

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

BAY MATERIALS, LLC,	)	
	)	
Plaintiff,	)	C.A. No. 21-1610-RGA-JLH
	)	
v.	)	REDACTED PUBLIC VERSION
	)	
3M COMPANY,	)	
	)	
Defendant.	)	
	)	

**3M COMPANY’S ANSWERING BRIEF IN OPPOSITION TO PLAINTIFF’S
MOTION FOR PRELIMINARY INJUNCTION**

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I. INTRODUCTION AND SUMMARY OF THE ARGUMENT

Bay Materials, LLC (“Plaintiff”) is a disgruntled would-be supplier to 3M Company (“3M”) that brought this suit after multiple failed attempts to sell its thermoplastic materials to 3M. For years, Plaintiff solicited 3M in the hopes of selling its materials for use in 3M’s orthodontic aligners. 3M declined the offers—in part because it determined that Plaintiff’s costly materials were lacking in performance compared to 3M’s independently-developed and superior single-layer and five-layer materials. Unable to land 3M as a customer, or as a royalty-paying licensee of the Asserted Patents, Plaintiff filed this lawsuit and moved for a preliminary injunction. Plaintiff’s motion should be denied.

First, Plaintiff falls woefully short of establishing that it will be irreparably harmed, relying exclusively on sheer speculation about potential future harm to two of its customers. Indeed, Plaintiff’s declarants admit there is no evidence that 3M’s sales of Clarity™ Aligners Flex over the last eight months have harmed Plaintiff or its customers in any way. Moreover, even if Plaintiff could establish such harm, monetary damages would undoubtedly suffice. Further, Plaintiff has failed to prove the required nexus between the alleged harm and 3M’s alleged infringement.

Second, Plaintiff is unlikely to succeed on the merits. Plaintiff is unlikely to prove that 3M’s five-layer material infringes, and 3M has raised substantial questions of validity based on prior art and indefiniteness. Finally, the balance of hardships and public interest favor allowing 3M’s superior five-layer aligner to remain on the market, where it has been sold since July 2021 (without any harm to Plaintiff) and is being used by patients across the United States.

II. NATURE AND STAGE OF THE PROCEEDINGS

Plaintiff filed its Complaint and Motion for Preliminary Injunction on November 15, 2021. (D.I. 1, 6.) 3M submits this Answering Brief and accompanying declarations of Douglas G.

Kidder, Alan Jeffrey Giacomini, PhD, Richard Liu, and Adam Pivovar¹.

III. FACTUAL BACKGROUND

A. 3M's Independent Development of Clarity™ Aligners Flex

[REDACTED]

3M is a diversified technology company that provides dental and orthodontic products, including clear aligners. (Kidder Decl., ¶¶9-13.) In 2016, 3M began considering multiple configurations of materials, including three- and five-layer designs and various polymers, for use in its clear aligners. (Liu Decl., ¶¶4-6, Exs. 1-5.) By August 2017, [REDACTED]

[REDACTED] was the highest performing configuration. (*Id.*, ¶¶7-8, Ex. 7.) This configuration ultimately resulted in the Accused Product—Clarity™ Aligners Flex. (Exs. A-B.) Beginning in 2018, 3M sought patent protection for its five-layer polymeric materials and thermoformed aligners. (Ex. D.) 3M initially entered the orthodontic aligner market in May 2018 with its single-layer Clarity™ Aligners (now known as Clarity™ Aligners Force). (Ex. C.)

B. The Relevant Clear Aligner Market

There are many manufacturers of clear aligners. (Ex. E; D.I. 11 (“[REDACTED] Decl.”), Ex. 2; Kidder Decl., ¶¶38-43.) In 2013, Align Technology (Invisalign) became the first to provide aligners made with a multi-layer material. (Ex. DD (Ross Tr.), 51:9-17; Exs. F-G.) Manufacturers

¹ Unless otherwise noted, all exhibits cited herein are attached to Dr. Pivovar's declaration.

operate in the doctor-directed market and/or the direct-to-consumer market, and within the doctor-directed market, there are two sales channels: (1) general practitioners (i.e., dentists) and (2) orthodontists. (Ex. E; [REDACTED] Decl., Ex. 2; Kidder Decl., ¶¶41, 46-47.) Align sells to both dentists and orthodontists and leads the doctor-directed channel [REDACTED] (Ex. EE, 58:7-25; Ex. E; Carsault Decl., Ex. 1; Kidder Decl., ¶¶44, 46-48.) [REDACTED]

[REDACTED].² (Exs. E, H; Ex. EE ([REDACTED] Tr.), 99:24-100:16; Kidder Decl., ¶¶39-47.)

