

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

BAY MATERIALS, LLC,

Plaintiff,

v.

3M COMPANY,

Defendant.

Civil Action No.

DEMAND FOR JURY TRIAL

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Bay Materials, LLC (“Plaintiff” or “Bay Materials”), by way of this Complaint for Patent Infringement under 35 U.S.C. § 271 against Defendant 3M Company (“Defendant” or “3M”), states on information and belief as follows:

NATURE OF THE ACTION

1. Bay Materials brings this action for patent infringement after 3M copied Bay Materials’ patented, industry-leading multilayer polymer sheet material used in orthodontic clear aligners and recently released an infringing multilayer orthodontic aligner. Bay Materials is seeking a preliminary injunction to stop the irreparable harm resulting from 3M’s infringement, as well as damages and a permanent injunction.

2. In particular, this is an action for infringement by Bay Materials against 3M for infringement of U.S. Patent Nos. 10,870,263 (“the ’263 patent”) and 10,946,630 (“the ’630 patent”) (collectively, “patents-in-suit”) by making, using, offering to sell, selling, and/or importing multilayer polymeric orthodontic materials and appliances sold under the brand name “Clarity™ Aligners Flex,” including at least the Clarity Aligners Flex + Force aligner system,

Clarity Aligners Flex, the thermoplastic material used for the Clarity Aligners Flex, and any other product or system incorporating the Clarity Aligners Flex or similar product (the “Accused Products”).

3. Bay Materials is the industry leader in high-performance thermoformable materials for orthodontic clear aligner therapy. Bay Materials developed the first-generation advanced clear aligner material in 1999, which exhibited better performance than standard polyesters used for aligners at that time. Bay Materials improved on that material, calling it Zendura™ and making it available to orthodontic suppliers and dental suppliers in 2003. *See* Ex. C at 1. Bay Materials’ Zendura brand of thermoformable material quickly became regarded as the best commercially available clear thermoplastic material for fabricating orthodontic clear aligners and post-treatment retainers. *See* Ex. D at 1.

4. Bay Materials has continued to develop innovative, high performance thermoformable material for orthodontic clear aligners as part of its Zendura brand. In November 2018, Bay Materials announced the commercial release of Zendura FLX, a new and unique thermoformable material engineered specially for fabricating clear aligner appliances. *See* Ex. E at 1. Zendura FLX quickly became a top-of-the-line, industry leading thermoformable material for fabrication of clear aligner orthodontic appliances.

5. Zendura FLX is a three-layer polymeric material, having outer layers that provide a dual-shell structure and an elastomeric inner layer. The unique dual-shell design provides a combination of exceptional force characteristics and elasticity for teeth movement and patient comfort. *See* Ex. F at 1. The dual shell of the Zendura FLX material grips the teeth evenly and firmly, while the elastomeric layer applies gentle yet consistent and continual pressure to move teeth reliably and predictably. *See* Ex. E at 1.

6. Zendura FLX generates less initial force than other materials on the market, leading to improved patient comfort and acceptance. *Id.* Additionally, Zendura FLX retains more orthodontic force after a normal wear period than other competing materials. *Id.* Orthodontic appliances made from Zendura FLX provide an optimum balance of stress retention, durability, elasticity, clarity, and stain resistance.

7. Before 3M released its Clarity Aligners Flex, which is a multi-layer aligner, 3M obtained sheets of Zendura FLX. In April 2018, and January 2020, 3M obtained sheets of Zendura FLX. On information and belief, in April 2018 and January 2020, 3M did not have a multi-layer orthodontic aligner or a material for multi-layer orthodontic aligners commercially available.

8. On information and belief, 3M has been aware of and had knowledge of the '263 patent since at least January 2021. For example, on January 5, 2021, Bay Materials announced the issuance of the '263 patent claiming thermoformable sheets and orthodontics appliances, which Bay Materials stated covers its Zendura FLX aligner materials. *See* Ex. G at 1. On information and belief, in January 2021, 3M did not have multi-layer orthodontic aligners or a material for multi-layer orthodontic aligners commercially available.

9. In January 2021, 3M's orthodontic business leader, Jay Issa, emailed Bay Materials stating that he had seen Bay Materials' press release on Bay Materials' patent on the Zendura FLX and that 3M was interested in having a conference call to discuss this topic. Upon information and belief, a meeting between 3M and Bay Materials was held on January 13, 2021, where 3M sought a license to Bay Materials' intellectual property regarding polymeric thermoformable material and dental appliances. Despite initiating negotiations involving Bay Materials' intellectual property, 3M never obtained a license to the patents-in-suit. 3M

nonetheless released the Clarity Aligners Flex, copying Bay Materials' Zendura FLX and incorporating Bay Materials' intellectual property. 3M even copied Bay Materials' product naming convention by naming its new multi-layer Clarity aligner "Flex," similar to Bay Materials' Zendura "FLX."

10. As discussed in greater detail below, 3M has infringed and continues to infringe one or more claims of each of the patents-in-suit literally and/or under the doctrine of equivalents by making, using, selling, offering for sale, and/or importing the Accused Products, and all reasonably similar products.

