

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAY MATERIALS, LLC,

Plaintiff,

v.

3M COMPANY,

Defendant.

C.A. No. 21-1610-RGA-JLH

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

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There is no real dispute regarding Bay's likelihood of success, as demonstrated by 3M's scattershot and conclusory infringement and validity arguments. And while 3M tries to minimize the harm to Bay from 3M's willful infringement, 3M has targeted Bay and its customers with its infringing multilayer aligner causing irreparable harm. Before 3M knowingly circumvented Bay with an infringing multilayer aligner, [REDACTED]

[REDACTED] 3M tries to portray Bay as a "disgruntled would-be supplier" of second-rate materials, but 3M's documents tell a different story. While 3M's [REDACTED] [REDACTED] single-layer aligner struggled, Bay's technologically leading Zendura FLX multilayer aligner became the benchmark to which all other aligners, [REDACTED], are compared. 3M mischaracterizes the harm to Bay as speculative, overlooking both the cascading nature of harms in the complex aligner market and evidence that 3M targets Bay and its downstream customers.

I. ARGUMENT

A. Bay Materials Is Likely to Succeed on the Merits

Bay has shown that the asserted claims are likely infringed and valid. D.I. 7 at 8-13. In response, 3M makes conclusory arguments while broadly citing Dr. Giacomini's declaration. *See, e.g.*, D.I. 76 at 17 (one sentence for non-infringement of the '263 patent), 18 (one sentence for obviousness), 15-16 (three sentences for enablement). 3M waived these arguments by failing to sufficiently articulate them in its brief. *See, e.g., Shure Inc. v. ClearOne, Inc.*, C.A. No. 19-1343-RGA (D.I. 571) (Mem. Order) at 2 (D. Del. Oct. 7, 2021); *see also Monec Holding AG v. Motorola Mobility, Inc.*, 2014 WL 4402825, *1-2 (D. Del. Sept. 5, 2014) (improper to circumvent page-limit requirements by citing expert reports for legal analysis).

1. 3M fails to raise a substantial question as to infringement

There is no dispute that Bay correctly identified the materials in 3M's infringing aligners or that the properties of those materials meet the claim limitations. 3M thus resorts to a tortured

construction of “inner layer B” to argue noninfringement of the ’630 patent (D.I. 76 at 16-17) and, in a single sentence, the ’263 patent (*id.* at 17). 3M improperly rewrites the claim, asserting that “‘inner layer B’ means ‘the middle core layer B’ of a multilayer polymeric sheet.” *Id.* at 16; *see also* D.I. 77, ¶ 59. As Dr. Giacomini explained, however, he made a “correction of the word ‘inner’ to ‘middle,’” based on the prosecution of the unasserted ’511 patent where a claim was expressly amended to have that language.¹ *See, e.g.*, Ex. A at 111:19-112:22, 115:8-22, 119:3-18; D.I. 77, ¶¶ 60-62. Here, the claims do not recite “middle” (or core or innermost), and the intrinsic records of the ’630 and ’263 patents do not support rewriting the plain claim language.

Claim 1 of the ’630 patent includes “layer B,” as well as “layers A and C,” and defines the layers as polymers with specific properties. Claim 1 specifies the layers’ relative placement: “two outer layers A and C” and “elastomeric inner layer B.” Because claim 1 uses the term “comprising,” it is not limited to three layers. And claim 11 of the ’263 patent recites at least three inner layers, showing that “inner layer” does not refer only to a core, middle, or innermost layer. *See Kara Tech. Inc. v. Stamps.com Inc.*, 582 F.3d 1341, 1347-48 (Fed. Cir. 2009) (“The claims, not specification embodiments, define the scope of patent protection.”).

3M’s construction is also inconsistent with the specification, which teaches that a “sheet or device may be comprised of more than two rigid layers, for example a third rigid layer may be disposed between two or more elastomeric layers,” (’630 and ’263 patents at 5:37-39), demonstrating that elastomeric inner layer B need not be the “middle core layer B.” 3M’s construction thus ignores the full import of the specification. *See Broadcom Corp. v. Emulex Corp.*, 732 F.3d 1325, 1333 (Fed. Cir. 2013) (“This court has clarified that an interpretation which ‘excludes a [disclosed] embodiment from scope is rarely, if ever, correct.’”); *see also* Ex.

¹ 3M says Bay “characterized the inventions of the ’630 patent as ‘*tri-layer polymer sheets*,’” but cites *only* the ’511 patent file history. D.I. 76 at 16; D.I. 77, ¶¶ 60-62; Ex. A at 108:19-121:7.