When deciding which clear aligners to purchase, dentists and orthodontists consider many factors, including the case management and treatment design software, whether the manufacturer

² Mr. [REDACTED] Vice President of Sales and Marketing for [REDACTED] in North America, relied on a market report from Credit Suisse in his declaration to state that [REDACTED] has [REDACTED] market share in the GP segment. (See [REDACTED] Decl., Ex. 1.) When asked about the figures within the Straumann Group report, Mr. [REDACTED] conceded that this report accurately reflects market share, while the Credit Suisse report instead pertains to “market penetration.” (Ex. EE, 94:10-97:9.) He then admitted that [REDACTED] market share in the GP segment is [REDACTED]%. (*Id.*, 97:10-14.)

accepts digital 3D tooth models from the intraoral scanner used by the practitioners, the training and support (including from technicians) manufacturers offer, and the price of the aligners. (Ex. EE, 82:7-88:17 (discussing Ex. I); *see also* D.I. 9 (“Schoettelkotte Decl.”), ¶109.) These considerations can lead to “customer inertia” (or, as Plaintiff describes it, “stickiness”) in the market, whereby customers stick with a provider and do not change brands. (Kidder Decl., ¶¶91-95.)

Critically, Plaintiff is not a clear aligner manufacturer; rather, it is an aligner material supplier. (Ex. DD, 126:11-16, 127:19-128:8.) Plaintiff supplies its single-layer material, Zendura A, and its three-layer material, Zendura FLX, to manufacturers [REDACTED] and to labs and dental practices. (*Id.*, 65:9-11.) [REDACTED]

[REDACTED] (*Id.*, 68:11-15, 70:2-6, 73:9-14.) Plaintiff’s competitors include “thin film manufacturers,” such as Scheu, Dentsply/Sirona, Erkodent, and Dreve. (*Id.*, 126:17-127:10.) 3M, unlike Plaintiff, “produces material for [its] own aligner production,” and does not “supply materials separately” to other aligner manufacturers. (*Id.*, 127:19-128:2.) Accordingly, Plaintiff and 3M do not compete. (*Id.*, 128:3-8.)

In 2019, Plaintiff was acquired by Straumann Group. (Kidder Decl., ¶16.) Straumann was aware that Plaintiff had customers who were [REDACTED] but it was “key” for Straumann to [REDACTED]

(Ex. J.) [REDACTED]
[REDACTED] (Exs. L, HH.) Indeed, [REDACTED]

³ [REDACTED]
(*Id.*, 80:14-16; Ex. EE, 18:22-19:4.)

_____ including after 3M’s launch of Clarity™ Aligners Flex. (Ex. DD, 86:16-21; Ex. K; Kidder Decl., ¶¶21, 77, 83.)

C. Plaintiff Failed to Sell its Materials to 3M

Plaintiff doggedly pursued 3M as a potential customer. Beginning in 2015, Ray Stewart, Plaintiff’s founder, and Daniel Skamser from 3M began discussing Zendura A. (Ex. M.) Throughout 2017, Mr. Stewart repeatedly emailed and met with 3M personnel regarding 3M’s testing of Zendura A. (Ex. DD, 102:19-107:9; Exs. M-Q; Kidder Decl., ¶73.) 3M ultimately developed its own single-layer Clarity™ Aligners. (Ex. C.)

In early 2018, Mr. Stewart reminded 3M of the availability of Zendura A and also pitched “Zendura XL” (ultimately sold as Zendura FLX). (Ex. DD, 107:13-109:5; Ex. R; Kidder Decl., ¶73.) In May 2018, Mr. Stewart introduced Zendura FLX to 3M representatives. (Ex. DD, 109:9-110:14; Ex. T.) After that meeting, Mr. Stewart persistently followed up. (Ex. DD, 110:11-14; Ex. U.) 3M, however, determined that Zendura FLX was costly, had a limited handling shelf-life, and lacked in certain performance characteristics. (Exs. P, V-W.) Accordingly, 3M informed Plaintiff that it was not interested in purchasing Zendura FLX. (Ex. X.)

In early 2021, 3M contacted Plaintiff regarding a press release concerning Plaintiff’s patents. (Ex. DD, 114:21-115:23, 117:14-125:19; Exs. Y, CC; Kidder Decl., ¶74.) Between January and March 2021, the parties discussed a potential patent license agreement. (Ex. DD, 114:21-115:23, 117:14-125:19; Exs. Y, AA-BB; Kidder Decl., ¶¶74-75.) Mr. Stewart expressed Plaintiff’s willingness to grant a license, but the negotiations broke down because, in Mr. Stewart’s view, 3M’s proposal did not include “a large enough dollar amount and did not have an ongoing compensation to Bay Materials.” (Ex. DD, 124:16-125:5, 114:21-115:23, 117:14-124:14; Exs. Y, AA-BB; Kidder Decl., ¶¶74-75.)

