world, as a product that was safe and efficacious for adults when it knew or should have known that claims made about AGGA making three-dimensional changes in the nasomaxillary complex of adults was contrary to Galella's education and training, and to medical science, and was unproven, that AGGA was neither safe nor efficacious in regard to making three-dimensional changes in the adult nasomaxillary complex including forward movement of the maxilla, had limited utility for adults, that it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by plaintiff, all as aforesaid;

c. failed to warn purchasers of AGGA and dentists to whom it taught the course including defendant Cortes and other similar courses, or anyone else:

(i) of the limitations of AGGA's utility for adults in that it would move teeth

through bone, but could not make three-dimensional changes in the adult nasomaxillary complex including that it cannot move or grow the maxilla, cannot open an adult user's airway, and is in no way a substitute for jaw surgery in an adult;

(ii) that AGGA should not be used for the purpose of attempting to make dimensional changes in the adult nasomaxillary complex including attempting to move the maxilla;

(iii) that using AGGA for the purpose of attempting to make dimensional changes in the adult nasomaxillary complex including attempting to move or grow the maxilla, could result in serious injury including causing teeth to flare out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth.

(iv) that claims made about AGGA making three-dimensional changes in the nasomaxillary complex of adults were contrary to medical science and unproven; and,

(v) if AGGA were used in an adult, the patient should be closely monitored to ensure it was not causing gum recession, root resorption or other injury indicative of excessive movement of teeth through bone.

d. produced the treatment plan for defendant Cortes for the installation of the second AGGA device on plaintiff –after significant injury to plaintiff was caused by the first AGGA but before additional damage was done by the second AGGA -when it knew or should have known that claims made about AGGA making three-dimensional changes in the nasomaxillary complex of adults was contrary to Galella's education and training, and to medical science and was

unproven, that AGGA was neither safe nor efficacious in regard to making three-dimensional changes in the adult nasomaxillary complex including forward movement of the maxilla, it had limited utility for adults in creating movement of teeth through bone, that it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by plaintiff, all as aforesaid; and, that such movement had to be monitored to ensure it was not causing gingival recession, root resorption or other injury; and,

e. produced the treatment plan for defendant Cortes for the installation of the second AGGA device on plaintiff –after significant injury to plaintiff was caused by the first AGGA but before additional damage was done by the second AGGA –without providing warnings in said plan that claims made about AGGA making three-dimensional changes in the nasomaxillary complex of adults was contrary to Galella's education and training, and to medical science, and was unproven, that AGGA was neither safe nor efficacious in regard to making three-dimensional changes in the adult nasomaxillary complex including forward movement of the maxilla, that AGGA had limited utility for adults in creating movement of teeth through bone, that it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by plaintiff, all as aforesaid; and, that such movement had to be monitored to ensure it was not causing gingival recession, root resorption or other injury.

107. Defendant FBI acted with reckless disregard for the safety of others, including plaintiff.

108. As a direct and proximate result of the negligence of defendant FBI, and its reckless disregard for the safety of others including plaintiff as aforesaid, plaintiff has been substantially and permanently injured and damaged as outlined above.

109. This action falls within one or more exceptions to CPLR §1602.

**WHEREFORE, PLAINTIFF BOJA KRAGULJ DEMANDS JUDGMENT IN THE AMOUNT OF TEN MILLION DOLLARS ($10,000,000.00) AGAINST DEFENDANT FACIAL BEAUTY INSTITUTE, PLUS INTEREST AND COSTS**

**COUNT VI (Negligence against defendant OrthoMatrix)**

110. Plaintiff reaffirms and realleges Paragraphs 1 through 109 above as if specifically affirmed and alleged herein.

111. Defendant OrthoMatrix was negligent in that, *inter alia,* it, either directly or by or through its division or trade name FBI and/or OrthoLogic:

a. taught the course to defendant Cortes, informing her and others that the AGGA device was safe and efficacious for use by adults, when it knew or should have known that the theory behind AGGA regarding its use on adults and its alleged function of making three-dimensional changes in the nasomaxillary complex including forward movement of the maxilla of adults, was contrary to Galella's education and training, and to medical science, and was unproven, that AGGA was neither safe nor efficacious in regard to making three-dimensional changes in the nasomaxillary complex including forward movement of the maxilla of adults, had limited utility for adults, that it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by plaintiff, all as aforesaid;

b. marketed AGGA to defendant Cortes, to plaintiff and to dentists and consumers throughout the world, as a product that was safe and efficacious for adults when it knew or should have known that claims made about AGGA making three-dimensional changes in the nasomaxillary complex of adults was contrary to Galella's education and training, and to medical science, and was unproven, that AGGA was neither safe nor efficacious in regard to making three-dimensional changes in the adult nasomaxillary complex including forward movement of the maxilla, had limited utility for adults, that it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by plaintiff, all

as aforesaid;

c. failed to warn purchasers of AGGA and dentists to whom it taught the course including defendant Cortes and other similar courses, or anyone else:

