

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

BAY MATERIALS, LLC,

Plaintiff,

v.

3M COMPANY,

Defendant.

C.A. No. 21-1610-UNA



**OPENING BRIEF IN SUPPORT OF PLAINTIFF BAY MATERIALS'
MOTION FOR PRELIMINARY INJUNCTION**

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I. INTRODUCTION

Plaintiff Bay Materials, LLC (“Bay”) seeks a preliminary injunction to protect its industry-leading multilayer polymer sheet material, Zendura™ FLX. Defendant 3M Company (“3M”) is knowingly infringing Bay’s patents covering Zendura FLX.

Zendura FLX is used in orthodontic clear aligners for straightening teeth and is Bay’s flagship product. While 3M was developing its new aligner, it obtained samples of Zendura FLX and sought, but did not obtain, a license to Bay’s patents. 3M nonetheless recently released Clarity™ Aligners Flex orthodontic aligners (“Clarity Flex”), which copy Bay’s patented invention. Now, armed with a copy of Bay’s multilayer aligner material, 3M can use its size, existing dental business and relationships, and position as both a polymer sheet manufacturer and aligner supplier, to take customers from Bay and the companies that buy Zendura FLX for its superior qualities. 3M’s release of Clarity Flex also robs Bay of its key market differentiator. The resulting loss of sales, revenue, customers, and market share will be devastating to Bay.

A preliminary injunction is needed to protect Bay’s relationship with its customers, business opportunities, revenue, market share, and future growth. Bay asks that 3M be preliminarily enjoined from making, using, selling, and offering for sale its Clarity Flex aligner and the polymer sheet material used to make Clarity Flex, which infringe Bay’s U.S. Patent Nos. 10,870,263 and 10,946,630, so that Bay is not irreparably harmed before trial.

II. NATURE AND STAGE OF THE PROCEEDINGS

Bay filed this action on November 15, 2021, and also moved for a preliminary injunction. Bay submits this opening brief in support of that motion, along with the accompanying declarations of Tim A. Osswald, PhD, W. Todd Schoettelkotte, John Lahlouh, Tom Ross, Christophe Carsault, and Diyun Huang. Bay will also seek targeted and expedited discovery.

III. SUMMARY OF THE ARGUMENT

1. Bay is likely to succeed on the merits. 3M's Clarity Flex infringes the '263 and '630 patents, as shown by testing of a sample Clarity Flex aligner and 3M's own advertising and patent application. This is not surprising as 3M obtained samples of Bay's patented Zendura FLX before releasing Clarity Flex and then unsuccessfully sought a license to Bay's patents.

2. Bay will be irreparably harmed absent a preliminary injunction. Zendura FLX is Bay's core product and one of only two products it sells. Allowing 3M's infringement to go unchecked will have devastating consequences for Bay and its customers, [REDACTED].

[REDACTED]

3. The balance of hardships weighs heavily in favor of a preliminary injunction. 3M only recently launched Clarity Flex and can continue marketing its single-layer aligner. But Bay will be devastated by loss of sales, opportunities, and future growth caused by 3M's infringement.

4. It is also in the public interest to stop infringing products, particularly in this case where 3M knowingly and purposefully copied Bay's Zendura FLX.

IV. STATEMENT OF FACTS

A. Bay Materials is the leader in polymer material for clear aligners

Bay, a once-small start-up founded in 1999 by Ray Stewart PhD, is now the technological leader and innovator in polymeric materials used for clear aligners. Ross Decl. ¶¶ 9-15; Lahlouh Decl. ¶¶ 5-11. That did not happen overnight or accidentally. Instead, through years of innovation, Bay established itself as the provider of the best clear aligner material on the market.

Clear aligners are used in place of braces to apply gentle pressure to move teeth. Carsault Decl. ¶ 16. Aligners are made from a polymer sheet material that is thermoformed or pressed to conform to a patient's teeth. *Id.* The treatment requires creating a series of aligners that are used sequentially by patients until their teeth reach the desired position. *Id.* On average, the process

takes 12 months but can vary from 6 months to 36 months, depending on the case complexity. *Id.* The quality of the aligner material is central to its effectiveness and to patients' and practitioners' perceptions of the aligner. *Id.* ¶¶ 19-20; Ross Decl. ¶¶ 7, 15.

Dr. Stewart and Bay developed the advanced polymer material that Align Technology used in its original Invisalign clear aligner. Ross Decl. ¶ 9; Lahlouh Decl. ¶ 5. After creating this first aligner material, Bay developed an improved material in 2010, which it now calls "Zendura A." Lahlouh Decl. ¶¶ 5-6. Zendura A, a single-layer polymer that can be thermoformed into an aligner or retainer, became the industry benchmark material. *Id.* But even with the top aligner material on the market, Bay sought an even better material. *Id.* ¶ 9. Bay recognized that single-layer polymer aligners had shortcomings. If the single layer is too hard, it can be uncomfortable to wear and have difficulty withstanding certain forces. *Id.* ¶ 13; Ross Decl. ¶ 12. A softer material may not be strong enough to move a patient's teeth and may scratch or stain easily. *Id.* After years of research and investigating at least two hundred materials and various processing conditions, Bay developed Zendura FLX, a transformative multi-layer aligner material. Lahlouh Decl. ¶¶ 9-12.