11. As discussed in greater detail below, 3M indirectly infringes the patents-in-suit by inducing its customers to directly infringe one or more claims of the patents-in-suit. 3M, with knowledge that its customers directly infringe the patents-in-suit at least when using and/or making the Accused Products as intended, and by intentionally encouraging such acts, is liable for induced infringement under 35 U.S.C. § 271(b).

12. As discussed in greater detail below, 3M also indirectly infringes the patents-in-suit by contributing to the direct infringement of one or more claims of the patents-in-suit by its customers. 3M knows that the Accused Products are especially made or adapted for use by its customers in a manner that directly infringe the patents-in-suit under 35 U.S.C. § 271(a). Because the Accused Products also are not staple articles of commerce and are not suitable for substantial noninfringing uses, 3M is liable for contributory infringement under 35 U.S.C. § 271(c).

THE PARTIES

13. Plaintiff Bay Materials, LLC, is a limited liability company duly organized and existing under the laws of the State of California with its principal place of business at 48450 Lakeview Blvd, Fremont, California 94538.

14. Bay Materials is in the business of developing, manufacturing, and marketing advanced thermoplastic materials for the orthodontic and dental industries.

15. On information and belief, Defendant 3M Company is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 3M Center, St. Paul, Minnesota 55133.

16. On information and belief, 3M is in the business of making, using, selling, offering for sale, and/or importing dental and orthodontic devices throughout the United States.

17. On information and belief, 3M has an Oral Care Solutions Division responsible for dental and orthodontic products for dentists and orthodontists, including the Clarity Aligners Flex.

JURISDICTION AND VENUE

18. This action arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq*, including 35 U.S.C. § 271. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

19. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391 and 1400(b), at least because 3M is incorporated in and resides in Delaware and in this District.

20. This Court has personal jurisdiction over 3M, because 3M is incorporated in Delaware and resides in this District for purposes of 28 U.S.C. §§ 1391 and 1400. 3M also has

systematic and continuous contacts in this judicial district, regularly transacts business within this district, and regularly avails itself of the benefits of this District.

21. This Court also has personal jurisdiction over 3M under 10 Del. C. § 3104(c) because at least one provision of the Delaware long-arm statute is satisfied. On information and belief, 3M satisfies at least § 3104(c)(1) (“[t]ransacts any business or performs any character of work or service in the State”), § 3104(c)(2) (“[c]ontracts to supply services or things in this State”), § 3104(c)(3) (“[c]auses tortious injury in the State by an act or omission in this State”), § 3104(c)(4) (“[c]auses tortious injury in the State or outside of the State by an act or omission outside the State if the person regularly does or solicits business, engages in any other persistent course of conduct in the State or derives substantial revenue from services, or things used or consumed in the State”), and § 3104(c)(5) (“[h]as an interest in, uses or possesses real property in the State”).

22. 3M has also purposely availed itself of this forum for purposes of patent disputes by filing complaints and asserting counterclaims in this District.

THE PATENTS-IN-SUIT

U.S. Patent 10,870,263

23. The '263 patent, titled “Dual Shell Dental Appliance and Material Constructions,” was duly and legally issued by the United States Patent and Trademark Office (“USPTO”) on December 22, 2020. A true and correct copy of the '263 patent is attached hereto as Exhibit A.

24. Bay Materials is the assignee and owner of the '263 patent by way of assignment from inventors Ray F. Stewart and John Lahlouh.

U.S. Patent 10,946,630

25. The '630 patent, titled "Dual Shell Dental Appliance and Material Constructions," was duly and legally issued by the USPTO on March 16, 2021. A true and correct copy of the '630 patent is attached hereto as Exhibit B.

26. Bay Materials is the assignee and owner of the '630 patent by way of assignment from inventors Ray F. Stewart and John Lahlouh.

THE ACCUSED PRODUCT

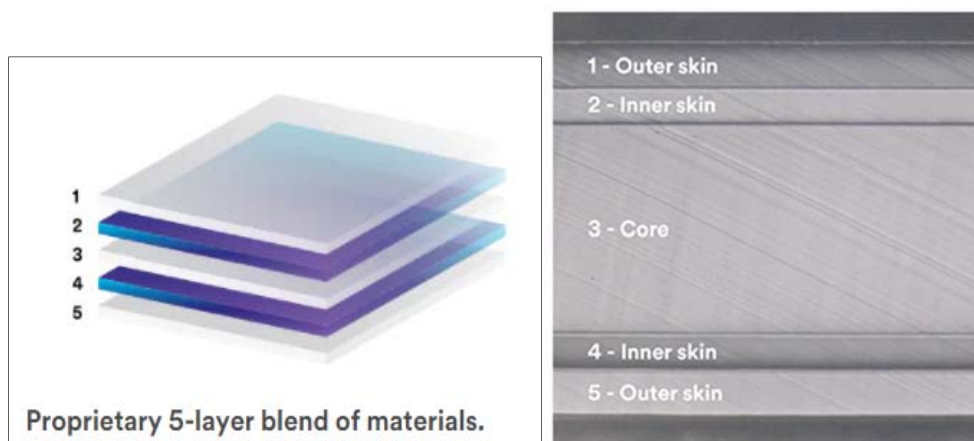
27. 3M has made, used, sold, imported, and/or offered for sale, and/or continues to make, use, sell, import, and/or offer for sale, products in the United States consisting of at least multilayer polymeric orthodontic materials and appliances sold under the brand name Clarity Aligners Flex, including at least the Clarity Aligners Flex + Force aligner system, Clarity Aligners Flex, the thermoplastic material used for the Clarity Aligners Flex, and any other product or system incorporating the Clarity Aligners Flex or a similar product (collectively, "Accused Products"). Although 3M did not obtain a license to the '263 and '630 patents from Bay Materials, 3M announced on July 12, 2021, the commercial launch of the Clarity Aligners Flex in the United States, which are clear dental appliances for orthodontic tooth treatment.