(i) of the limitations of AGGA's utility for adults in that it would move teeth through bone, but could not make three-dimensional changes in the adult nasomaxillary complex including that it cannot move or grow the maxilla, cannot open an adult user's airway, and is in no way a substitute for jaw surgery in an adult;

(ii) that AGGA should not be used for the purpose of attempting to make dimensional changes in the adult nasomaxillary complex including attempting to move the maxilla;

(iii) that using AGGA for the purpose of attempting to make dimensional changes in the adult nasomaxillary complex including attempting to move or grow the maxilla, could result in serious injury including causing teeth to flare out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth.

(iv) that claims made about AGGA making three-dimensional changes in the nasomaxillary complex of adults were contrary to medical science and unproven; and, if AGGA were used in an adult, the patient should be closely monitored to ensure it was not causing gum recession, root resorption or other injury indicative of excessive movement of teeth through bone.

d. produced the treatment plan for defendant Cortes for the installation of the second AGGA device on plaintiff –after significant injury to plaintiff was caused by the first AGGA but before

additional damage was done by the second AGGA -when it knew or should have known that claims made about AGGA making three-dimensional changes in the nasomaxillary complex of adults was contrary to Galella's education and training, and to medical science, and was unproven, that AGGA was neither safe nor efficacious in regard to making three-dimensional changes in the adult nasomaxillary complex including forward movement of the maxilla, it had limited utility for adults, that it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by plaintiff, all as aforesaid; and,

e. produced the treatment plan for defendant Cortes for the installation of the second AGGA device on plaintiff –after significant injury to plaintiff was caused by the first AGGA but before additional damage was done by the second AGGA –without warning defendant Cortes or plaintiff that AGGA should not be installed in adults for the purpose of making changes in the nasomaxillary complex, that it had limited utility for adults in creating movement of teeth through bone, and that such movement had to be monitored to ensure it was not causing gingival recession, root resorption or other injury.

112. Defendant OrthoMatrix acted with reckless disregard for the safety of others, including plaintiff.

113. As a direct and proximate result of the negligence of defendant OrthoMatrix, and its reckless disregard for the safety of others including plaintiff as aforesaid, plaintiff has been substantially and permanently injured and damaged as outlined above.

114. This action falls within one or more exceptions to CPLR §1602.

**WHEREFORE, PLAINTIFF BOJA KRAGULJ DEMANDS JUDGMENT IN THE AMOUNT OF TEN MILLION DOLLARS ($10,000,000.00) AGAINST DEFENDANT ORTHOMATRIX CORP., INC., PLUS INTEREST AND COSTS**

**COUNT VII (Product liability-breach of warranties against defendant John's Dental)**

115. Plaintiff reaffirms and realleges Paragraphs 1 through 114 above as if specifically

affirmed and alleged herein.

116. At the time that the AGGA devices that were sold to defendant Cortes as aforesaid last left the possession, custody or control of defendant John's Dental, said devices were inherently defective by virtue of its design, were not fit for their intended purpose nor for the specific purpose for which they were sold for installation in plaintiff's mouth, were not of merchantable quality, were not reasonably or minimally safe, and were unreasonably dangerous and defective, all at the time each left the possession, custody and control of defendant John's Dental, for reasons that were described above, in regard to their use by adults.