Since its release in November 2018, Zendura FLX has been a huge success. Sales of Zendura FLX have overtaken and far surpassed Zendura A to become Bay's core product. Ross Decl. ¶ 14; Schoettelkotte Decl. ¶¶ 61-68. Bay's annual sales grew from about [REDACTED], largely due to Zendura FLX. Ross Decl. ¶ 14. In 2021, about [REDACTED] come from Zendura FLX. *Id.* ¶ 9. The remaining sales come from Zendura A. *Id.* ¶¶ 9-10, 14. Based on the strength and success of Zendura FLX, Bay was acquired by the Straumann Group in October 2019. *Id.* ¶ 9.

B. Zendura FLX and the '263 and '630 patents

Zendura FLX is a multi-layer aligner material that has two harder polymer outer layers

with a softer elastomer inner layer in between, called a “hard-soft-hard” configuration. Lahlouh Decl. ¶ 12. The inventors discovered that this configuration provided desirable properties that a single-layer material could not. *Id.* ¶ 10. They discovered that using a harder polymer with certain properties as the outer layers and a different, softer polymer with certain properties as the inner layer yielded an aligner that, surprisingly, had greater force persistence for moving teeth, better elastic properties for patient comfort, and greater resistance to cracking, tearing, and staining than other aligner material. *Id.* ¶¶ 12-29; ’630 patent at 16:33-17:46, 18:32-19:25, 20:10-22. The specific polymers and properties of Zendura FLX provide an ideal combination of consistent force for teeth movement and good comfort levels for patients. Lahlouh Decl. ¶ 11.

When Bay developed Zendura FLX, the industry believed that the outer aligner layer near a patient’s teeth should be soft to provide comfort. *Id.* ¶ 13. It was also known that hard polymers were prone to stress cracking and degradation when used in wet, humid environments like the mouth. *Id.*; ’630 patent at 19:63-66. As a result, one would not have sought to use a hard polymer material as an outer layer in a multilayer sheet for an aligner. Lahlouh Decl. ¶ 13. In other words, based on common knowledge in the aligner materials field, the hard-soft-hard structure of Zendura FLX should not have been successful. *Id.* ¶ 12. But it has been successful and has exceeded all expectations due to its unique configuration. *Id.* ¶¶ 11, 15-29.

Zendura FLX has significantly better properties than other aligner materials, including a multilayer aligner material made by Align with a soft-hard-soft structure. Lahlouh Decl. ¶¶ 14-26; ’630 patent at 16:33-17:46, 18:32-19:25, 20:10-22. For instance, Zendura FLX has a substantially lower initial force (making it more comfortable when inserted in the mouth) but retains a higher force over time (meaning it can maintain forces on teeth longer), which is critical to successfully moving teeth. Lahlouh Decl. ¶¶ 7, 17-29; ’630 patent at 17:25-38. Zendura FLX

also exponentially improves tear resistance and has much less stress cracking. Lahlouh Decl.

¶¶ 17-20; '630 patent at 17:39-56, 20:10-22. It is also more elastic and stain resistant than other aligner materials, which is important because patients directly observe those properties. Lahlouh Decl. ¶¶ 24-25; '630 patent at 18:32-55; Carsault Decl. ¶¶ 11 19-20.

Bay sought and obtained patents, such as the '263 and '630 patents, covering its inventive multilayer polymer materials, including Zendura FLX. In the '263 and '630 patents, the inventors disclose multilayer aligner sheets with improved properties. The patents disclose three-layer aligner sheets having a hard-soft-hard configuration, as well as five-layer aligner sheets having a hard-soft-hard-soft-hard configuration. The patents also describe the polymers and properties that provide the improved aligner characteristics.

C. Clear Aligner Market

Aligners are generally sold through two markets: (1) the doctor-directed market, where companies supply aligners to dentists and orthodontists who provide them to their patients, and (2) the direct-to-consumer market, where companies target consumers directly. Carsault Decl. ¶ 5; Ross Decl. ¶ 5. The doctor-directed market further has an orthodontic channel and a general practitioner channel, which includes dentists. Carsault Decl. ¶ 6; Ross Decl. ¶ 5. Dentists and orthodontists often practice as part of groups. They also frequently join dental service organizations (DSOs), which can manage and support affiliated practices, or group purchasing organizations (GPOs), which negotiate supply contracts for members. Carsault Decl. ¶¶ 7-9.

Align has the largest share of the clear aligner market, including around 85% of the doctor-directed market. Carsault Decl. ¶ 13; Schoettelkotte Decl. ¶ 20. The market behind Align is very competitive, with the remaining aligner firms competing for the other 15% while also trying to cut into Align's share. Carsault Decl. ¶ 13; Ross Decl. ¶¶ 8, 15. When competing in that tight space, the quality of the material used for the aligner can be a key differentiator from Align

and other competitors. Carsault Decl. ¶ 13; Ross Decl. ¶ 15; Schoettelkotte Decl. ¶¶ 78-100.