28. 3M introduced Clarity Aligners Flex + Force as "a new aligner system." *See* Ex. H at 1. 3M describes and advertises the Clarity Aligners Flex as a "flexible 5-layer material." *See* Ex. I at 1. 3M states and advertises that the Clarity Aligners Flex can be used alone or with the Clarity Aligners Force. *See id.* at 1-2.

29. The Clarity Aligners Flex is a five-layer polymeric aligner designed as an orthodontic treatment to fix dental malocclusion. 3M's submission to the FDA filed on April 21, 2021, describes the Clarity Aligners Flex as a device "composed of thermoplastic resin" that

“moves the teeth by continuous gentle force for treatment of minor tooth malocclusion.” More specifically, 3M describes the Clarity Aligners Flex as being made from copolyesters. *See* Ex. J at 2.

30. In designing the Clarity Aligners Flex, 3M states that it set out to create “multi-layer material for the aligner tray application.” *See* Ex. K at 1. 3M states that the “Clarity Aligners Flex features 5-layers of contrasting materials.” *See* Ex. L at 1. 3M also shows the Clarity Aligners Flex being made of two contrasting polymer materials. For the Clarity Aligners Flex, 3M illustrates the “outer skin” layers and “core” layer as being the same and the two “inner skin” layers as being the same. *See* Ex. J at 1; Ex. I at 1.

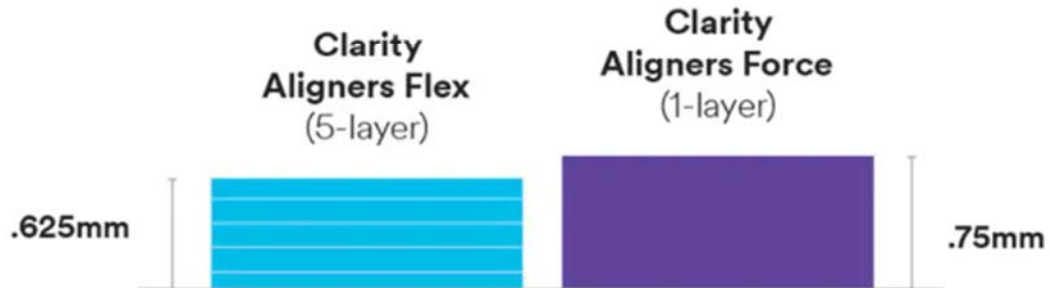


31. Again describing the two different types of layers for the Clarity Aligners Flex, 3M states that “the outer layer needed to resist staining, scratching and discoloration” and the “inner layers needed to provide mechanical durability such as cracking and tearing resistance, force persistence, flexibility and ultimately, resilience.” *See* Ex. J at 1; Ex. K at 1; *see also* Ex. I at 1.

32. 3M describes the five layers of the polymer sheet material used to form Clarity Aligners Flex as having “uniform thickness” with a combined thickness of 0.625 mm (625 microns) for all five layers. *See* Ex. K at 2; Ex. J at 1; Ex. L at 3.

Uniformed Material Thickness

Clarity Aligners Flex: thin yet durable.



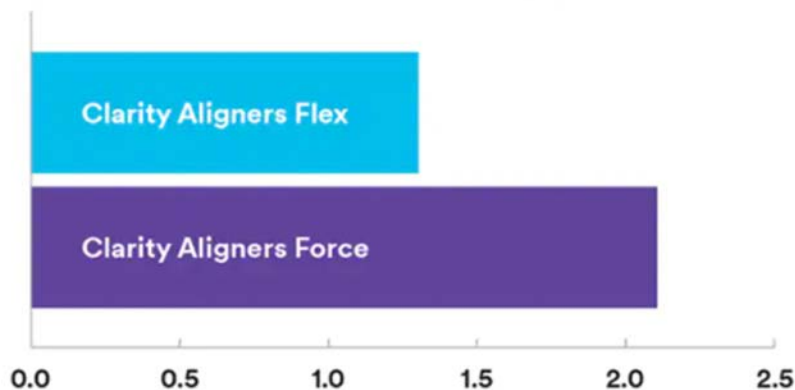
33. On information and belief, the combined thickness of the two outer layers or “outer skins” and the two soft inner layers or “inner skin” of the polymer sheet material used to form Clarity Aligners Flex is about 270-280 microns.

34. On information and belief, the combined thickness of the two outer layers or “outer skins” and the “core” layer of the polymer sheet material used to form Clarity Aligners Flex is about 490 microns.