D. The Asserted Patents

U.S. Patent No. 10,946,630 (the “’630 patent”) and the continuation-in-part U.S. Patent No. 10,870,263 (the “’263 patent”) (collectively, the “Asserted Patents”) are entitled “Dual Shell Dental Appliance And Material Constructions.” Asserted claims 1, 2, and 9 of the ’630 patent are directed to layered polymeric sheets stacked in an “ABC” configuration wherein the “layers A and C” form an outer shell around an “inner layer B” comprised of a “soft” elastomeric material. (’630 patent, cls. 1, 2, 9; *see generally id.*) The shell “layers A and C” have a “flexural modulus” of 1,000 – 2,500 MPa. (*Id.*, cls. 1, 2, 9.) The “inner layer B” has a hardness of A80 – D75. (*Id.*) Asserted claims 11, 12, and 18 of the ’263 patent are directed to a layered polymeric sheet composition wherein “rigid or hard outer layers A and C” form a dual shell around “soft inner layers B and B’” and a “rigid or hard inner layer D.” (’263 patent, cls. 11, 12, 18.) Layers A, C, and D have a “modulus” of 1,000 – 2,500 MPa, and layers B and B’ have a hardness of A60 – D85. (*Id.*)

IV. LEGAL STANDARD

“[A] preliminary injunction is a drastic and extraordinary remedy that is not to be routinely granted.” *Intel v. ULSI Sys. Tech.*, 995 F.2d 1566, 1568 (Fed. Cir. 1993). Plaintiff has the burden to prove: “(1) a reasonable likelihood of success on the merits; (2) irreparable harm if an injunction is not granted; (3) a balance of hardships tipping in its favor; and (4) the injunction’s favorable impact on the public interest.” *Amazon.com v. Barnesandnoble.com*, 239 F.3d 1343, 1350 (Fed. Cir. 2001).

V. ARGUMENT

A. Plaintiff Has Not Proven It Will Be Irreparably Harmed.

Courts look “to evidence of what actual damage was likely due to any continuation of [the accused infringer]’s alleged infringing sales and whether money damages will provide adequate

compensation and vindication of [the patentee]’s patent rights.” *Reebok Int’l v. J. Baker*, 32 F.3d 1552, 1557 (Fed. Cir. 1994). Accordingly, there must be a “causal nexus between the alleged infringement and the alleged harm” as “[e]vidence of potential lost sales alone does not demonstrate irreparable harm.” *Metalcraft of Mayville v. The Toro Co.*, 848 F.3d 1358, 1368 (Fed. Cir. 2017). “[N]either the difficulty of calculating losses in market share, nor speculation that such losses might occur, amount to proof of special circumstances justifying the extraordinary relief of an injunction prior to trial.” *Nutrition 21 v. U.S.*, 930 F.2d 867, 871 (Fed. Cir. 1991).

1. Any Harm to Plaintiff is Purely Speculative.

Plaintiff has no proof of any actual harm; its irreparable harm case is premised on rank speculation about potential future lost sales for two of its customers, with no evidence of any causal nexus or special circumstances justifying an injunction. First, none of Plaintiff’s declarants could identify a single lost customer or lost sale for [REDACTED] or Plaintiff due to Clarity™ Aligners Flex. (Ex. DD, 77:12-80:10, 82:11-17 (“Q. Does Bay Materials have any proof of any harm to Bay Materials from 3M’s Sale of Clarity Aligners Flex? A. So the – I have no proof of existing harm at this time.”); Ex. EE, 53:25-55:12, 56:4-24; Ex. FF (Schoettelkotte Tr.), 15:15-17:5, 32:11-20.) Plaintiff’s “bare assertion of irreparable harm” is insufficient to meet the exacting standard to impose a preliminary injunction. *Takeda Pharms. U.S.A. v. Mylan Pharms.*, 967 F.3d 1339, 1349-50 (Fed. Cir. 2020); *Metalcraft*, 848 F.3d at 1368 (“[e]vidence of potential lost sales alone does not demonstrate irreparable harm”).

Second, Plaintiff’s speculative arguments are fatally flawed given the realities of the market. Plaintiff’s allegation that it competes with 3M is belied by the evidence, including the admission by Plaintiff’s COO Mr. Ross that “3M competes directly with [REDACTED]” “rather than with [Plaintiff].” (Ex. DD, 128:3-8.) The party seeking an injunction “must show that *it* has suffered an irreparable injury.” *Voda v. Cordis*, 536 F.3d 1311,

1329 (Fed. Cir. 2008) (affirming denial of injunction where patentee failed to prove that it, personally, suffered irreparable harm even though it showed that its non-party exclusive licensee may have suffered harm) (emphasis added; citation omitted). Plaintiff has utterly failed to show any injury to it stemming from 3M's sales of Clarity™ Aligners Flex. Rather, Plaintiff's motion relies entirely on conjecture about potential future harm to [REDACTED]. Even if one assumed that future harm to these customers were inevitable, that would be insufficient to establish irreparable harm to Plaintiff. *See Ever Victory Tech. v. SAS Grp.*, 19-cv-486, 2019 WL 4291670, at *7 (S.D.N.Y. Sept. 11, 2019) (“But the fact that a party—or its sister company—will lose income absent a preliminary injunction is insufficient to establish the sort of irreparable harm that would justify recourse to that extraordinary remedy.”).