Bay sells Zendura FLX to aligner companies, DSOs, and dental and orthodontic practices. Ross Decl. ¶ 16. Two of Bay's biggest U.S. customers for Zendura FLX are [REDACTED]. Ross Decl. ¶ 16. Their purchases make up the majority of Bay's U.S. revenue. Schoettelkotte Decl. ¶¶ 38, 46, 74-77. Ross Decl. ¶¶ 16-17. [REDACTED]

[REDACTED]. Ross Decl. ¶ 18. In that way, Bay's customers have leading positions [REDACTED].

Dentists and orthodontists usually stick to one aligner provider. Ross Decl. ¶ 7; Carsault Decl. ¶¶ 10-12. There are several reasons for this, including that the comfort and effectiveness of an aligner directly impacts the practitioner-patient relationship. Carsault Decl. ¶¶ 8-11. Aligner companies also frequently provide discounts, which encourages practices, and especially DSOs, to order one brand of aligners in high volumes and stick with that brand. *Id.* Practitioners may also incur upfront training costs, leading them not to switch brands. *Id.*

In the doctor-directed market, practitioners act as an intermediary between patients and aligner companies. *Id.* ¶¶ 7-12. Aligner companies thus seek to obtain dentist and orthodontist customers, including practice groups, DSOs, and GPOs, who will purchase aligners for their patients for many years. *Id.* As a result, aligner companies do not lose individual sales to competitors in a traditional sense. They lose entire practice groups or even DSOs and GPOs, which leads to losing many sales to those members' patients for years. *Id.* In this way, the loss of one "customer" is far reaching and has a long-term impact. *Id.* In turn, the aligner manufacturer that supplies aligner sheets to that aligner company suffers an equivalent loss. Ross Decl. ¶ 19.

D. 3M and Clarity Aligners Flex + Force

3M is a large, established provider of dental and orthodontic products. Carsault Decl. ¶ 25. Its products can be found in most dentist and orthodontic offices. 3M’s business includes bracket and wire braces. *Id.* When 3M sought a clear aligner in 2018, it turned to Bay for help. Ross Decl. ¶ 20. While 3M liked Bay’s Zendura material, it wanted something cheaper. *Id.* In May 2018, 3M released its single-layer Clarity aligner. *Id.* Despite 3M’s size and experience in the dental and orthodontics space, it has struggled to compete effectively in a market that is moving on to multi-layer aligners. *Id.*; Carsault Decl. ¶ 25. When 3M wanted to enter the multi-layer aligner market, it again turned to Bay. In January 2021, the head of 3M’s Orthodontic Business emailed Bay, stating that he saw Bay’s press release about its patent covering Zendura FLX and that 3M was interested in discussing it. Ross Decl. ¶ 22. 3M representatives met with Bay about licensing the ’263 patent and other patents. *Id.* 3M did not obtain a license.

In July 2021, 3M nonetheless announced the release of Clarity Flex, a knockoff five-layer version of Bay’s hard-soft-hard aligner. Clarity Flex’s configuration is disclosed and claimed in Bay’s patents. 3M says it created “a new aligner from scratch.” D.I. 1, Ex. K at 3. It didn’t. In April 2018, 3M obtained samples of Zendura FLX from Bay. Ross Decl. ¶ 21. And in January 2020, 3M purchased Zendura FLX. *Id.* Instead of selling aligners made from Zendura FLX, 3M copied it. 3M touts all the same improved properties of Zendura FLX, *id.* ¶ 24, as taught by the ’263 and ’630 patents. 3M even borrowed Bay’s product name, using “Flex” instead of “FLX,” signaling to Bay’s customers and others that Clarity Flex is equivalent to Zendura FLX.

V. ARGUMENT

A court may grant preliminary injunctive relief “to prevent the violation of any right secured by patent.” 35 U.S.C. § 283. Federal Circuit law governs the decision to preliminarily enjoin patent infringement. *Revision Military, Inc. v. Balboa Mfg. Co.*, 700 F.3d 524, 525 (Fed.

Cir. 2012). Courts must evaluate four factors: “(1) the likelihood of the patentee’s success on the merits; (2) irreparable harm if the injunction is not granted; (3) the balance of hardships between the parties; and (4) the public interest.” *Tinnus Enterprises, LLC v. Telebrands Corp.*, 846 F.3d 1190, 1202 (Fed. Cir. 2017). Courts “weigh and measure each factor against the other factors and against the form and magnitude of the relief requested.” *Hybritech Inc. v. Abbott Labs.*, 849 F.2d 1446, 1451 (Fed. Cir. 1988). Granting injunctive relief “is an act of equitable discretion by the district court.” *eBay Materials Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006).

A. Bay Materials Is Likely to Succeed on the Merits

To show likelihood of success, a patentee must demonstrate that it “will likely prove infringement of one or more claims of the patents-in-suit, and that at least one of those same allegedly infringed claims will also likely withstand the validity challenges presented by the accused infringer.” *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1050 (Fed. Cir. 2010) (citation and internal quotation omitted). Bay focuses this motion on a subset of infringed claims: claims 11, 12, and 18 of the ’263 patent and claims 1, 2, and 9 of the ’630 patent.