35. 3M states that the Clarity Aligners Flex have an elastic modulus between 1.0 GPa and 1.5 GPa (or 1000 MPa to 1500 MPa). See Ex. I at 1; Ex. J at 2; Ex. K at 3.

Elastic Modulus (GPa)

Two levels of flexibility.



36. On information and belief, 3M manufactures the thermoplastic material that constitutes the Clarity Aligners Flex. 3M claims that it “designed a new manufacturing process” for the Clarity Aligners Flex. *See* Ex. K at 2.

37. On information and belief, 3M has sought to protect its Clarity products and related technology, filing patent applications disclosing multilayered, polymer-based sheets and dental appliances and methods of making both. *See* Ex. M (WO 2020/225657 (“the ’657 publication”)); Ex. N (WO 2020/225651 (“the ’651 publication”)); Ex. O (WO 2021/059101 (“the ’101 publication”)); Ex. P (WO 2020/141440 (“the ’440 publication”)). Consistent with 3M’s advertised 5-layer Clarity Aligners Flex, the ’657 publication, the ’101 publication, and the ’440 publication disclose examples of 5-layer polymeric films and dental appliances. *See* Ex. M (’657 publication) at ¶¶ [0092]-[0097]; Ex. O (’101 publication) at pp. 12-18; Ex. P (’440 publication) at ¶¶ [0063]-[0077].

38. 3M’s advertising of the Clarity Aligners Flex tracks its patent disclosures. 3M states that the “5 layers of polymer materials [] achieve somewhat contradictory objectives. For example, the material is flexible, so it fits well but it also offers excellent force persistence” *See* Ex. L at 1. 3M further states that the “outer layer of Clarity Aligners Flex was developed to resist tearing, staining and scratches,” *see id.* at 1, and “[t]he inner layers needed to provide mechanical durability such as cracking and tear resistance, force persistence, flexibility and ultimately, resilience.” *See* Ex. J at 1. Likewise, the ’657 publication, titled “Multi-Layered Dental Appliance,” discloses such appliances having “at least 5 polymeric layers, with softer polymeric interior layers disposed between a harder polymeric core layer and two harder polymeric outer layers.” *See* Ex. M (’657 publication) at ¶ [0009]. The ’657 publication states that the “hard core layer can enhance dimensional stability, while the softer middle layers

positioned close to the outer skin layers can improve patient comfort and strain recovery.” *Id.* at ¶ [0009]. The ’657 publication discloses that such appliances have “multiple layers of high flexural modulus and low flexural modulus polymeric materials to improve patient comfort while maintaining an acceptable level of force persistence” and, when combined, provide “good stain resistance.” *Id.* at ¶ [0008].

39. In Example 4 in the ’657 publication, 3M describes a 5-layer polymeric film having an “overall sheet thickness” of 0.625 mm—exactly the same thickness 3M advertises for its Clarity Aligners Flex. *See* Ex. M at ¶ [0097]; Ex. I at 1. Example 4 of the ’657 publication describes a “5-layer CBABC (MX710/ECDEL /MX710/ECDEL9967/ MX710) film.” Ex. M at ¶ [0097].

40. The ’657 publication describes ECDEL, or Ecdel 9967, as a “copolyester ether elastomer from Eastman Chemicals.” *See* Ex. M at ¶ [0078]. The technical data sheet for Ecdel 9967 describes the polymer as an elastomer having a Shore A hardness of 95 and a Shore D hardness of 55. *See* Ex. Q at 2.

41. The ’657 publication describes Tritan MX710 as a “copolyester from Eastman Chemicals.” *See* Ex. M at ¶ [0078]. The ’657 publication describes MX710 as having a flexural modulus of 1.55 GPa. *Id.* at ¶ [0079]. The technical data sheet for Tritan MX710 likewise states that the polymer is a copolyester and that its flexural modulus is 1.55 GPa according to ASTM D 790. *See* Ex. R at 1.

42. On information and belief, the Clarity Aligners Flex has a flexural modulus of from about 750 MPa to 2,000 MPa.

43. On information and belief, the Clarity Aligners Flex has a flexural modulus of about 1,300 MPa.

44. On information and belief, the Clarity Aligners Flex includes two hard outer layers and one hard inner layer each made of a thermoplastic polymer having a modulus from 1,000 MPa to 2,5000 MPa.

45. On information and belief, the two hard outer layers and hard inner layer of the Clarity Aligners Flex are each made of an Eastman Tritan polymer having a modulus from 1,000 MPa to 2,500 MPa.

46. On information and belief, the hard outer layers and hard inner layer of the Clarity Aligners Flex are made from a Tritan polymer, including MX710, TX1000, or TX1001, which have similar mechanical properties, including having a flexural modulus of around 1,550 MPa.

47. On information and belief, the hard outer layers and hard inner layer of the Clarity Aligners Flex are made from Tritan MX710 having a flexural modulus of around 1,550 MPa.

48. On information and belief, the Clarity Aligners Flex includes two soft inner layers made from an elastomeric polymer having a hardness from about A 60 to D 85.

49. On information and belief, the two soft inner layers are made from an Eastman Ecdel elastomer, including Ecdel 9967 having a Shore hardness of A95 or D50.