Further, [REDACTED]. As Mr. [REDACTED] testified, [REDACTED]
[REDACTED] (Ex. EE, 61:2-5.)

But 3M [REDACTED]
[REDACTED] % market share. (Exs. E, H; Kidder Decl., ¶46.) [REDACTED]
[REDACTED] Plaintiff has no proof of any actual harm to [REDACTED] and
[REDACTED]
[REDACTED] (Ex. K; Kidder Decl., ¶¶23, 37, 83.)

In addition, Plaintiff sells its Zendura materials, including Zendura FLX, [REDACTED]
[REDACTED] (Ex. DD, 65:5-11), and even within the market in which Plaintiff operates—the sale of aligner materials—there are many competitors. (*Id.*, 126:17-127:10.) Lost sales (to the extent there even are any) in such crowded markets do not constitute irreparable harm. *See Nabors Drilling Techs. USA v. Helmerich & Payne Int'l Drilling*, 3:20-cv-03126-M, 2022 WL 504393, at *4 (N.D. Tex. Feb. 18, 2022); *TeleSign v. Twilio*, 15-cv-3240, 2015 WL 12532491, at *6-*7 (C.D. Cal. Oct.

19, 2015) (presence of additional competitors weighed against plaintiff's claim of irreparable harm). Furthermore, Mr. Schoettelkotte relies on the "stick[iness]" of the clear aligner market to explain the lack of proof of harm, stating that doctors "tend to stick" with one clear aligner provider and "not change brands." (Schoettelkotte Decl., ¶¶130-131.) This argument, however, cuts both ways. Because of this "stickiness," [REDACTED] are less likely to lose customers to 3M, [REDACTED] (Kidder Decl., ¶14.) Finally, Mr. Schoettelkotte wrongly assumes that doctors use only one aligner manufacturer. This is belied by the evidence in the Straumann market report, in which doctors indicated a "secondary brand" they use and answered that they, on average, use 1.67 aligner brands. (Kidder Decl., ¶98; Ex. EE, 104:4-17; Ex. E.)

2. Monetary Damages Are Adequate.

"An injury cannot be 'irreparable' if money would be an adequate remedy, and that is exactly what is suggested by Plaintiffs' offering to license their patents to Defendants and other competitors." *Vertigo Media v. Earbuds*, 21-cv-120-MN, 2021 WL 4806410, at *4 (D. Del. Oct. 14, 2021) (citing *High Tech Med. Instrumentation v. New Image Indus.*, 49 F.3d 1551, 1557 (Fed. Cir. 1995) (explaining that because plaintiff "offered a license to [defendant], [] it is clear that [plaintiff] is willing to forgo its patent rights for compensation")). Here, the parties engaged in licensing discussions in early 2021. (Ex. DD, 114:3-115:23, 117:23-125:5; Exs. Y-CC; Kidder Decl., ¶¶74-76.) Mr. Stewart was "interested in a license" and was "championing 3M's request for a license in the larger Straumann organization[.]" (Ex. DD, 121:23-123:14.) The negotiations ultimately broke down over money. (*Id.*, 123:15-125:5 (discussing that 3M's proposal did not have a "large enough" lump sum payment and did not include an ongoing royalty).) When asked why 3M's alleged infringement was not compensable by money now, Mr. Ross testified that he did not "have an answer to that question" and that the question was "at least one or two pay grades above

[his] position.” (*Id.*, 125:20-126:9.) Mr. Ross also testified that Plaintiff was highly interested in supplying its materials to 3M in the past and that, “[o]n par for similar volume, it is possible” that Plaintiff would still be willing to “supply 3M with Zendura A and FLX at a price on par with [REDACTED].” (*Id.*, 112:11-14, 97:14-17; Ex. GG.) Thus, money is more than adequate to compensate Plaintiff for the alleged infringement. (Kidder Decl., ¶¶74-76, 106-117.)

3. **There is No Causal Nexus Between the Alleged Infringement and Alleged Harm.**

“To show irreparable harm, it is necessary to show that the infringement caused harm in the first place.” *Apple v. Samsung Elecs.*, 678 F.3d 1314, 1324 (Fed. Cir. 2012). Plaintiff is unable to do so here for three reasons: (1) multiple unpatented features drive the purchase of clear aligners; (2) even if the material used factors into a purchasing decision, many doctors are unaware of *which* material is used to create the clear aligners they purchase, and the patented features are not market differentiators; and (3) Messrs. [REDACTED] and Ross testified there is harm to [REDACTED] [REDACTED] even from a competitor’s *authorized* use of Plaintiff’s patented product, so any potential harm to those customers is unrelated to the alleged infringement.