1. Bay Materials is likely to succeed on infringement

3M infringes the asserted claims by making, using, and selling Clarity Flex aligners. The declaration of Dr. Tim Osswald, an expert in polymers, sets forth an element-by-element analysis of 3M’s infringement. Osswald Decl. ¶¶ 93-139. Dr. Osswald explains how testing performed on a Clarity Flex aligner sample, as well 3M’s own descriptions of Clarity Flex and disclosures in its patent applications, show that Clarity Flex has the specific polymer materials and properties recited in the asserted claims. *Id.* The evidence of infringement is summarized below.

a. Claim 11 of the ’263 patent and claim 1 of the ’630 patent

Clarity Flex has the claimed layers

Clarity Flex is a “polymeric sheet composition” with the layers of claim 11 of the ’263

patent and claim 1 of the '630 patent. Clarity Flex is made from a five-layer polymeric sheet having sequential rigid-soft-rigid-soft-rigid layers. Clarity Flex thus has two rigid outer layers A and C (layers "1" and "5"), two soft inner layers B and B' (layers "2" and "4"), and a rigid core layer D (layer "3"), as in claim 11 of the '263 patent. Osswald Decl. ¶¶ 56-60, 124-31. It also has two outer layers A and C and an elastomeric inner layer B, as in claim 1 of the '630 patent. *Id.* ¶¶ 56-60, 98-103. 3M depicts layers 1, 3, and 5 as being made from the same polymer and layers 2 and 4 as being made from the same polymer, but different from layers 1, 3, and 5. *Id.* ¶¶ 56-60. Testing confirms that layers 1, 3, and 5 of Clarity Flex are the same hard or rigid copolyester and layers 2 and 4 are the same soft elastomeric polymer. *Id.* ¶¶ 68-92, 97, 102-05, 129-33. 3M also describes Clarity Flex as made from "copolyesters," which are polymers, and states that it "developed the layers with varying levels of stiffness and flexibility." D.I. 1, Ex. K at 3.

Clarity Flex has the claimed rigid layers and claimed outer layers

Clarity Flex has at least two rigid outer layers and a rigid core layer comprising a thermoplastic polymer having a modulus from 1,000 MPa to 2,500 MPa, as in claim 11 of the '263 patent. Likewise, Clarity Flex has at least two outer layers comprising a polyester or copolyester having a modulus from 1,000 MPa to 2,500 MPa, as in claim 1 of the '630 patent.

Outer layers 1 and 5 and core layer 3 of Clarity Flex are made from a polymer that has a modulus greater than 1,000 MPa, making those layers rigid. *See, e.g.*, '263 patent at Abstract; 5:15-25, 9:20-28, 10:52-64, 12:31-34. Testing of a Clarity Flex aligner sample showed that outer layers 1 and 5 and core layer 3 are made from Tritan MX710 or a polymer with similar properties. Osswald Decl. ¶¶ 75, 77, 89-90, 102-103, 129-30. Tritan MX710 is a polymer having a modulus of 1,550 MPa. Osswald Decl. ¶¶ 67, 104-105, 128, 132. 3M's patent application, disclosing 5-layer aligners, confirms that layers 1, 3, and 5 of Clarity Flex are likely made from

Tritan MX710. Osswald Decl. ¶¶ 64-66, 101, 127-28. There, 3M discloses an embodiment having the exact same sheet thickness as the marketed Clarity Flex and describes layers 1, 3, and 5 as being made from Tritan MX710. *Id.*; *see also* WO '657, ¶ 97.

Clarity Flex has the claimed soft inner layers and claimed elastomeric layer

Clarity Flex has at least two soft inner layers comprised of an elastomeric material having hardness from about A 60 to D 85, as in claim 11 of the '263 patent. Likewise, the Clarity Flex aligner has at least one elastomeric inner layer comprised of an elastomeric material having a hardness from about A 80 to D 75, as in claim 1 of the '630 patent.

Inner layers 2 and 4 of Clarity Flex are made from an elastomeric polymer and are soft, elastic inner layers. Osswald Decl. ¶¶ 102-07, 129-34. Testing of a Clarity Flex aligner sample showed that inner layers 2 and 4 are made from Ecdel 9967 or a polymer with similar properties. *Id.* ¶¶ 72-76, 79, 91-92, 102-07, 129-34. Ecdel 9967 is an elastomeric polymer with a Shore hardness of A95 or D55. *Id.* ¶¶ 67, 106, 133. 3M's patent application example matching Clarity Flex confirms that layers 2 and 4 are likely made from Ecdel 9967. *Id.* ¶¶ 101, 127-28.

Clarity Flex has the flexural modulus claimed in the '630 patent

Clarity Flex has a flexural modulus of about 1,300 MPa, within the 750 to 2,000 MPa range of claim 1 of the '630 patent. Osswald Decl. ¶¶ 108-110. 3M reports the elastic modulus of Clarity Flex as about 1.3 GPa or 1,300 MPa. *Id.* ¶¶ 63, 108. As Dr. Osswald explains, the flexural modulus of Clarity Flex is similar to its elastic modulus and can be related through specific equations. *Id.* ¶¶ 29-47, 109. Using those equations, he confirmed that Clarity Flex's flexural modulus is about 1,300 MP, within the range in claim 1 of the '630. *Id.* ¶¶ 108-110.

b. Claim 12 of the '263 patent and claim 2 of the '630 patent

Clarity Flex has a combined thickness of from 250 to 2,500 microns and a flexural modulus of from 500 to 2,500 MPa, as in claim 12 of the '263 patent. 3M states that Clarity Flex

sheet material is 625 microns thick. Osswald Decl. ¶¶ 61, 65, 111, 135. As noted above, Clarity Flex has a flexural modulus of about 1,300 MPa. *Id.* ¶¶ 108-10, 138.