50. On information and belief, the two soft inner layers are made from Ecdel 9967 having a Shore hardness of A95 or D50.

51. On information and belief, prior to thermoforming, the hard outer layers and two soft inner layers of the Clarity Aligners Flex have a combined thickness greater than 250 microns.

52. On information and belief, 3M instructs customers on how to assemble, install, make, and/or use the Clarity Aligners Flex and the Clarity Aligners Flex + Force system. 3M

offers orthodontic continuing education and training, including for the Clarity Aligners Flex and the Clarity Aligners Flex + Force system.

53. On information and belief, 3M has given classes and continues to give classes to practitioners, encouraging practitioners and training practitioners on how to use Clarity Aligners Flex. On information and belief, 3M offered a class entitled “Practice with Clarity: Virtual Classroom Experience” on Friday, October 29, 2021, at 2 p.m. CST. *See* Ex. S (https://www.3m.com/3M/en_US/orthodontics-us/education/). On information and belief, 3M also offered such a class at least on Wednesday, September 22, 2021, at 8 p.m. CST. On information and belief, 3M is offering such a class at least on Thursday, December 9, 2021, at 7 p.m. CST.

54. 3M offers additional education and training for orthodontic professionals on its website (*see* Ex. T), where 3M offers, among other things, on demand continuing education, product tutorials, and live webinars.

55. To attract orthodontists to its aligners, 3M offers a sell sheet for Clarity Aligners, including on its website. *See* Ex. U. According to 3M’s website, 3M will also put people interested in obtaining Clarity Aligners Flex in touch with a “Smile Specialist” “to help you find a doctor in your area.” *See* Ex. V at 3.

56. The FDA granted approval to market the Clarity Aligners Flex on April 23, 2021, under 510K Number K211190. *See* Ex. W at 1.

57. 3M’s manufacture, use, sale, offer for sale, and/or importation of the Clarity Aligners Flex + Force aligner system, Clarity Aligners Flex, and the thermoplastic material used for the Clarity Aligners Flex in the United States constitute acts of direct infringement of the ’263 and ’630 patents.

COUNT I FOR PATENT INFRINGEMENT

Infringement of the '263 Patent

58. In violation of 35 U.S.C. 271(a), 3M has infringed, and will continue to infringe literally and/or under the doctrine of equivalents, one or more claims of the '263 patent, including at least claims 1, 2, 3, 4, 11, 12, 13, 14, 16, and 18, by making, using, selling, offering for sale, and/or importing into the United States one or more of the Accused Products.

59. On information and belief, the Accused Products include a polymeric sheet composition comprised of at least two outer layers A and C comprised of a Tritan thermoplastic polymer or a similar copolyester having a flexural modulus of about 1,550 MPa, which is from about 1,000 MPa to 2,500 MPa as recited in claim 1 of the '263 patent. On information and belief, the polymeric sheet composition of the Accused Products has two elastomeric inner layers B comprised of Ecdel 9967 having a Shore hardness of A95 or D55, and thus has at least one elastomeric inner layer B comprised of an elastomeric material having a hardness from about A 60 to D 85 as claimed in claim 1 of the '263 patent.

60. The A, B, and C, layers of the polymeric sheet composition of the Accused Products have a combined thickness of from 250 microns to 2,000 microns as recited in claim 2 of the '263 patent. The polymeric sheet composition of the Accused products also has a flexural modulus of about 1,300 MPa, which is from about 500 MPa to 1,500 MPa, as recited in claim 2 of the '263 patent.

61. On information and belief, the outer layers A and C of the polymeric sheet composition of the Accused Products are comprised of a Tritan thermoplastic polymer or a similar copolyester, which is a copolyester, and are thus comprised of one or more of a polyester, a co-polyester, a polycarbonate, a polyester polycarbonate blend, a polyurethane, a polyamide, a

polyolefin, a micro-crystalline polyamide, a co-polyester of terephthalic acid, cyclohexane dimethanol, and 2,2,4,4-tetramethyl-1,3-cyclobutanediol, a co-polyester of terephthalic acid, ethylene glycol and diethylene glycol, an aromatic polyurethane based on MDI and hexanediol, an aromatic polyurethane with aliphatic diols, a co-polymer of propylene, ethylene and C4 to C8 alpha olefin, a cycloaliphatic polyamide, a (meth) acrylic polymer, a vinyl polymer, polyvinyl chloride, and a fluoropolymer, as recited in claim 3 of the '263 patent.

62. On information and belief, the inner layers B of the polymeric sheet composition of the Accused Products are comprised of Ecdel 9967, which is a polyester elastomer, and are thus comprised of one of more of a polyurethane elastomer, an aromatic polyether polyurethane, a polyolefin elastomer, a polyester elastomer, a styrenic elastomer, a polyamide elastomer, a polyether polyamide (polypropylene oxide-based or polytetramethylene oxide-based), a cyclic olefin elastomer, an acrylic elastomer, an aromatic or aliphatic polyether, a polyester polyurethane, a siloxane elastomer, a polyether elastomer, a polyolefin elastomer, an olefin copolymer, and a fluoroelastomer, as recited in claim 4 of the '263 patent.