117. The defective nature of the AGGA devices includes their lack of warnings, at the time each last left the possession, custody and control of defendant John's Dental, in in that it failed to warn purchasers of AGGA, or anyone else:

a. of the limitations of AGGA's utility for adults in that it would move teeth through bone, but could not make three-dimensional changes in the adult nasomaxillary complex including that it cannot move or grow the maxilla, cannot open an adult user's airway, and is in no way a substitute for jaw surgery in an adult;

b. that AGGA should not be used for the purpose of attempting to make dimensional changes in the adult nasomaxillary complex including attempting to move or grow the maxilla;

c. that using AGGA for the purpose of attempting to make dimensional changes in the adult nasomaxillary complex including attempting to move or grow the maxilla, could result in serious injury including causing teeth to flare out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth.

d. that claims made about AGGA making three-dimensional changes in the nasomaxillary complex of adults were contrary to medical science and unproven; and,

e. if AGGA were used in an adult, the patient should be closely monitored to ensure it

was not causing gum recession, root resorption or other injury indicative of excessive movement of teeth through bone.

118. When used for the purpose for which it was intended, AGGA has limited utility for adults and presents a risk of serious and permanent injury to adults when used as intended by the designer, manufacturer and seller to make dimensional changes in the nasomaxillary complex, all as aforesaid.

119. As a result of the foregoing, defendant John's Dental was in breach of the implied warranties of merchantability and fitness for a particular purpose in regard to the aforesaid AGGA devices sold to defendant Cortes and installed in plaintiff's mouth.

120. Plaintiff relied on the aforementioned implied warranties in agreeing to the installation of the AGGA devices.

121. As a direct and proximate result of those breaches of implied warranties, separately and together, plaintiff has been substantially and permanently injured and damaged as outlined above.

122. This action falls within one or more exceptions to CPLR §1602.

**WHEREFORE, PLAINTIFF BOJA KRAGULJ DEMANDS JUDGMENT IN THE AMOUNT OF TEN MILLION DOLLARS ($10,000,000.00) AGAINST DEFENDANT JOHN'S DENTAL LABORATORY, INC., PLUS INTEREST AND COSTS**

**COUNT VIII (Product liability-strict liability against defendant John's Dental)**

123. Plaintiff reaffirms and realleges Paragraphs 1 through 122 above as if specifically affirmed and alleged herein.

124. At the time the AGGA devices were sold by defendant John's Dental to defendant Cortes for use on plaintiff, an adult at the time, said devices were not reasonably safe for her use, were defectively designed as aforesaid including its lack of adequate warnings as aforesaid, and in a condition not reasonably contemplated by plaintiff, the ultimate user, including for the reasons

that the utility of the product was limited in adults to moving teeth through bone which utility was far outweighed by the risk of using the product for the purpose for which it was widely sold –changing the nasomaxillary complex in three dimensions for adults including moving the maxilla, which carried substantial risk of serious injury.

125. At the time the AGGA devices were sold by defendant John's Dental to defendant Cortes for use on plaintiff, said products posed a substantial likelihood of harm to plaintiff or any other adult user and were unreasonably dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it with the ordinary knowledge common to consumers, including because the product's tendency, rather than to move the adult maxilla, is to push the upper teeth forward and out of their proper position within the alveolar bone, causing the teeth to flare out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth, all as happened to plaintiff as a result of the use of the product.

126. No reasonable person who knew the true utility of AGGA at the time of manufacture would conclude that the utility of the product outweighed the risk to users.

127. The defective design of the AGGA devices installed in plaintiff's mouth was the sole and/or substantial cause and/or factor in bringing about her injuries or damages.

128. This action falls within one or more exceptions to CPLR §1602.

**WHEREFORE, PLAINTIFF BOJA KRAGULJ DEMANDS JUDGMENT IN THE AMOUNT OF TEN MILLION DOLLARS ($10,000,000.00) AGAINST DEFENDANT JOHN'S DENTAL LABORATORY, INC., PLUS INTEREST AND COSTS**

**COUNT IX (GBL §349 liability against defendant Galella)**

129. Plaintiff reaffirms and realleges Paragraphs 1 through 128 above as if specifically affirmed and alleged herein.

130. New York General Business Law §349 makes unlawful any deceptive acts or practices in

the conduct of any business, trade or commerce or in the furnishing of any service in New York State.

131. Defendant Galella has engaged in consumer-oriented conduct that is materially misleading, in that said defendant has, in the course of marketing AGGA to consumers (including New York consumers) directly, and to dentists (including New York dentists) for the purpose of enticing consumers (including New York consumers) to use AGGA, represented falsely that, in regard to adults:

a. AGGA is a device that mechanically causes the maxilla to move forward over time;

b. that by touching and thereby stimulating a nerve in the upper palate, AGGA causes new bone to grow at the maxillary tuberosity (the most distal aspect of the upper jaw) and other places, which in turn causes the maxilla to move forward, effectively lengthening the upper jaw;

c. that as the maxilla moves forward, upper teeth move with it;

d. that by adhering bite plates to the lower molars, the lower jaw moves forward as the upper jaw moves forward;

e. that the movement of the jaws has the effect of opening the airway, and moving the jaws into a position more natural for the user's face;

f. is reasonably safe for installation into dental patients' mouths; and,

g. can be utilized as a substitute for jaw surgery.