A at 103:18-24 (a skilled artisan would not ignore this teaching).

2. 3M fails to raise a substantial question of validity

a. The asserted claims are definite and enabled

3M fails to show a likelihood that any claim is indefinite. The claimed flexural modulus is definite as the patents and literature describe measuring flexural modulus by the ASTM D790 test. '630 and '263 patents at 7:14-15; D.I. 77-2, Ex. 10 at 239; *see also* Ex. A at 155:21-156:22, 158:22-159:10, 160:19-21. No other standard is suggested. *Kinetic Concepts, Inc. v. Blue Sky Med. Grp., Inc.*, 554 F.3d 1010, 1022 (Fed. Cir. 2009) (limitation definite when “several methods for [measurement] are available but the specification discloses one particular method.”).

The terms “layer A,” “layer B,” and “layer C” are also definite. Claim 1 of the '630 patent recites a polymeric sheet composition with at least three separate layers labeled layers A, B, and C, and recites the properties of those layers. A skilled artisan would understand the claim's scope. *Nevro Corp. v. Boston Sci. Corp.*, 955 F.3d 35, 39 (Fed. Cir. 2020). Further, the specification explains that the layers “may be comprised of more than one layer,” i.e., sub-layers. '630 and '263 patents at 3:47-55, Fig. 1B. It also explains that an elastomeric inner layer B separates layers A and C and allows those layers to be displaced and restored relative to each other. *Id.* at 3:56-61, Figs. 2A and 2B. Sample 8 in Table 8 is one embodiment of a 5-layer polymeric sheet with four outer layers—two hard sub-layers in layer A and layer C—separated by an elastomeric inner layer B which allows layers A and C, including the sub-layers, to be displaced and restored. *Id.* at Table 8. Nothing about the description makes the claims indefinite.

Finally, 3M's three-sentence enablement argument (D.I. 76 at 15-16) does not prove that 3M is likely to “show by clear and convincing evidence that a [skilled artisan] would not be able to practice the claimed invention without ‘undue experimentation.’” *Alcon Rsch. Ltd. v. Barr Labs., Inc.*, 745 F.3d 1180, 1188 (Fed. Cir. 2014). As explained above and noted by 3M and Dr.

Giacomin, (D.I. 76 at 13; D.I. 77, ¶ 63), layers A and C can comprise sub-layers and thus can have more than two outer layers ('630 and '263 patents at 3:47-55, Fig. 1B, Table 8).

b. The '263 patent is entitled to an earlier priority date and is valid in view of WO 2020/225657 to Yu et al. ("Yu")

Claims 11, 12, and 18 of the '263 patent recite a polymeric sheet having at least five layers, including two rigid outer layers, two soft inner layers, and a rigid inner layer. Because these claims are supported by the '511 patent, Yu is not prior art and thus not invalidating. A patent may claim priority to an application that satisfies § 112. *Callicrate v. Wadsworth Mfg.*, 427 F.3d 1361, 1373 (Fed. Cir. 2005). 3M's single sentence on priority (D.I. 76 at 19) does not show that 3M is likely to prove that the claims lack § 112 support from the '511 patent.

3M's expert opined that the application for the '511 patent does not support the claims because it does not "mention" the term "layer D," which is "a rigid or hard inner layer." D.I. 77, ¶ 163. But an application need not provide word-for-word support under § 112. *Pozen v. Par Pharm., Inc.*, 696 F.3d 1151, 1167 (Fed. Cir. 2012). The '511 patent states that a "polymeric sheet or device may be comprised of more than two rigid layers, for example a third rigid layer may be disposed between two or more elastomeric layers."² '511 patent at 5:35-37. This disclosure of a third rigid layer informs a skilled artisan of the claimed "layer D" and supports having two rigid outer layers, two soft inner layers, and an inner rigid layer. The '511 patent also discloses the claimed elastomeric layer hardness range of 60A to 85D.³ *See, e.g., id.* at 19:4-10; *see also id.* at 3:9-12, 9:31-34. Yu, therefore, is not prior art and cannot invalidate the claims.

c. The '630 patent is valid in view of WO 2010/043419 to Hinz

3M fails to raise a substantial question of validity of claims 1, 2, and 9 of the '630 patent.

²

³ Dr. Giacomin's hardness-to-modulus calculation is inconsistent with the relevant ASTM standard and the asserted patents. Ex. A at 189:7-198:15, 201:19-210:8.