Outer layers 1 and 5 and inner layers 2 and 4 of the sheet material used for Clarity Flex have a combined thickness greater than 250 microns and less than 2,000 microns, as in claim 2 of the '630 patent. Thermoforming reduces the thickness of a polymer sheet. *Id.* ¶¶ 112-16. As a result, a sample Clarity Flex thermoformed into an aligner was measured to be between 422-508 microns, rather than 625 microns, thick. *Id.* ¶¶ 112-16, 136. Dr. Osswald extrapolated the thickness that each layer of the sample would have had prior to thermoforming and determined that outer layers 1 and 5 and inner layers 2 and 4 would have a combined thickness greater than 250 microns and less than 2,000 microns. *Id.* ¶¶ 116-17.

c. Claim 18 of the '263 patent and Claim 9 of the '630 patent

Clarity Flex is a dental appliance conformal to one or more teeth, as in claim 18 of the '263 patent and claim 9 of the '630 patent. 3M promotes Clarity Flex as an orthodontic device “composed of thermoplastic resin” that “moves the teeth by continuous gentle force for treatment of minor tooth malocclusion” and thus conforms to teeth. Osswald Decl. ¶¶ 118, 139.

2. Bay Materials Is Likely to Succeed on Validity

A patent is presumed valid, and this presumption applies through all stages of litigation, including in a preliminary injunction proceeding. 35 U.S.C. § 282; *see also Canon Computer Sys., Inc. v. Nu-Kote Int'l, Inc.*, 134 F.3d 1085, 1088 (Fed. Cir. 1998). For that reason, “the burden is on the challenger to come forward with evidence of invalidity, just as it would be at trial.” *Titan Tire Corp. v. Case New Holland, Inc.*, 566 F.3d 1372, 1377 (Fed. Cir. 2009). 3M must show that “it is more likely than not that [it] will be able to prove at trial, by clear and convincing evidence, that the patent is invalid.” *Id.* at 1379.

Here, 3M will not be able to show clear and convincing evidence of invalidity. This is

particularly so because the claimed inventions unexpectedly provide greatly improved properties over existing aligner material, were copied by 3M, and have had great commercial success. *See, e.g., Forest Labs., Inc. v. Ivax Pharms., Inc.*, 501 F.3d 1263, 1267, 1269 (Fed. Cir. 2007) (finding that commercial success, unexpected results, and copying supported validity); *Dow Chem. Co. v. Am. Cyanamid Co.*, 816 F.2d 617, 621-23 (Fed. Cir. 1987) (same).

Zendura FLX surpasses the other aligner materials on the market, including Align’s multilayer aligner. Lahlouh Decl. ¶¶ 15-29. Zendura FLX has improved tear strength, stress relaxation, durability, force retention, and elastic recovery, as well as reduced stress cracking and staining. *Id.* Contrary to conventional thinking, even though Zendura FLX has a hard outer layer, it is also more elastic and more comfortable than Align’s aligner with soft outer layers. *Id.*, ¶¶ 11-29. And Zendura FLX is effective at moving teeth over a longer time. *Id.*, 17-29.

3M itself recognizes and touts the “synergistic” effect that the claimed combination of layers provides. D.I. 1, Ex. K at 3. When developing Clarity Flex, 3M acknowledged that “it’s challenging to combine the flexibility needed for easy insertion and removal with the durability needed for force persistence and cracking resistance.” *Id.* at 2. To meet that challenge, 3M did not imitate Align’s soft-hard-soft configuration, nor did 3M create a novel material of its own. Instead, it obtained Zendura FLX samples, Ross Decl. ¶ 21, and then copied them. 3M chose a hard-soft-hard configuration just like Bay’s claimed inventions—opting for the hard-soft-hard-soft-hard embodiment in Bay’s patents.

Zendura FLX has also been hugely successful, undermining any argument of obviousness. *Supra*, V.B. Zendura FLX is covered by and coextensive with at least one claim of each of the ’263 and ’630 patents. Osswald Decl. ¶¶ 51-55. And it has not only driven Bay’s growth, [REDACTED]. Ross Decl. ¶¶ 9, 14, 16-18; Carsault Decl.

¶ 21; Schoettelkotte Decl. ¶¶ 61-68, 86-91, 99. Bay's success is directly attributable to the claimed invention, as it outperformed Bay's single-layer Zendura A polymer. Schoettelkotte Decl. ¶¶ 61-68. [REDACTED]

[REDACTED] Carsault Decl. ¶ 23. [REDACTED]. *Id.*; Schoettelkotte Decl. ¶ 97. Given the strong evidence of nonobviousness, 3M will not be able to prevail on a validity challenge.