132. The aforementioned false representations are material in that they go to the essence of the function of AGGA as claimed by defendant Galella, and their falsity means that the product has limited utility in adults, and that the products risks outweigh utility in adults.

133. AGGA is unreasonably dangerous as designed and manufactured, and can cause substantial and permanent damage, as set forth above.

134. As a direct and proximate result of the aforementioned material misrepresentations, plaintiff allowed AGGA to be installed in her mouth, and as a result suffered serious and

permanent injury as described above.

135. The aforementioned conduct of defendant Galella has affected and will continue to affect not just plaintiff but also consumers at large within the State of New York who seek to reconfigure their jaws for a host of reasons including resolving issues of insufficient airway, severe dental crowding, disfigurement of chin or jawline or other reasons.

136. The aforementioned conduct of defendant Galella has also affected and will continue to affect New York dentists who, based on those misrepresentations, will utilize AGGA on adult New York consumers and thereby visit substantial and permanent injury on such consumers who seek to reconfigure their jaws for a host of reasons including resolving issues of insufficient airway, severe dental crowding, disfigurement of chin or jawline or other reasons.

137. Defendant Galella, through his aforementioned material misrepresentations, has violated New York General Business Law §349, thereby causing plaintiff severe and permanent injury and damage as described above.

**WHEREFORE, PLAINTIFF BOJA KRAGULJ DEMANDS JUDGMENT IN THE AMOUNT OF TEN MILLION DOLLARS ($10,000,000.00) AGAINST DEFENDANT STEVE GALELLA, D.D.S., PLUS INTEREST AND COSTS, AND ATTORNEYS FEES AS PROVIDED FOR BY GENERAL BUSINESS LAW § 349**

**COUNT X (GBL 349 liability against defendant FBI)**

138. Plaintiff reaffirms and realleges Paragraphs 1 through 137 above as if specifically affirmed and alleged herein.

139. Defendant FBI has engaged in consumer-oriented conduct that is materially misleading, in that said defendant has, in the course of marketing AGGA to consumers (including New York consumers) directly, and to dentists (including New York dentists) for the purpose of enticing consumers (including New York consumers) to use AGGA, represented falsely that, in regard to adults:

a. AGGA is a device that mechanically causes the maxilla to move forward over time;

b. that by touching and thereby stimulating a nerve in the upper palate, AGGA causes new bone to grow at the maxillary tuberosity (the most distal aspect of the upper jaw) and other places, which in turn causes the maxilla to move forward, effectively lengthening the upper jaw;

c. that as the maxilla moves forward, upper teeth move with it;

d. that by adhering bite plates to the lower molars, the lower jaw moves forward as the upper jaw moves forward;

e. that the movement of the jaws has the effect of opening the airway, and moving the jaws into a position more natural for the user's face;

f. is reasonably safe for installation into dental patients' mouths; and,

g. can be utilized as a substitute for jaw surgery.

140. The aforementioned false representations are material in that they go to the essence of the function of AGGA as claimed by defendant FBI, and their falsity means that the product is useless for its claimed function in adults, i.e. to change the nasomaxillary complex in three dimensions, including advancing the maxilla forward.

141. AGGA is unreasonably dangerous as designed and manufactured, and can cause substantial and permanent damage, as set forth above.

142. As a direct and proximate result of the aforementioned material misrepresentations, plaintiff allowed AGGA to be installed in her mouth, and as a result suffered serious and permanent injury as described above.

143. The aforementioned conduct of defendant FBI has affected and will continue to affect not just plaintiff but also consumers at large within the State of New York who seek to reconfigure their jaws for a host of reasons including resolving issues of insufficient airway, severe dental crowding, disfigurement of chin or jawline or other reasons.