Hinz was considered during the '630 patent's prosecution, which "makes [3M]'s burden of proving invalidity . . . especially difficult." *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1375 (Fed. Cir. 2006). Dr. Giacomini acknowledges that Hinz does not explicitly disclose several claim limitations. D.I. 77, ¶ 116 (polyesters), ¶ 118 (flexural modulus), ¶ 120 (elastomeric inner layers), ¶ 121 (hardness), ¶¶ 122-123 (overall sheet flexural modulus calculation). Thus, 3M's anticipation position is based on inherency. D.I. 76 at 17-18. But 3M fails to show that the "prior art necessarily functions in accordance with, or includes, the claimed limitations," as required for inherency. *Bettcher Indus., Inc. v. Bunzl USA, Inc.*, 661 F.3d 629, 639 (Fed. Cir. 2011).

Hinz generally discloses dental splints with three layers of polymers, but the missing claimed properties are not necessarily present. For example, Dr. Giacomini admits that thermoplastic polyurethanes can have a hardness of less than 80A (Ex. A at 135:3-7, 173:2-7) and certain polycarbonate-based polymers have moduli greater than 2,500 MPa (*id.* at 176:8-178:10). Moreover, despite asserting that he would not form an opinion on a polymer's modulus based on "a single column entry" in a textbook (*id.* at 178:17-180:20), Dr. Giacomini did just that—using "a single column entry" for a polymer's modulus in his overall sheet flexural modulus calculation (D.I. 77, ¶ 125).⁴ Dr. Giacomini's calculations, therefore, are unreliable.

3M has only a throwaway sentence on obviousness (D.I. 76 at 18), which is not enough to show that it will likely prove invalidity by clear and convincing evidence. Moreover, 3M does not dispute Bay's considerable evidence of secondary indicia of non-obviousness. *Apple Inc. v. Samsung Elecs. Co., Ltd.*, 839 F.3d 1034, 1048 (Fed. Cir. 2016) (*en banc*).

B. 3M's Infringing Aligner Irreparably Harms Bay Materials

While Bay faces irreparable harm from 3M's infringing aligner, 3M hides behind the

⁴ Dr. Giacomini also did not understand how various factors, such as the bonding between film layers, would affect the overall multilayer sheet flexural modulus. *See, e.g.*, Ex. A at 66:7-68:13.

complex aligner market and obfuscates its own actions to argue that it cannot cause irreparable harm. Without support, 3M argues that it “[REDACTED],” does not compete with Bay, “[REDACTED],” and has been “[REDACTED]” customers.⁵ D.I. 76 at 3, 7, 8, 9. The documents, however, show that [REDACTED] while competing with Bay and its customers. In fact, [REDACTED]. This loss is unquantifiable and irreparable.

1. Bay Materials suffers *concrete* harm from 3M’s competition

3M developed its infringing Clarity Flex aligner because its single-layer, [REDACTED] aligner (called Clarity or Clarity Force), which was [REDACTED] could not compete. Ex. D at 23; Ex. E at 134857; Ex. F at [REDACTED] 3M expects Clarity Flex’s [REDACTED] [REDACTED] [REDACTED] Ex. E at 134868-69 (projecting [REDACTED] in 10-year incremental sales and market-share growth [REDACTED] Ex. F at 7336-7 (“3M Growth: [REDACTED]” and [REDACTED] incremental sales over 10 years”).

3M’s growth will, and indeed already has, come from 3M’s direct competition with Bay and Bay’s customers. *See, e.g.*, [REDACTED] [REDACTED] [REDACTED] Ex. J at 155378; Ex. C at 62:24-65:9, 69:22-71:3. While 3M refers to Bay’s “thousand[s]” of customers, D.I. 76 at 8, those customers include large DSOs, group purchasing organizations (“GPOs”), and individual practices: Bay sells aligner sheets directly to these customers. *See* Ex. C at 97:3-100:11; D.I. 10, ¶ 16; Ex. K at 133:3-135:2. 3M’s documents show that it seeks to sell to these customers. *E.g.*,

⁵ 3M did not provide testimony on its marketing strategy. Its economic expert, Mr. Kidder, did not investigate it, including whether 3M targets Bay or its customers or why 3M released Clarity Flex. Ex. C at 49:23-50:15, 86:1-89:14, 103:13-106:9. He did not even speak to anyone at 3M about sales and marketing. *E.g., id.* at 48:25-50:15, 106:1-9, 132:24-133:10.