First, as Mr. [REDACTED] testified, doctors make purchasing decisions based on a variety of factors, including the quality of the software provided by aligner manufacturers and price. (Ex. EE, 42:14-19, 44:12-23, 46:7-47:20; Ex. I.) Mr. Schoettelkotte likewise emphasized the quality of the software as a reason the market is “sticky.” (Ex. FF, 46:23-47:15.) According to Mr. Schoettelkotte, it is these additional features that have helped Align maintain its market position, and accordingly, he has been unable to discern any impact that Plaintiff’s purportedly superior material, Zendura FLX, has had on Align’s market share. (*Id.*, 22:16-23:8.) Because features unrelated to the Asserted Patents, such as pricing, quality of software, and brand recognition, affect consumer demand, there is no nexus between Plaintiff’s alleged harm and 3M’s alleged

infringement. *See Apple v. Samsung Elecs.*, 695 F.3d 1370, 1374 (Fed. Cir. 2012).

Second, even if the material is a factor that doctors consider, Plaintiff has not shown that doctors actually know which material is used to make the aligners they order. Mr. Ross testified he was unaware of any dentist or orthodontist who knows that [REDACTED] [REDACTED] (Ex. DD, 147:21-148:10, 70:7-73:8.) [REDACTED] [REDACTED] [REDACTED] (*Id.*, 73:9-14.) Accordingly, even if doctors take the material into account, they are unaware of what the material is and what its patented features are. Moreover, Plaintiff has not offered any evidence that the patented features (such as a hard-soft-hard configuration) have even partially driven 3M's sales of Clarity™ Aligners Flex.

Third, as Messrs. [REDACTED] and Ross acknowledged,

(Ex. EE, 51:16-24.)

(Ex. DD, 76:24-77:2.)

Mr. Ross additionally testified that if 3M purchased Zendura FLX from Plaintiff, [REDACTED] [REDACTED] would still face the same harm from 3M. (*Id.*, 75:16-21, 76:10-23.) Accordingly, the

alleged irreparable harm to Plaintiff from Clarity™ Aligners Flex has no nexus to the alleged infringement; if 3M switched to using Zendura FLX, or obtained a patent license from Plaintiff, [REDACTED] would still face the same competitive threat from 3M. Plaintiff thus fails to distinguish “between irreparable harm caused by patent infringement and irreparable harm caused by otherwise lawful competition.” *Apple v. Samsung Elecs.*, 735 F.3d 1352, 1361 (Fed. Cir. 2013).

B. Plaintiff Has Not Established a Likelihood of Success.

Plaintiff cannot show that it will “likely prove” infringement and that the Asserted Patents “will likely withstand” 3M’s invalidity challenges. *Metalcraft*, 848 F.3d at 1364. 3M need only raise a substantial question concerning either infringement or validity by asserting a defense that Plaintiff cannot prove “lacks substantial merit.” *Tate Access Floors v. Interface Architectural Res.*, 279 F.3d 1357, 1365 (Fed. Cir. 2002). Here, there is far more than a “substantial question” regarding invalidity and non-infringement.

As a threshold matter, Plaintiff’s infringement theories fail because they do not account for the specific definition and meaning ascribed by the intrinsic record to the claim language, such as the terms “layer A,” “layer B,” “layer C,” and “inner layer B.” The declaration of Plaintiff’s technical expert, Dr. Osswald, does not set forth any interpretation of the claims, instead relying on his own undisclosed “belief” as to what the claim terms mean to him. (D.I. 8 (“Osswald Decl.”), ¶15.) Dr. Osswald admitted that he “did not do an analysis on the meaning of words in the claim[s]” but merely “compared the words in the claims to the 3M product.” (Giacomin Decl., Ex. 4 (Osswald Tr.), 10:16-17, 14:5-7.) Dr. Osswald’s opinions are legally deficient because they are not based on a proper construction of the claims. *See Markman v. Westview Instruments*, 52 F.3d 967, 976 (Fed. Cir. 1995) (“comparing the properly construed claims to the device”).

1. The Asserted Claims are Indefinite.

a. “layer A,” “layer B,” and “layer C” are indefinite

All Asserted Claims recite some permutation of “layer A,” “layer B,” and “layer C.” (*See* Giacomini Decl., ¶49.) These terms have no established plain meaning in the art. (*Id.*) The Asserted Patents define them as follows: “Each layer A, B and C, may be a [*sic*] comprised of a single layer or multiple layers and each layer may be comprised of one or more materials or a blend of materials.” (’630 patent, 3:47-55; ’263 patent, 3:47-55; *see also* Giacomini Decl., Ex. 4, 155:11-13; Giacomini Decl., ¶¶49-55.) This express definition is the proper construction. *See Vitronics v. Conceptronic*, 90 F.3d 1576, 1582 (Fed. Cir. 1996).