B. Bay Materials Will Suffer Irreparable Harm Absent Injunctive Relief

“A party seeking a preliminary injunction must establish that it is likely to suffer irreparable harm if the preliminary injunction is not granted and there is a causal nexus between the alleged infringement and the alleged harm.” *Metalcraft of Mayville, Inc. v. The Toro Co.*, 848 F.3d 1358, 1368 (Fed. Cir. 2017). “Where the injury cannot be quantified, no amount of money damages is calculable, and therefore the harm cannot be adequately compensated and is irreparable.” *Id.* At the same time, “the simple fact that one could, if pressed, compute a money damage award does not always preclude a finding of irreparable harm.” *Celsis In Vitro, Inc. v. Cellzdirect, Inc.*, 664 F.3d 922, 930 (Fed. Cir. 2012). Injuries found to be irreparable are wide-ranging, including lost customers, business opportunities, market share, or reputation. *See, e.g., id.*; *Metalcraft*, 848 F.3d at 1368; *Nevro Corp. v. Stimwave Techs., Inc.*, 2019 WL 3322368, at *14-15 (D. Del. Jul. 24, 2019); *M/A-COM Tech. Solutions Holdings, Inc. v. Laird Techs., Inc.*, 2014 WL2727198, at *15-23 (D. Del. June 13, 2014).

Bay faces irreparable harm from 3M's infringement. Bay and its customers, [REDACTED], rely on Zendura FLX and its superior properties to differentiate themselves in a competitive market. [REDACTED] do not just lose sales to individuals who use a competitor's aligner—they lose customers who provide aligners to their patients and thus represent an untold number of lost sales over the course of a long-term relationship.

Permitting 3M's infringement to continue unchecked will eliminate the key differentiator that Zendura FLX provides, resulting in lost customers, business opportunities, market share, and growth. Further, practitioners in this field generally use one aligner brand and stick with it, so customers and market share are difficult to recover. This risk is particularly acute where the accused infringer has a large presence in a competitive field, as 3M does in the dental and orthodontic field. Economic expert Todd Schoettelkotte explains why these harms are irreparable and why Bay could not be fully compensated for them. Schoettelkotte Decl. ¶¶ 53-166.

1. 3M's infringing sales will cause Bay Materials to lose customers, business opportunities, revenue, and market share for its core, flagship product

The clear aligner market is highly competitive, particularly in the space behind Align. Schoettelkotte Decl. ¶ 21; Carsault Decl. ¶ 13. Bay's ability to differentiate itself as the leader for innovative aligner material has been critical to its success. Schoettelkotte Decl. ¶¶ 60, 64, 78-100; Carsault Decl. ¶¶ 19-20, 28; Ross Decl. ¶¶ 9, 15. [REDACTED]

[REDACTED] Additionally, Zendura FLX is the best aligner material on the market today. Lahlouh Decl. ¶¶ 12-29. Zendura FLX is the reason for Bay's success today. Ross Decl. ¶¶ 9, 14-15. It also enables Bay's customers [REDACTED] to differentiate themselves and lead the aligner market [REDACTED]. *Id.* ¶¶ 14-19; Carsault Decl. ¶¶ 19-24, 28; Schoettelkotte Decl. ¶¶ 78-100. 3M's entrance with an infringing multi-layer aligner threatens to erase Bay's hard-fought gains and limit Bay's future growth.

a. Bay Materials directly competes with 3M in the doctor-directed market

Bay's sales to DSOs, dentists, and orthodontists who thermoform Zendura FLX into aligners allow Bay to directly compete with 3M in the doctor-directed market. Ross Decl. ¶ 16. And Bay's two largest U.S. partners, [REDACTED] also compete directly with 3M

[REDACTED]. Ross Decl. ¶ 8; Carsault Decl. ¶ 14. [REDACTED] have achieved these [REDACTED] based on the differentiating and superior properties of Zendura FLX. Ross Decl. ¶ 14-15, 18; Carsault Decl. ¶ 23; Schoettelkotte Decl. ¶¶ 86-92, 100, 161. Losing this market differentiator will cause long-lasting and irreversible harm to their market positions and to Bay's ability to sell aligner material. Schoettelkotte Decl. ¶¶ 100, 113-114, 129, 160, 164-166. Indeed, when [REDACTED] lose a customer and the resulting sales to patients for many years, Bay loses an equivalent number of sales. *Id.*; Ross Decl. ¶ 19.

3M has been touting the same features that make Zendura FLX superior and differentiate it from other aligner materials, making it likely that 3M will get traction with [REDACTED] customers. Carsault Decl. ¶ 26; Ross Decl. ¶ 24. 3M also has a full suite of products in the dental and orthodontic channels. Schoettelkotte Decl. ¶¶ 120-129. With its infringing aligner, 3M is in a unique position to leverage its size, resources, relationship with practitioners, and market share in adjacent markets to capture the customers and market of [REDACTED]—Bay's leading customers. *Id.* See *SiOnyx, LLC v. Hamamatsu Photonics K.K.*, 2019 WL 3358599, at *3 (D. Mass. July 25, 2019), *aff'd*, 981 F.3d 1339 (Fed. Cir. 2020) (“SiOnyx was a small startup, competing against a large foreign manufacturer, and it is impossible to quantify the full extent of the harms, including such things as loss of market share, lost business opportunity, and harm to reputation.”).