Ex. J at 155378 (targeting a practitioner that uses Zendura FLX); Ex. C at 62:24-63:14.⁶

3M's assertions that the aligner market has many competitors ignores that the *multilayer* aligner market [REDACTED]. *See* D.I. 10, ¶ 25; Ex. K at 132:9-22.⁷ 3M does not appear to dispute this. Ex. C at 97:3-16. Nor does 3M dispute that it [REDACTED] (Ex. F at [REDACTED], 7332, 7334; Ex. E at 134860; Ex. C at 62:3-63:14, 70:20-71:3, 90:25-91:25), using its size, sales forces, conveyed discounts, and presence in doctors' practices to leverage its new aligner made from differentiating multilayer material. *E.g.*, Ex. L at 669-671; Ex. C at 83:16-84:8; Ex. V at 152265; [REDACTED]. 3M even modeled its Clarity Flex aligner on Zendura FLX, evidencing its industry-leading position. *E.g.*, Ex. M at 61936, 61943; [REDACTED] [REDACTED]; [REDACTED], [REDACTED]); Ex. F at [REDACTED]; Ex. N at 1 (noting possible confusion between Zendura FLX and Clarity Flex).

Bay is also irreparably harmed by 3M's direct competition with Bay's customers, such as [REDACTED]. *See Mytee Prods., Inc. v. Harris Rsch., Inc.*, 439 F. App'x 882, 888 (Fed. Cir. 2011) (irreparable harm experienced through patentee's franchisees); *Novozymes A/S v. Genencor Intern., Inc.*, 474 F. Supp. 2d 592, 612-13 (D. Del. 2007) (direct competition with the patentee's subsidiary caused irreparable harm). 3M directly targets [REDACTED] and [REDACTED] customers. *E.g.*, [REDACTED] (targeting [REDACTED] aligner provider); [REDACTED]; [REDACTED]; Ex. C at 69:22-71:3; *see also* Ex. F at [REDACTED] Ex. P at 32:11-33:11; [REDACTED]. As demonstrated by 3M's documents and expert, [REDACTED], a [REDACTED] DSO customer in the

⁶ 3M's cases involving harm solely to a sister company or licensee are thus inapposite.

⁷ 3M's reliance on cases involving "many competitors" are inapplicable here, where the [REDACTED]

general practitioner channel, has been captured by 3M as a “new customer.” D.I. 79-1 at Ex. 4, p. 3; Ex. U. [REDACTED] is a growing DSO ([REDACTED])

[REDACTED]), making any losses even more harmful. D.I. 7 at 15-18.

It is thus not “rank speculation” that 3M directly competes with Bay and its customers. Nor is it speculative that such direct competition eviscerates [REDACTED]. Such harm is concrete and irreparable. *See Trebro Mfg., Inc. v. Firefly Equip., LLC*, 748 F.3d 1159, 1171 (Fed. Cir. 2014) (court abused discretion in denying preliminary injunction when the parties were in direct competition). Bay explained that, due to market dynamics, it takes considerable time to identify lost customers. *See, e.g.*, D.I. 11, ¶ 29; D.I. 9, ¶¶ 137-39. 3M does not dispute this. D.I. 76 at 9 (addressing only market “stickiness”). And, as Bay predicted, lost customers are now becoming apparent. Bay thus has provided detailed and supported explanations of the market and the harm 3M’s infringement causes.⁸

Any increases in sales by Bay, or in purchases by customers like [REDACTED] do not negate the presence of these irreparable harms. The clear aligner market is growing rapidly, and, with its cutting-edge Zendura FLX material, Bay is poised to grow rapidly, too. *E.g.*, D.I. 81-6, Ex. FF at 47:16-50:6; Ex. C at 102:17-103:12. 3M’s new infringing multilayer aligner threatens Bay’s potential, and the nature of the market complexities, including the market’s growth, evidences the difficulty in quantifying such harm. *See Celsis In Vitro, Inc. v. CellzDirect, Inc.*, 664 F.3d 922, 930 (Fed. Cir. 2012); *Douglas Dynamics, LLC v. Buyers Prods. Co.*, 717 F.3d 1336, 1344-45 (Fed. Cir. 2013) (reversing permanent injunction denial because market share increase after infringing product launch could be “for a variety of reasons”). Indeed, 3M’s infringing Clarity

⁸ 3M’s cases involving contract interpretation or vague assertions of harm are thus inapposite.

Flex is [REDACTED]. *See* D.I. 79-1 at Ex. 3 (reporting that Clarity Flex sales [REDACTED] of 3M’s aligner sales within 7 months); Ex. Q.