63. On information and belief, the Accused Products also include a polymeric sheet composition comprised of at least two rigid or hard outer layers A and C and a rigid or hard inner layer D comprised of a Tritan thermoplastic polymer or a similar copolyester having a flexural modulus of about 1,550 MPa, which is from about 1,000 MPa to 2,500 MPa as recited in claim 11 of the '263 patent. On information and belief, the polymeric sheet composition of the Accused Products has two soft inner layers B and B' individually comprised of Ecdel 9967, which is an elastomeric material having a hardness of A95 to D55, and thus have a hardness from about A 60 to D 85 as claimed in claim 11 of the '263 patent.

64. The polymeric sheet composition of the Accused Products has a combined thickness of 625 microns, which is from 250 microns to 2,000 microns as recited in claim 12 of the '263 patent. The polymeric sheet composition of the Accused products has a flexural modulus of about 1300 MPa, which is from about 500 MPa to 1,500 MPa, as recited in claim 12 of the '263 patent.

65. On information and belief, the rigid or hard layers A, C, and D of the Accused Products are comprised of a Tritan thermoplastic polymer or a similar copolyester, which is a copolyester, and are thus each comprised of one or more of a polyester, a co-polyester, a polycarbonate, a polyester polycarbonate blend, a polyurethane, a polyamide, a polyolefin, a micro-crystalline polyamide, a co-polyester of terephthalic and/or isophthalic acid, cyclohexane dimethanol, and 2,2,4,4-tetramethyl-1,3-cyclobutanediol, a co-polyester of terephthalic and/or isophthalic acid, ethylene glycol and diethylene glycol, an aromatic polyurethane based on MDI and hexanediol, an aromatic polyurethane with aliphatic diols, a co-polymer of propylene, ethylene and C4 to C8 alpha olefin, a cycloaliphatic polyamide, a (meth) acrylic polymer, a vinyl polymer, polyvinyl chloride, and a fluoropolymer, as recited in claim 13 of the '263 patent.

66. On information and belief, the soft inner layers B and B' of the polymeric sheet composition of the Accused Products are comprised of Ecdel 9967, which is a polyester elastomer, and are thus comprised of one or more of a polyurethane elastomer, an aromatic polyether polyurethane, a polyolefin elastomer, a polyester elastomer, a styrenic elastomer, an anhydride functionalized styrenic elastomer, a polyamide elastomer, a polyether polyamide (polypropylene oxide-based or polytetramethylene oxide-based), a cyclic olefin elastomer, an acrylic elastomer, an aromatic or aliphatic polyether, a polyester polyurethane, a siloxane

elastomer, a polyether elastomer, a polyolefin elastomer, an olefin copolymer, an acrylic elastomer and a fluoroelastomer, as recited in claim 14 of the '263 patent.

67. The A, C, and D layers of the polymeric sheet composition of the Accused Products have a combined thickness of about 490 microns, which is from about 100 microns to about 750 microns, as recited in claim 16 of the '263 patent.

68. The Accused Products further include a dental appliance conformal to one or more teeth comprising the polymeric sheet composition as claimed in claim 18 of the '263 patent.

69. 3M has been aware of and on notice of the '263 patent since at least January 8, 2021. 3M has also been on notice of the '263 patent since at least as early as the service of this complaint. 3M's continued actions of making, using, selling, offering for sale, and/or importing into the United States any of the Accused Products after knowledge of the patent, including after service of the Complaint, would be with 3M's knowledge of the '263 patent, knowledge of infringement of the '263 patent, intent to encourage others (e.g., its customers) to infringe the '263 patent through the Accused Products, and knowledge that 3M's encouraging acts actually result in direct infringement of the '263 patent by 3M's customers.

70. 3M had knowledge of the '263 patent or was willfully blind to the patented features of the '263 patent before the filing and service date of this Complaint. 3M's request for a license to the '263 patent shows that 3M was aware of and sought to use the patented invention of the '263 patent. 3M was also aware that Bay Materials' Zendura FLX is covered by the '263 patent. 3M's intention of using Bay Materials' patented invention is further illustrated by 3M's use of the name "Flex," similar to Bay Materials' "FLX," for 3M's multi-layer aligner.

71. 3M, in violation of 35 U.S.C. 271(b), has indirectly infringed and continues to indirectly infringe literally and/or under the doctrine of equivalents at least claims 1, 2, 3, 4, 11, 12, 13, 14, 16, and 18, of the '263 patent by actively inducing others to use, make, sell, offer for sale and/or import one or more of the Accused Products in an infringing manner, knowing such acts would constitute infringement of the '263 patent. 3M's customers who use, make, sell, offer for sale, and/or import the Accused Products in accordance with 3M's instructions infringe at least claims 1, 2, 3, 4, 11, 12, 13, 14, 16, and 18 of the '263 patent, in violation of 35 U.S.C. § 271(a).

72. 3M actively instructs, encourages, and/or aids such infringement through various activities, including by training dental, orthodontic, and other professionals to use one or more of the Accused Products in a manner consistent with one or more claims of the '263 patent, through descriptions on its website, promotional videos, promotional material, and through product documentation.

