

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

SOLMETEX, LLC,

Plaintiff,

V.

DENTAL RECYCLING NORTH AMERICA,
INC.,

Defendant.

C.A. No. 23-602-MN

**DEFENDANT DRNA'S OPENING BRIEF
IN SUPPORT OF ITS MOTION TO DISMISS**

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Exhibit No.	Exhibit Title
1	U.S. Patent No. 11,660,175
2	Excerpts of the File History for U.S. Patent No. 11,660,175
3	https://drna.com/products/Cartridge-2-Compatible-with-Solmetex-r-NXT-Hg5-r-**-ONLY-p454946180 , which was cited by D.I. 1 at ¶ 27
4	https://vimeo.com/509905162 , included on https://drna.com/products/Cartridge-2-Compatible-with-Solmetex-r-NXT-Hg5-r-**-ONLY-p454946180 , which was cited by D.I. 1 at ¶ 27

¹ Exhibits are attached to the concurrently-filed Declaration of Ryan Iwahashi and referred to as "Ex. __" herein.

This case—which is the second attempt of the market incumbent Solmetex, LLC ("Solmetex") to quash competition from upstart Dental Recycling North America, Inc. ("DRNA") through meritless litigation—should be dismissed at the outset. Solmetex, which manufactures wastewater filtration "amalgam separators" for dental offices, seeks to bar DRNA from supplying replacement filtration "cartridges" (or "containers") for those systems, asserting one claim for patent infringement and two claims for false advertising under the Lanham Act and the Delaware Deceptive Trade Practices Act ("DTPA"). All fail on the pleadings.

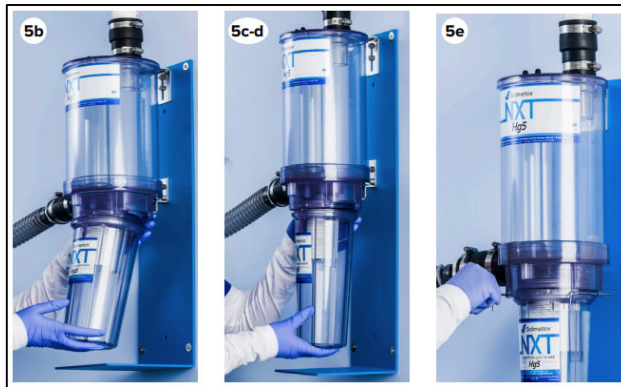
Solmetex's claim for infringement of U.S. Patent No. 11,660,175 ("the '175 patent") should be dismissed because, accepting Solmetex's allegations as true, the '175 patent is invalidated by both Solmetex's allegedly embodying cartridge and DRNA's allegedly infringing cartridge. The complaint alleges that (1) both cartridges practice the claims of the '175 patent; and (2) both cartridges were on the market more than a year **before** the '175 patent was filed. Although the '175 patent is part of a chain of patent applications and claims priority on its face to an earlier filing date, the prosecution history—which is part of the record on a motion to dismiss—establishes that the '175 patent is not entitled to that priority date. Namely, in an apparent effort to target DRNA's preexisting cartridge, Solmetex added new features, new text, and new annotations to the specification during prosecution of the '175 patent. Because that new matter is incorporated into **every independent claim**, no claim of the '175 patent may claim the priority date of its parent applications, and Solmetex has pled itself out of court.

Solmetex's tagalong false advertising claims fare no better. Solmetex's reliance on baseless information-and-belief pleading does not meet Rule 8 standards, and the disconnect between Solmetex's "interpretations" of DRNA's advertisements and the actual text of those ads means that it has not adequately pled that any consumer would have been misled.

II. BACKGROUND

A. The Parties and Their Products

The Environmental Protection Agency requires dental offices to employ an amalgam separator that filters out solid waste (e.g., dental amalgam from patients' fillings, such as mercury) from wastewater to protect the public water supply. (D.I. 1 ("Compl."), ¶¶ 8-9.) Solmetex's NXT Hg5 amalgam separator system, depicted below, captures waste in a detachable "collection container." (*Id.*, ¶ 13.) When the container fills up, it must be properly disposed of and replaced with a new container. (*Id.*, ¶ 16.)



(*Id.*, ¶ 17.)