b. A customer lost to 3M will cause cascading, unquantifiable harms

The nature of the doctor-directed aligner market compounds the likely harm to Bay. An aligner company does not lose only a direct sale to an end user (the patient) to a competitor—it loses entire DSOs, GPOs, and dental/orthodontic practices, who in turn provide aligners to numerous patients, effectively acting as regional sales hubs. Carsault Decl. ¶¶ 7-12. Particularly

for regional DSOs, but also for dentists or orthodontists in smaller communities, losing one customer can represent the loss of an entire region, with profound impacts on future business opportunities in that region. *Id.* Also, DSO and GPO memberships often continue to grow, so losing even one of them can lead to lost access to substantial current and future business. *Id.*

¶ 12; Schoettelkotte Decl. ¶¶ 143-150. Monetary damages cannot compensate for this harm. *See Metalcraft*, 848 F.3d at 1368 (“[T]he loss by [patentee] of customers may have far-reaching, long-term impact on its future revenues, and the sales lost by [patentee] are difficult to quantify due to ecosystem effects, where one company’s customers will continue to buy that company’s products and recommend them to others.”) (citation and internal quotations omitted). Loss of customers, as well as loss of access to current and potential future customers, is precisely the type of harm courts have recognized when granting preliminary injunctions. *See Metalcraft*, 848 F.3d at 1368 (agreeing that “it is impossible to quantify the damages caused by the loss of a potentially lifelong customer”); *Robert Bosch LLC v. Pylon Mfg. Corp.*, 659 F.3d 1142, 1151-55 (Fed. Cir. 2011) (finding irreparable harm where patentee showed lost market share and access to potential customers); *Celsis*, 664 F.3d at 930 (stating that loss of business opportunities supports irreparable harm).

Further, practitioners generally use only one brand of aligner and stick with that brand. Carsault Decl. ¶¶ 10-12; Schoettelkotte Decl. ¶¶ 60, 130-151. They usually do not purchase some aligners from one company and some from another company. Carsault Decl. ¶¶ 10-12. This is particularly true for DSOs who get deep discounts based on purchase volume and represent many practitioners. *Id.* ¶¶ 8, 11. The “stickiness” in this market is even more pronounced because a patient’s treatment plan requires using several aligners that progressively move the patient’s teeth over the course of months to years, so Bay and its customers lose numerous “sales” every

time a practitioner starts just one patient on a treatment plan using another company's aligners. *Id.* ¶ 12. As a result, aligner companies do not lose sales in the traditional sense—they lose practitioner customers who account for untold sales of aligners to their patients, now and in the future. *Id.*; Schoettelkotte Decl. ¶¶ 136, 151.

██████████ were able to overcome these market barriers based on the patented and differentiating Zendura FLX aligner material ██████████. If 3M's infringement continues, ██████████ will lose their key differentiator, leading to potential loss of customers, relationships, market presence, and future growth, not just sales, to 3M. *See, e.g., Nevro*, 2019 WL 3322368, at *14. The loss of even one customer by ██████████ can have a significant, negative impact on Bay's sales of aligner material, profits, market position, and future growth. Schoettelkotte Decl. ¶¶ 136, 151, 160-166. *See Mytee Prod., Inc. v. Harris Rsch., Inc.*, 439 F. App'x 882, 888 (Fed. Cir. 2011) (affirming permanent injunction awarded for harm experienced through the patentee's franchisees).

Here, the potential loss of customers and market share must be stopped at the outset because the harm will occur long before it can be detected. Market dynamics, including the duration of a patient's treatment plan and the long but varied product cycle of clear aligners, means that an aligner company cannot immediately know it has lost a customer. Carsault Decl. ¶ 29; Schoettelkotte Decl. ¶ 151. Once the company learns that a customer has switched, that customer has already started patients on new treatment plans with the new aligner; it is too late to get the customer back. Carsault Decl. ¶ 29. This issue is exacerbated for Bay, which does not know when aligner company customers lose their customers, but later feels the impact when their orders are reduced. Ross Decl. ¶ 19; Schoettelkotte Decl. ¶ 151. *See Celsis*, 664 F.3d at 922 ("There is no effective way to measure the loss of sales or potential growth—to ascertain the

people who do not knock on the door or to identify the specific persons who do not reorder because of the existence of the infringer.’’). Injunctive relief thus is particularly appropriate here.

c. Bay Materials’ core product will be harmed, and Bay will lose its position as the technological leader and innovator in the aligner material market

Any threat to Zendura FLX will devastate Bay. *See* Schoettelkotte Decl. ¶¶ 58-68. It is Bay’s flagship product and is expected to account for ████████ of Bay’s global profits in the next few years. *Id.* ¶¶ 65-66. Zendura FLX is the “whole reason” it is around and losing exclusivity over it “would be devastating.” *Nevro*, 2019 WL 3322368, at *14 (finding irreparable harm relating to patentee’s core product); *see also Celsis*, 664 F.3d at 930 (finding irreparable harm to a “flagship” product entering the phase with “highest revenues and strongest market position”). As in *Nevro* and *Celsis*, harm to Zendura FLX imperils Bay’s future.