144. The aforementioned conduct of defendant FBI has also affected and will continue to

affect New York dentists who, based on those misrepresentations, will utilize AGGA on adult New York consumers and thereby visit substantial and permanent injury on such consumers who seek to reconfigure their jaws for a host of reasons including resolving issues of insufficient airway, severe dental crowding, disfigurement of chin or jawline or other reasons.

145. Defendant FBI, through its aforementioned material misrepresentations, has violated New York General Business Law §349, thereby causing plaintiff severe and permanent injury and damage as described above.

**WHEREFORE, PLAINTIFF BOJA KRAGULJ DEMANDS JUDGMENT IN THE AMOUNT OF TEN MILLION DOLLARS ($10,000,000.00) AGAINST DEFENDANT FACIAL BEAUTY INSTITUTE, PLUS INTEREST AND COSTS, AND ATTORNEYS FEES AS PROVIDED FOR BY GENERAL BUSINESS LAW § 349**

**COUNT X (GBL 349 liability against defendant OrthoMatrix)**

146. Plaintiff reaffirms and realleges Paragraphs 1 through 145 above as if specifically affirmed and alleged herein.

147. Defendant OrthoMatrix, through its division and/or trade name FBI, has engaged in consumer-oriented conduct that is materially misleading, in that said defendant has, in the course of marketing AGGA to consumers (including New York consumers) directly, and to dentists (including New York dentists) for the purpose of enticing consumers (including New York consumers) to use AGGA, represented falsely that, in regard to adults:

a. AGGA is a device that mechanically causes the maxilla to move forward over time;

b. that by touching and thereby stimulating a nerve in the upper palate, AGGA causes new bone to grow at the maxillary tuberosity (the most distal aspect of the upper jaw) and other places, which in turn causes the maxilla to move forward, effectively lengthening the upper jaw;

c. that as the maxilla moves forward, upper teeth move with it;

d. that by adhering bite plates to the lower molars, the lower jaw moves forward as the upper jaw moves forward;

e. that the movement of the jaws has the effect of opening the airway, and moving the jaws into a position more natural for the user's face;

f. is reasonably safe for installation into dental patients' mouths; and,

g. can be utilized as a substitute for jaw surgery.

148. The aforementioned false representations are material in that they go to the essence of the function of AGGA as claimed by defendant OrthoMatrix, and their falsity means that the product is useless for its claimed function in adults, i.e. to change the nasomaxillary complex in three dimensions, including advancing the maxilla forward.

149. AGGA is unreasonably dangerous as designed and manufactured, and can cause substantial and permanent damage, as set forth above.

150. As a direct and proximate result of the aforementioned material misrepresentations, plaintiff allowed AGGA to be installed in her mouth, and as a result suffered serious and permanent injury as described above.

151. The aforementioned conduct of defendant OrthoMatrix has affected and will continue to affect not just plaintiff but also consumers at large within the State of New York who seek to reconfigure their jaws for a host of reasons including resolving issues of insufficient airway, severe dental crowding, disfigurement of chin or jawline or other reasons.

152. The aforementioned conduct of defendant OrthoMatrix has also affected and will continue to affect New York dentists who, based on those misrepresentations, will utilize AGGA on adult New York consumers and thereby visit substantial and permanent injury on such consumers who seek to reconfigure their jaws for a host of reasons including resolving issues of

insufficient airway, severe dental crowding, disfigurement of chin or jawline or other reasons.

153. Defendant OrthoMatrix, through its aforementioned material misrepresentations, has violated New York General Business Law §349, thereby causing plaintiff severe and permanent injury and damage as described above.

**WHEREFORE, PLAINTIFF BOJA KRAGULJ DEMANDS JUDGMENT IN THE AMOUNT OF TEN MILLION DOLLARS ($10,000,000.00) AGAINST DEFENDANT ORTHOMATRIX CORP., INC., PLUS INTEREST AND COSTS, AND ATTORNEYS FEES AS PROVIDED FOR BY GENERAL BUSINESS LAW § 349**

**PLAINTIFF DEMANDS TRIAL BY JURY ON ALL COUNTS**

Dated: September 10, 2021

Plaintiff,
By her attorneys,

/SEC/
Scott E. Charnas, SC7167
CHARNAS LAW FIRM, P.C.
455 East 51st Street
New York, NY 10022
Tel: 212-980-6800
Fax: 212-980-1871
Email: scharnas@charnaslawfirm.com

CERTIFICATE OF SERVICE

I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF).

/s/ SEC
Scott E. Charnas

Dated: September 10, 2021