DRNA and Solmetex both sell replacement containers that are compatible with the NXT Hg5. The complaint establishes that Solmetex has been selling its collection containers in the United States since at least March 2019. (*See id.*, Ex. B at 9.) Solmetex alleges that its "Collection Container practices one or more claims of the '175 Patent." (*See Compl.*, ¶ 24.) The complaint establishes that DRNA has been selling its replacement containers (the "Cartridge 2") since at least February 8, 2021. (*See Exs. 3-4 (cited by Compl.*, ¶ 27).) Solmetex alleges that the Cartridge 2 infringes the '175 patent. (*See Compl.*, ¶¶ 25, 63.)

B. The '175 Patent and its Prosecution

The '175 patent, which generally relates to an amalgam separation system, was filed less than a year ago, on October 13, 2022. (*Compl.*, Ex. A at 1.) This was over three years after

Solmetex began selling the containers it now alleges practice this patent, and a year and a half after DRNA began selling the allegedly infringing Cartridge 2.

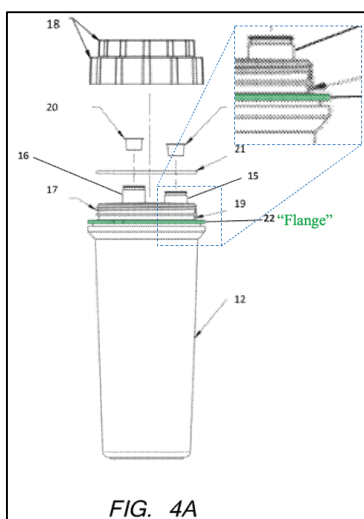
On its face, the '175 patent claims priority to a chain of patent applications dating back to a provisional application filed in 2016. (See Ex. 1 at (60), (63).) But the '175 patent is not entitled to this earlier priority date because all three of its independent claims rely on substantive new matter—including structures, text, and annotations—that was added to the specification during prosecution *within the last year*. Namely, all claims recite (with minor variation):

"at least one **radially protruding structure** located below the generally cylindrical upper region, the at least one **radially protruding structure for engaging the at least one retaining pin** of the dental amalgam separation system."

(*Id.* at cl. 1; *see also id.* at cls. 12, 18.) This claim language is supported by just two passages and one figure of the specification, reproduced below:

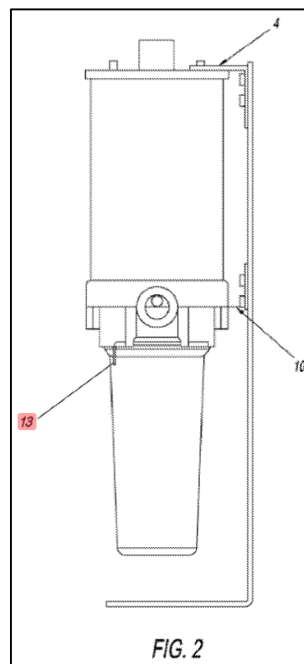
"[The recycling container includes] **a flange structure 22 that protrudes radially** away from the central axis of the main body of the recycling container 12. The **removable retaining pins 13**, described above with respect to FIG. 2, **fit within the region below the flange structure 22.**" (*Id.*, 7:65-8:2.)

"[The removable pins] **engage radially protruding structures** of the recycling container" (*Id.*, 7:30-32.)



(*Id.*, Fig. 4A (green and blue annotations added).) This disclosure is not redundant; it is the **only** support for limitations included in every claim of the '175 patent.

This disclosure is also entirely new. The original specification of the '175 patent filed on October 13, 2022—i.e., the specification inherited from the earlier applications to which the '175 patent claims priority—does not mention the term "radially protruding structure," nor the related term "flange." (Ex. 2, PDF pp. 203-215.) Nor does it describe this structure in other terms. Fig. 4A lacked even a numeral to identify the supposed "flange." At most, the specification mentioned once in passing that "[t]he system is provided with . . . removable retaining pins 13," which were depicted (illegibly) only in Fig. 2. (*Id.*, PDF p. 213)



('175 patent, Fig. 2 (red annotation added).) But the specification did not purport to disclose the use of retaining pins in conjunction with a "radially protruding structure" or "flange" to secure a container in place, as the claims recite.