The definition of “layer A,” “layer B,” and “layer C” renders the claims indefinite because they do not have reasonably certain claim scope. (Giacomini Decl., ¶¶63-70.) *See Halliburton Energy Servs. v. M-ILLC*, 514 F.3d 1244, 1251 (Fed. Cir. 2008). The Asserted Claims recite “layer A,” “layer B,” and “layer C” using capital letters. The specification, however, uses **both** small and capital letters as well as prime (“'”) to identify single layers of a multi-layer sheet, such as a, a', A, and A'. (Giacomini Decl., ¶64.) As a result, identification of “layer A,” “layer B,” and “layer C” is ambiguous—either a single layer or multiple layers—as exemplified in the following:

TABLE 8

Layers

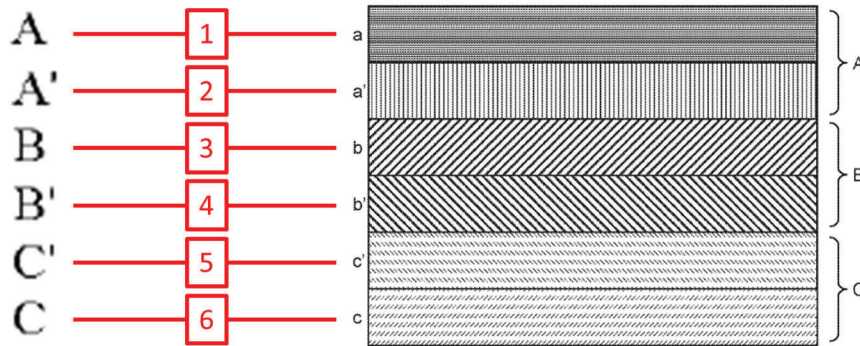


FIG. 1B

(*Id.*)

For instance, “layer A” can be single layer “1” per Table 8 or multiple layers “1” and “2” per Figure 1B. (*Id.*, ¶65.) Because different embodiments permit different and non-uniform identifications of what constitutes “layer A,” the scope of the claims does not have reasonable certainty. (*Id.*, ¶¶65-66.) These permissible alternatives would be outcome-determinative in determining claim scope, such that a given polymeric sheet could both infringe and not infringe depending on which embodiment is followed. (*Id.*, ¶¶69-70.) The claims are therefore indefinite. *See Nautilus v. Biosig Instruments*, 134 S. Ct. 2120, 2129 (2014).

b. “flexural modulus” cut-off values are indefinite

The Asserted Claims recite “flexural modulus” ranges of “about 1,000 MPa to 2,500 MPa,” “about 750 MPa to 2,000 MPa,” and “500 MPa to 1,500 MPa.” (’263 patent, cl. 12.) Different accepted standards exist for determining “flexural modulus,” and those different standards yield different values—some falling within the Asserted Claims’ scope and others falling outside the Asserted Claims’ scope. The Asserted Patents do not specify which standard or method to use. As a result, these terms are indefinite. (Giacomin Decl., ¶¶71-81.)

As Plaintiff's expert confirmed, there are different accepted methods for determining a flexural modulus of a material, including ISO-178 and ASTM D790. (*Id.*) As Dr. Giacomini explains, these different standards yield different results—even for the same material with identical testing data—such that a single material can both fall within and outside the claimed ranges depending on the method selected. (*Id.*) One example of how the different values of flexural modulus between the different standards yield different outcomes regarding claim scope is depicted below, in that the ISO-178 method gives a flexural modulus value within the claimed range, while the ASTM D790 method is outside the claimed range:



(*Id.*, ¶78.)

Consequently, the Asserted Claims do not have reasonable certainty in scope and are therefore invalid. *See, e.g., Teva Pharms. USA v. Sandoz*, 789 F.3d 1335 (Fed. Cir. 2015); *Butamax Advanced Biofuels LLC v. Gevo, Inc.*, 117 F. Supp. 3d 632, 642 (D. Del. 2015) (indefinite because multiple legitimate methods exist and such methods of measurement can yield different results).

2. The Asserted Claims Lack Enablement.

All Asserted Claims recite “at least two” outer layers A and C. There is no embodiment in the patents of a polymeric sheet that has more than “two outer layers A and C”—every embodiment has two “outer layers A and C.” (Giacomini Decl., ¶84.) The full scope of the claims is not enabled

because the patents do not teach how to make a polymeric sheet with three or more “outer layers A and C.” (*Id.*, ¶85.) See *Martek Biosciences v. Nutrinova*, 579 F.3d 1363, 1378 (Fed. Cir. 2009).