2. 3M’s harm to Bay Materials cannot be repaired with money damages

3M does not address the cascading and wide-ranging harms Bay raised, beyond arguing that harm is “speculative.”⁹ D.I. 76 at 7-9. 3M contends that harm to Bay is not irreparable because “the parties engaged in licensing discussions” and Bay was “interested in supplying its materials to 3M in the past.” D.I. 76 at 9-10. But 3M approached Bay for a license and asked Bay to make a counteroffer. *Id.* at 5; Ex. R at 10754, 10752, 10749, 10745. Bay did not. 3M also understood that Bay was willing to consider a broader collaboration—not just money. Ex. T at 7399, 7402, 7404. None of 3M’s identified “key takeaways” from the discussions were about granting a monetary license. *Id.* at 7402. 3M’s cases involving patentees *offering* licenses to the accused infringers are thus inapplicable. And allowing a willful infringer to immunize itself from injunctive relief by offering a pittance of a license, as 3M suggests, would be absurd.

Contrary to 3M’s arguments, a decision on licensing can be, and was, based on a variety of factors not relevant to whether 3M’s activity in the market would irreparably harm Bay. *See, e.g.*, Ex. S (discussing concerns that 3M will get what it wants one way or another). Nor would Bay’s purported willingness to sell Zendura materials to 3M “in the past” negate irreparable harm. Such hypothetical sales would not give 3M the right to manufacture its own sheets for its own product and eviscerate Bay’s control over the multilayer aligner market behind Align.

3. 3M’s infringement directly causes the irreparable harm to Bay

Bay’s and Zendura FLX’s successes are due to the patented features, including improved

⁹ 3M relies on Mr. Kidder to argue that money damages are adequate. D.I. 76 at 10. But Mr. Kidder assumes away any harm and is thus unreliable. Mr. Kidder assumed, for example, that 3M’s market share would decrease and Bay’s customers, [REDACTED], would gain market share and would never lose any customers. Ex. C at 114:3-116:18.

force persistence and comfort, as well as improved stain, crack, and scratch resistance, which drive purchasing decisions. D.I. 12, ¶¶ 12-29; D.I. 10, ¶¶ 13-15; D.I. 11, ¶¶ 18-24; Ex. M at 61943 (3M stating that “Zendura FLX . . . performs exceptionally well with near-constant force over 2 week duration”); Ex. F at [REDACTED] (comparing positive attributes of [REDACTED] over others); D.I. 79, ¶ 88 (stating that “‘hard-soft-hard’ material provides some advantage”); Ex. P at 78:10-79:10. Indeed, 3M advertises these properties of its infringing aligner. Ex. F at [REDACTED]; Ex. M at 61943; D.I. 10, ¶ 24; D.I. 11, ¶ 26. That other factors play a role in purchasing decisions does not undermine a nexus finding. *See, e.g., Apple Inc. v. Samsung Elecs. Co.*, 735 F.3d 1352, 1364 (Fed. Cir. 2013) (nexus only requires that “a patented feature is one of several features that cause consumers to make their purchasing decision.”). Finally, whether Bay’s customers advertise Bay’s or Zendura FLX’s name is irrelevant to nexus. Regardless of label, 3M, Bay, [REDACTED] all advertise the patented features when marketing their products. *E.g.*, D.I. 1-1 at Exs. F, H; D.I. 11-1 at Exs. 3, 4; [REDACTED]. And dentists, orthodontists, and patients seek out these aligners based on those features. D.I. 9, ¶¶ 78-100, 152-166; D.I. 11, ¶¶ 19-20.

C. The Balance of Hardships and Public Interest Factors do not Favor 3M.

3M’s investment in willful infringement cannot weigh against a preliminary injunction. *See Pfizer, Inc. v. Teva Pharms. USA, Inc.*, 429 F.3d 1364, 1382 (Fed. Cir. 2005). 3M can keep selling its noninfringing aligner. 3M’s arguments that its single-layer aligner cannot compete and that its market share would go “to zero,” (D.I. 76 at 20), further supports nexus. And because Bay’s invention is not yet in the public domain, *Apple Inc. v. Samsung Elecs. Co.*, 809 F.3d 633, 647 (Fed. Cir. 2015), 3M’s argument that an injunction would harm the public interest of “free competition” in “the public domain” is meritless, D.I. 76 at 20.

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CERTIFICATE OF SERVICE

I hereby certify that on the 1st day of April 2022, the attached **REPLY BRIEF IN SUPPORT OF PLAINTIFF BAY MATERIALS' MOTION FOR PRELIMINARY INJUNCTION** was served upon the below-named counsel of record at the addresses and in the manner indicated:

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