Rather, all these features were added to the specification during prosecution of the '175 patent to escape rejections. Namely, in a January 20, 2023 office action, the examiner rejected

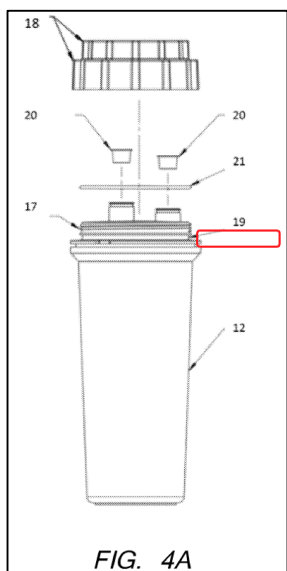
all pending claims under 35 U.S.C. § 112 for lack of enablement. As the examiner explained:

"The specification ***fails to sufficiently disclose*** and describe ***the 'radially protruding structures' and the 'pair of pin engaging surfaces'*** (claims 13, 25, 31), ***the 'flange'*** (claims 20, 21, 28, 29), and [another feature]. It is also noted that, while disclosed in the specification, ***the 'pins' 13 are not sufficiently disclosed.***"

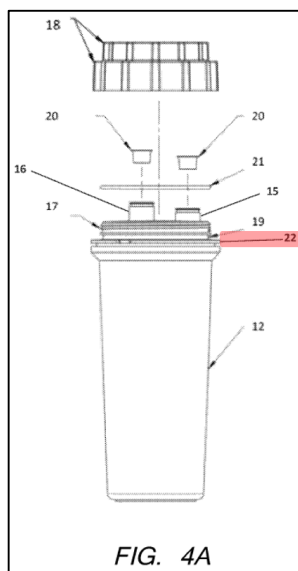
(Ex. 2, PDF p. 158.) In a responsive office action on February 7, 2023, Solmetex made three significant additions to the specification to disclose these features for the first time.

First, Solmetex amended Figs. 4A and 4B to "add reference numeral[] ... '22'" to identify—for the first time, more than six years after the claimed priority date—a blurry, indistinct, and heretofore obscure line of pixels as the purportedly novel "flange structure 22." (*Id.*, PDF p. 151.)

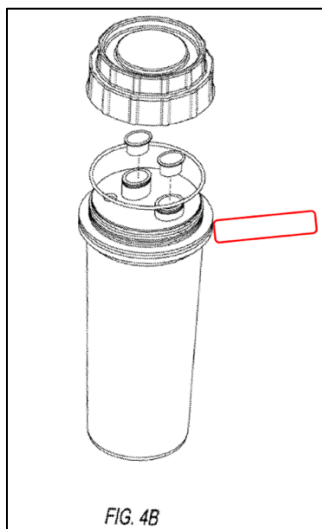
Original Fig. 4A
(No "Flange 22") (*Id.*, PDF p. 222)



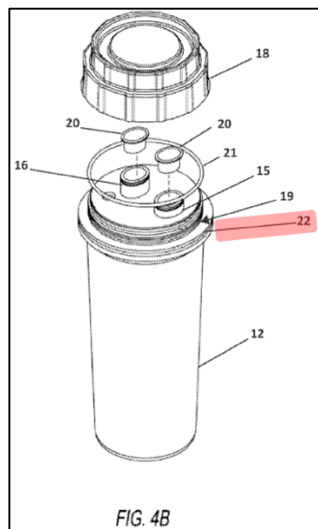
New Fig. 4A
(Adds "Flange 22") (*Id.*, PDF p. 103)



Original Fig. 4B
(No "Flange 22") (*Id.*, PDF p. 223)



New Fig. 4B
(Adds "Flange 22") (*Id.*, PDF p. 104)



Second, Solmetex "amend[ed] paragraph [0096] to describe the flange structure '22' in a manner ***consistent with what is illustrated in the figures***, as follows":

[96] **Figure 4a** shows a schematic diagram of the recycling container and cap system (see **Figure 5** for more cap **18** detail) according to the present invention. The cap **18** is a two tier shape to allow for a tight grip by both a big and smaller hand in order to achieve a strong seal as required by the invention. An O-ring **21** is provided and fits into an O-ring groove **19** on the recycling container **12** above a flange structure **22** that protrudes radially away from the central axis of the container **12**. The removable retaining pins **13**, described above with respect to **Figure 2**, fit within the region below the flange structure **22**. Plugs **20** are used to provide a first leak proof seal for the recycling container **12**. These plugs **20** are held in place by the cap **18** when the cap is threaded onto the recycling container as depicted in **Figure 5b**.

(*Id.*, PDF p. 129 (highlighting added, underlining in original).)