3. The Accused Product Does Not Infringe.

The term “*inner* layer B” has no established plain meaning. (Giacomin Decl., ¶56.) Accordingly, it should not be construed more broadly than the disclosure in the specification. See *Indacon v. Facebook*, 824 F.3d 1352, 1357 (Fed. Cir. 2016). The exact words “inner layer B” are not in the specification of the ’630 patent. (Giacomin Decl., ¶57.) Rather, all embodiments with “layer B” disclose it as the “*middle* layer B” or “*middle* B layer.” (*Id.*)

The specification discloses that the “inner elastomeric layer” is synonymous with the “core.” (*Id.*, Ex. 4, 240:10-12 (“Q. It’s referring to the inner elastomeric layer synonymously with the core, right? A. Correct.”).) There are no embodiments identifying more than one “layer B” and none where “layer B” is not the middle core. (*Id.*, ¶¶58-59.) This is consistent with the file history, wherein Plaintiff characterized the inventions of the ’630 patent as “*tri-layer polymer sheets*”—*i.e.*, just one core layer B. (See *id.*, ¶¶60-62.) Accordingly, “inner layer B” means “the middle core layer B” of a multilayer polymeric sheet. (*Id.*)

Claim 1 of the ’630 patent recites “the inner layer B is comprised of an elastomeric material having a hardness from about A80 to D75.” (’630 patent, cl. 1.) The Clarity™ Aligners Flex material does not infringe because the middle core layer (“3”) is not “comprised of an elastomeric material having a hardness from about A80 to D75.” (Giacomin Decl., ¶93.) The express disclosure of the five-layer polymeric sheet of Sample 8 in Table 8 further confirms non-infringement because layer 3 of a 5-layer sheet is the middle core layer B:

TABLE 8

Exemplary Multilayer Sheet Materials							
	Sample #6		Sample #7		Sample #8		
Layers	Material	Thickness	Material	Thickness	Material	Thickness	
A	Trogamide CX 7323	0.125 mm	Trogamide CX 7323/Polyamide 614 Blend 90:10	0.2 mm	Altuglas Luctor CR 13	0.125 mm	1 A
A'					Altuglas SG10	0.125 mm	2 A'
B	Pebax Clear 300	0.5 mm	Pellethane 2373 55D	0.3 mm	Kurarity LA4285	0.25 mm	3 B
B'							
C'	Trogamide CX 7323	0.125 mm	Trogamide CX 7323/Polyamide 614 Blend 90:10	0.2 mm	Altuglas SG10	0.125 mm	4 C'
C					Altuglas Luctor CR 13	0.125 mm	5 C

Altuglas SG10 is a transparent impact modified polymethyl methacrylate sold by Arkema

Altuglas Luctor CR13 is a transparent impact modified polymethyl methacrylate sold by Arkema

Kurarity LA4285 is an acrylic ABA block co-polymer of methyl methacrylate and butyl methacrylate

(*Id.*, ¶¶94 (layers 1-2-3-4-5 correspond to A-A'-B-C'-C, respectively).)

It is presumed that the same claim term in the same patent or related patents—like “inner layer B” here—carries the same construed meaning. *Omega Eng'g v. Raytek*, 334 F.3d 1314, 1334 (Fed. Cir. 2003). Consequently, there is also no infringement of claim 11 of the '263 patent. (Giacomin Decl., ¶¶106-109.)

4. The '630 patent's Asserted Claims are Invalid in View of Prior Art.

There are numerous prior art references that disclose, teach, and suggest the use of hard outer layers on a multilayer polymeric sheet with a soft core that render the asserted claims invalid for anticipation and obviousness. For example, Hinz (*Id.*, Ex. 7) discloses the allegedly inventive tri-layer hard-soft-hard configuration of the '630 patent for a dental appliance and anticipates the Asserted Claims, as depicted on the right. (*Id.*, ¶¶111-119.)

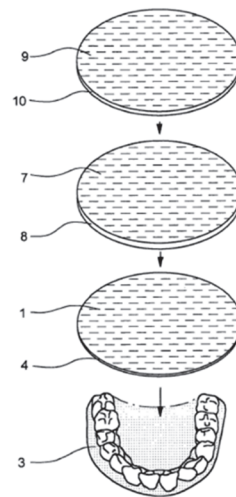


Fig. 2

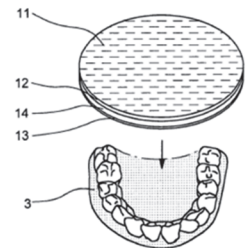


Fig. 3

Claim 1: Figure 3 of Hinz discloses “a three-layer structure having *two outer hard layers* 12, 13 made of polycarbonate and *a soft layer 14* made of polyurethane embedded between hard layers 12, 13.” (Hinz, 8:240-243 (emphasis added).) The hard polycarbonate anticipates a “polyester... having a flexural modulus of from about 1,000 MPa to 2,500 MPa.” (Giacomin Decl., ¶¶115-119.) The polyurethane soft layer 14 anticipates an “elastomeric inner layer B” with a hardness “from about A80 to D75.” (*Id.*, ¶¶120-121.) See *Genentech v. Hospira*, 946 F.3d 1333, 1338 (Fed. Cir. 2020). A skilled artisan would further recognize that Hinz’s film 11 (“**polymeric sheet composition**”) has a “flexural modulus” that anticipates the claimed range of “about 750 MPa to 2,000 MPa.” (Giacomin Decl., ¶¶122-126.)