Since developing the first advanced aligner material, Bay has been the industry-leading innovator of polymer material used for aligners. Bay’s reputation as the technological leader in the market has been vital to Bay’s brand and success. Ross Decl. ¶ 15. Now 3M claims that it created its “new aligner from scratch” while relying on its “60 years” of “[m]aterials science expertise.” D.I. 1, Ex. K at 3, 4. The harm to Bay caused by 3M selling copies of Bay’s patented material and calling itself the innovator cannot be quantified or remedied by money damages. *See, e.g., Douglas Dynamics, LLC v. Buyers Prods. Co.*, 717 F.3d 1336, 1344-45 (Fed. Cir. 2013) (stating that a patentee’s “reputation as an innovator will certainly be damaged if customers found the same ‘innovations’ appearing in competitors’” products).

2. There is a nexus between 3M’s infringement and harm to Bay Materials

A direct nexus exists between 3M’s infringement and the harm to Bay and its customers. One of the most important factors in an aligner company’s success is the quality of its aligner material. Schoettelkotte Decl. ¶¶ 78-100, 152-166; Carsault Decl. ¶¶ 19-20. Zendura FLX’s

superior properties have been key to Bay and its customers penetrating the sticky aligner market. *See Nevro*, 2019 WL 3322368, at *15 (finding nexus because patentee penetrated a sticky market due to demand for patented features). 3M markets Clarity Flex by touting the very same attributes that come from Bay's patented Zendura FLX. This is further evidence that 3M recognizes that the superiority of Bay's claimed multilayer aligner "is one of several features that cause consumers to make their purchasing decisions" and that "the inclusion of a patented feature makes a product significantly more desirable." *Id.* (citation omitted).

C. The Balance of Hardships Favors Bay Materials

The balance of hardships factor "assesses the relative effect of granting or denying an injunction on the parties." *Apple Inc. v. Samsung Elecs. Co.*, 809 F.3d 633, 645 (Fed. Cir. 2015) (citation omitted). This factor favors Bay. Without a preliminary injunction, Bay will be required "to compete against its own patented invention, with the resultant [irreparable] harm." *Robert Bosch*, 659 F.3d at 1156. In contrast, because a preliminary injunction preserves the status quo by keeping an alleged infringer from selling its product until a decision on the merits, 3M will suffer minimal losses if market entry is delayed until then. Indeed, 3M only recently entered the market with Clarity Flex, and Bay promptly brought this motion for preliminary injunction once it obtained and tested a sample Clarity Flex aligner to confirm infringement.

Without an injunction, Bay faces the loss of customers, business opportunities, revenue, its reputation as the industry-leading innovator, and goodwill. *See Solarex Corp. v. Advanced Photovoltaic Sys., Inc.*, 1995 WL 314742, at *8 (D. Del. Jan. 6, 1995) (stating that these types of losses weigh in favor of an injunction). The harm to Bay absent an injunction will be particularly acute because Zendura FLX is its flagship product and one of just two products it sells.

3M, on the other hand, is a large company with many products and only recently entered the market with its infringing Clarity Flex. *Impax Labs., Inc. v. Aventis Pharms., Inc.*, 235 F.

Supp. 2d 390, 396 (D. Del. 2002) (finding preliminary injunction causes minimal harm since defendant is “in the same position as it was in before the injunction was granted, i.e., excluded from the [] market”); *SiOnyx*, 2019 WL 3358599, at *3 (“The balance of hardship weighs heavily in favor of an injunction, as SiOnyx is a tiny company relying on a single type of technology, whereas HPK is a large company with a broad and diversified range of products.”). 3M can also sell its noninfringing aligner, so an injunction will not exclude it entirely from the market. And an infringer like 3M, that knows about a patent before selling its product, takes a calculated risk and cannot complain that the balance of hardships tips against it. *See Pfizer, Inc. v. Teva Pharms. USA, Inc.*, 429 F.3d 1364, 1382 (Fed. Cir. 2005).

D. The Public Interest Weighs in Favor of Injunctive Relief

A party seeking a preliminary injunction must establish that it is in the public interest. *Metalcraft*, 848 F.3d at 1369. “[T]he public interest nearly always weighs in favor of protecting property rights in the absence of countervailing factors, especially when the patentee practices his inventions. ‘The encouragement of investment-based risk is the fundamental purpose of the patent grant, and is based directly on the right to exclude.’” *Apple*, 809 F.3d at 647 (citation omitted); *see also Solarex*, 1995 WL 314742, at *8 (stating that the “public has an interest in upholding and preserving patent rights”). Allowing Clarity Flex to remain on the market goes against the public’s interest in preserving patent rights. Also, because 3M only recently released Clarity Flex, it is in the public interest to prevent further release so that the public does not prematurely rely on the availability of Clarity Flex. *Solarex*, 1995 WL 314742, at *8. Further, patient need in the clear aligner market is currently being met and can continue to be met without the recently released Clarity Flex, particularly with [REDACTED] aligners.

VI. CONCLUSION

Bay respectfully requests that the Court grant its motion for a preliminary injunction.

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