73. 3M, in violation of 35 U.S.C. § 271(c), has indirectly infringed and continues to indirectly infringe literally and/or under the doctrine of equivalents, at least claims 1, 2, 3, 4, 11, 12, 13, 14, 16, and 18 of the '263 patent by contributing to its customers' use, making, selling, offer for sale and/or importing of one or more of the Accused Products in an infringing manner, knowing that those products are especially made or especially adapted to practice one or more of the claims of the '263 patent. 3M's customers who make, use, sell, offer for sale, and/or import the Accused Products in accordance with 3M's instructions infringe at least claims 1, 2, 3, 4, 11, 12, 13, 14, 16, and 18 of the '263 patent, in violation of 35 U.S.C. § 271(a).

74. 3M contributes to infringement by providing to its customers the Accused Products or components thereof and instructing them how to assemble, install, make, and/or use

the Accused Products, knowing that those products are especially made or adapted for use in infringement of the '263 patent.

75. The Accused Products are not staple articles of commerce.

76. The Accused Products are not suitable for substantial noninfringing uses.

77. 3M's infringement of the '263 patent has damaged and continues to damage Bay Materials. Bay Materials' injuries are irreparable and will continue unless and until 3M is enjoined by this Court from further infringement.

78. 3M knew or should have known of the '263 patent and has acted, and continues to act, in an egregious and wanton manner by knowingly infringing the '263 patents. 3M's infringement of the '263 patent has been and continues to be willful and deliberate.

COUNT II FOR PATENT INFRINGEMENT

Infringement of the '630 Patent

79. In violation of 35 U.S.C. 271(a), 3M has infringed, and will continue to infringe literally and/or under the doctrine of equivalents, one or more claims of the '630 patent, including at least claims 1, 2, 3, 7, 8, 9, and 13, by making, using, selling, offering for sale, and/or importing into the United States one or more of the Accused Products.

80. On information and belief, the Accused Products include a polymeric sheet composition comprising at least two rigid or hard outer layers A and C, comprised of a Tritan thermoplastic polymer or a similar copolyester having a flexural modulus of about 1,550 MPa, which is from about 1,000 MPa to 2,500 MPa as recited in claim 1 of the '630 patent. On information and belief, the polymeric sheet composition of the Accused Products has two elastomeric inner layers B comprised of Ecdel 9967 having a Shore hardness of about A 80 to D 75 and thus has at least one elastomeric inner layer B comprised of an elastomeric material

having a hardness from about A 80 to D 75 as claimed in claim 1 of the '630 patent. The polymeric sheet composition of the Accused Products has a flexural modulus of about 1300 MPa, which is about 750 MPa to 2,000 MPa as claimed in claim 1 of the '630 patent.

81. The A, B, and C, layers of the polymeric sheet composition of the Accused Products have a combined thickness of from 250 microns to 2,000 microns, as recited in claim 2 of the '630 patent.

82. On information and belief, the Accused Products include a polymeric sheet composition comprised of outer layers A and C comprised of a Tritan thermoplastic polymer having a hardness of about R112, which is from about R121 to D55 as recited in claim 3 of the '630 patent.

83. On information and belief, the outer layers A and C of the polymeric sheet composition of the Accused Products are comprised of a Tritan thermoplastic polymer or a similar copolyester, which is a copolyester, and are thus comprised of one or more of a polyester, a co-polyester, a polycarbonate, a polyester polycarbonate blend, a polyurethane, a polyamide, a polyolefin, a micro-crystalline polyamide, a co-polyester of terephthalic acid, cyclohexane dimethanol, and 2,2,4,4-tetramethyl-1,3-cyclobutanediol, a co-polyester of terephthalic acid, ethylene glycol and diethylene glycol, an aromatic polyurethane based on MDI and hexanediol, an aromatic polyurethane with aliphatic diols, a co-polymer of propylene, ethylene and C4 to C8 alpha olefin, a cycloaliphatic polyamide, a (meth) acrylic polymer, a vinyl polymer, polyvinyl chloride, and a fluoropolymer, as recited in claim 7 of the '630 patent.

84. On information and belief, the inner layers B of the polymeric sheet composition of the Accused Products are comprised of Ecdel 9967, which is a polyester elastomer, and are thus comprised of one or more of a polyurethane elastomer, an aromatic polyether polyurethane,

a polyolefin elastomer, a polyester elastomer, a styrenic elastomer, a polyamide elastomer, a polypropylene oxide-based polyether polyamide, a polytetramethylene oxide-based polyether polyamide, a cyclic olefin elastomer, an acrylic elastomer, an aromatic or aliphatic polyether, a polyester polyurethane, a siloxane elastomer, a polyether elastomer, a polyolefin elastomer, an olefin copolymer, and a fluoroelastomer, as recited in claim 8 of the '630 patent.

85. The Accused Products also include a dental appliance conformal to one or more teeth comprising the polymeric sheet composition as claimed in claim 9 of the '630 patent.

86. On information and belief, the Accused Products further include a dental appliance conformal to one or more teeth comprising a polymeric sheet composition, wherein outer layers A and C each comprise a Tritan thermoplastic polymer or a similar copolyester and thus comprise the same material, as claimed in claim 13 of the '630 patent.