Claim 2: Hinz discloses that three-layer film 11 can have a “combined thickness” that anticipates “from about 250 microns to 2,000 microns.” (*Id.*, ¶127.)

Claim 9: Hinz discloses “a three-layer dental splint.” (*Id.*, ¶128.)

To the extent Plaintiff contends that Hinz’s film 11 does not anticipate all limitations of the claims, any such limitation would have been obvious over the combined teachings of Hinz and Sun. (*Id.*, Ex. 12; *id.*, ¶¶129-132.)

5. The '263 patent's Asserted Claims are Invalid in View of Prior Art.

3M’s research and development efforts have led to several patent applications covering its proprietary 5-layer materials for use in dental aligners. One such patent application (“Yu” (*id.*, Ex. 13)), discloses embodiments of 3M’s multilayer sheets that pre-date the effective filing date of the '263 patent. As noted above, the Accused Product does not infringe the '263 patent’s Asserted Claims under their proper interpretation. But [REDACTED]

[REDACTED] See *01 Communique Lab. v. Citrix Sys.*, 889 F.3d 735, 743 (Fed. Cir. 2018) (citation omitted).

The Asserted Claims of the '263 patent are entitled to an *effective* filing date no earlier than December 18, 2019, the date on which the continuation-in-part application that led to the patent was filed. (Giacomin Decl., ¶¶160-166). Yu was effectively filed before December 18, 2019 and thus qualifies as prior art with respect to subject matter described therein that was also described in the Yu Provisional (*id.*, Ex. 14), to which Yu is entitled to claim a right of priority. *See* §§102(a)(2), (d)(2) (AIA); (Giacomin Decl., ¶¶133-137.)

Both Yu and the Yu Provisional describe “Example 1,” which is a 5-layer film with an overall thickness of 760 microns and the following configuration of layers: *Tritan(TX1000)/Neostar(FN007)/Tritan(TX1000)/Neostar(FN007)/Tritan(TX1000)*. (Yu Provisional, [0088], [0075]; Yu, [0092], [0078].) [REDACTED]

Accordingly, [REDACTED] would necessarily result in every element of the Asserted Claims being satisfied and therefore anticipated by Yu. (Giacomin Decl., ¶¶138-155.) *See 01 Communique Lab.*, 89 F.3d at 742-43.

C. The Balance of the Hardships Favors 3M.

“An injunction should not be granted if its impact on the enjoined party would be more severe than the injury the moving part would suffer if it is not granted.” *Litton Sys. v. Sundstrand*, 750 F.2d 952, 959 (Fed. Cir. 1984). Contrary to Plaintiff’s assertion that an injunction would “delay” 3M’s entry into the market (Op. Br., 19-20), 3M has already been selling the Accused Product for almost nine months. *Cf. Impax Labs. v. Aventis Pharms.*, 235 F. Supp. 2d 390, 396 (D. Del. 2002) (defendant had not yet entered the relevant market).

An injunction would result in 3M’s loss of customers as well as a loss to patients who will not be able to use Clarity™ Aligners Flex for their oral health. Moreover, 3M “has invested substantial time and money developing” its five-layer product and will be irreparably harmed if

enjoined. *Impax Labs.*, 235 F. Supp. 2d at 396; (*see generally* Liu Decl.). Because 3M and Plaintiff are not competitors and Plaintiff has not established any loss of business, there is no comparable harm faced by Plaintiff. Thus, an injunction would not “maintain the status quo,” but would take 3M’s already comparatively small share of the aligner market “to zero pending trial.” *Waters v. Agilent Techs.*, 410 F. Supp. 3d, 702, 717 (D. Del. 2019). On balance, an injunction would greatly harm 3M, while providing little to no benefit to Plaintiff.

D. An Injunction Would Harm the Public Interest.

An injunction would harm a critical public interest in having access to Clarity™ Aligners Flex products. *See Metalcraft*, 848 F.3d at 1369. 3M independently developed its innovative five-layer material, and Plaintiff’s allegations of copying are baseless. (Liu Decl., ¶¶3-9.) There is an “important public interest in permitting full and free competition in the use of ideas which are in reality a part of the public domain.” *Yamashita v. Wilbur-Ellis*, 06-cv-01690-WHA, 2006 WL 1320470, at *8 (N.D. Cal. May 15, 2006) (quoting *Lear v. Adkins*, 395 U.S. 653, 670 (1969)). The public interest will not be served by excluding alternatives, such as Clarity™ Aligners Flex, from the market.

VI. CONCLUSION

For these reasons, the Court should deny Plaintiff’s motion for a preliminary injunction.

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