87. 3M has been aware and on notice that Bay Materials has intellectual property covering and protecting the Zendura FLX since at least January 8, 2021. 3M has also been aware of and on notice of the '630 patent since at least as early as the service of this complaint. 3M's continued actions of making, using, selling, offering for sale, and/or importing into the United States any of the Accused Products after knowledge of the '630 patent, including after service of the Complaint, would be with 3M's knowledge of the '630 patent, knowledge of infringement of the '630 patent, intent to encourage others (e.g., its customers) to infringe the '630 patent through the Accused Products, and knowledge that 3M's encouraging acts actually result in direct infringement of the '630 patent by 3M's customers.

88. 3M had knowledge of the '630 patent or patented features of the '630 patent, or was willfully blind to the patented features of the '630 patent, before the filing and service date of this Complaint. 3M's request for a license to the '263 patent and Bay Materials' intellectual

property covering the Zendura FLX show that 3M was aware of and sought to use Bay Materials' patented invention. 3M's intention of using Bay Materials' patented invention is further illustrated by 3M's use of the name "Flex," similar to Bay Materials' "FLX," for 3M's multi-layer aligner.

89. 3M, in violation of 35 U.S.C. 271(b), has indirectly infringed and continues to indirectly infringe literally and/or under the doctrine of equivalents at least claims 1, 2, 3, 7, 8, 9, and 13 of the '630 patent by actively inducing others to use, make, sell, offer for sale and/or import one or more of the Accused Products in an infringing manner, knowing such acts would constitute infringement of the '630 patent. 3M's customers who use, make, sell, offer for sale, and/or import the Accused Products in accordance with 3M's instructions infringe at least claims 1, 2, 3, 7, 8, 9, and 13 of the '630 patent, in violation of 35 U.S.C. § 271(a).

90. 3M actively instructs, encourages, and/or aids such infringement through various activities, including by training dental, orthodontic, and other professionals to use one or more of the Accused Products in a manner consistent with one or more claims of the '630 patent, through descriptions on its website, promotional videos, promotional material, and through product documentation.

91. 3M, in violation of 35 U.S.C. § 271(c), has indirectly infringed and continues to indirectly infringe literally and/or under the doctrine of equivalents, at least claims 1, 2, 3, 7, 8, 9, and 13 of the '630 patent by contributing to its customers' use, making, selling, offer for sale and/or importing of one or more of the Accused Products in an infringing manner, knowing that those products are especially made or especially adapted to practice one or more of the claims of the '630 patent. 3M's customers who make, use, sell, offer for sale, and/or import the Accused

Products in accordance with 3M's instructions infringe at least claims 1, 2, 3, 7, 8, 9, and 13 of the '630 patent, in violation of 35 U.S.C. § 271(a).

92. 3M contributes to infringement by providing to its customers the Accused Products or components thereof and instructing them how to assemble, install, make, and/or use the Accused Products, knowing that those products are especially made or adapted for use in infringement of the '630 patent.

93. The Accused Products are not staple articles of commerce.

94. The Accused Products are not suitable for substantial noninfringing uses.

95. 3M's infringement of the '630 patent has damaged and continues to damage Bay Materials. Bay Materials' injuries are irreparable and will continue unless and until 3M is enjoined by this Court from further infringement.

96. 3M knew or should have known of the '630 patent and has acted, and continues to act, in an egregious and wanton manner by knowingly infringing the '630 patents. 3M's infringement of the '630 patent has been and continues to be willful and deliberate.

REQUEST FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that the Court enter judgment in its favor and against 3M and grant the following relief:

A. The entry of judgment that 3M directly or indirectly infringes at least one claim of both the '263 and '630 patents under at least 35 U.S.C. §§ 271(a), (b) and/or (c);

B. The entry of a preliminary injunction, enjoining 3M and all persons acting in concert or participation with 3M from further acts of direct and/or indirect infringement of the '263 and '630 patents until there has been a trial on the merits;

C. An award to Plaintiff of damages adequate to compensate Plaintiff for 3M's acts of patent infringement, together with prejudgment and post-judgment interest under 35 U.S.C. § 284 and other permitted costs, expenses, and disbursements;

D. A declaration or order finding that 3M's infringement is willful and an award to Plaintiff of all other damages permitted by 35 U.S.C. § 284, including enhanced damages up to three times the amount of compensatory damages found;

E. The entry of a permanent injunction, enjoining 3M, all persons acting in concert or participation with 3M, all parent and subsidiary corporations and affiliates, and their assigns and successors in interest from continuing acts of infringement of the '263 and '630 patents;

F. The entry of a judgment that this is an exceptional case and awarding to Plaintiff its reasonable attorneys' fees and costs pursuant to 35 U.S.C. § 285; and

G. Such other and further relief in law or equity as the Court deems just and appropriate.

DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff respectfully requests a trial by jury on all claims and issues so triable.

ASHBY & GEDDES

/s/ Steven J. Balick

Steven J. Balick (#2114)
Andrew C. Mayo (#5207)
500 Delaware Avenue, 8th Floor
P.O. Box 1150
Wilmington, Delaware 19899
(302) 654-1888
sbalick@ashbygeddes.com
amayo@ashbygeddes.com

Attorneys for Bay Materials, LLC

Of Counsel:

J. Michael Jakes
Kathleen A. Daley
Charles T. Collins-Chase
Andrew E. Renison
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, LLP
901 New York Avenue, NW
Washington, DC 20001-4431
(202) 408-4000

Dated: November 15, 2021