Third, Solmetex represented to the examiner that the barely-visible retaining pins 13 (of Fig. 2, reproduced above) were in fact "L-shaped" with a "horizontal segment . . . [that] fits within the region directly below the flange structure 22, which radially protrudes away from the central axis of the container 12 as shown in FIGURES 4A and 4B." (*Id.*, PDF p. 98.) And although the application contained no such disclosure, Solmetex assured the examiner that "[t]o remove [the container], the removable retaining pin 13 is pulled in the left direction in FIGURE

2 such that the horizontal segment of the pin 13 is removed from the region directly below the flange structure 22." (*Id.*)

Then, in a March 16, 2023 office action, the examiner noted that "[t]he specification does not describe certain claim elements as recited in the claims," including the "radially protruding structure, [and] pin engaging surface." (*Id.*, PDF p. 77.) Again, Solmetex responded in a March 22, 2023 office action by simply adding the missing material to the specification:

<p>-- [0084] The system is provided with a simple back plate 1 for easy dental office placement as well as removable retaining pins 13 <u>that engage radially protruding structures of the detachable recycling container</u> to ensure the recycling container does not detach from the air-water separation tank 5 when there is no vacuum in the system. --</p>

(*Id.*, PDF p. 70 (highlighting added, underlining in original).)

In short, Solmetex added the sole support for the claimed "radially protruding structure" for engaging a retaining pin—which is recited in every claim—in a series of increasingly detailed additions to the specification **this year**. On the basis of these additions, the examiner dropped his § 112 rejection, and ultimately allowed the patent. (*Id.*, PDF p. 10.) The '175 patent issued on May 30, 2023. Two days later, on June 1, 2023, Solmetex filed this lawsuit.

III. LEGAL STANDARD

In ruling on a motion to dismiss pursuant to Rule 12(b)(6), the Court accepts factual allegations in the complaint as true and views them in the light most favorable to the plaintiff. *See Mayer v. Belichick*, 605 F.3d 223, 229 (3d Cir. 2010). But the "court need not 'accept as true allegations that contradict matters properly subject to judicial notice or by exhibit,' such as the claims and the patent specification." *Secured Mail Sols. LLC v. Universal Wilde, Inc.*, 873 F.3d 905, 913 (Fed. Cir. 2017) (quoting *Anderson v. Kimberly-Clark Corp.*, 570 F. App'x 927, 931 (Fed. Cir. 2014)). The file history is part of the public record associated with a patent and is properly considered in a Rule 12 motion. *See Data Engine Techs. LLC v. Google LLC*, 906 F.3d

999, 1008 n.2 (Fed. Cir. 2018) (applying Third Circuit law). Dismissal under Rule 12(b)(6) is appropriate if a complaint does not contain "sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quotation omitted); *see also Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009).

"It is elementary patent law that a patent application is entitled to the benefit of the filing date of an earlier filed application **only if** the disclosure of the earlier application provides support for the claims of the later application, as required by 35 U.S.C. § 112." *In re Chu*, 66 F.3d 292, 297 (Fed. Cir. 1995) (emphasis added). It is not enough that a claim limitation might have been obvious to a person of skill in the art; section 112 "requires that the written description **actually or inherently** disclose the claim element." *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1306 (Fed. Cir. 2008) (emphasis added). For disclosure to be inherent, "the missing descriptive matter must **necessarily be present** in the [original] application's specification" *Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 1159 (Fed. Cir. 1998) (emphasis added).

To survive a motion to dismiss a false advertising claim under the Lanham Act, a plaintiff must adequately plead that "the defendant made false or misleading statements or descriptions of fact in commercial advertising or promotion that 'misrepresent[ed] the nature, characteristics, qualities, or geographic origin of his ... goods, services, or commercial activities.'" *Robert Bosch LLC v. Pylon Mfg. Corp.*, 632 F. Supp. 2d 362, 366 (D. Del. 2009) (quoting 15 U.S.C. § 1125(a)(1)(B)). The DTPA similarly prohibits "disparage[ment] of the goods, services or business of another by false or misleading representations of fact," committed "in the course of a business, vocation, or occupation" or that generally "creates a likelihood of confusion or of misunderstanding." 6 Del. C. §§ 2532(a)(8) & (a)(12). The DTPA has a "lower pleading burden" in that DTPA plaintiffs "need not prove competition between the parties or actual

confusion or misunderstanding," but courts in the Third Circuit "typically treat DTPA claims and Lanham Act claims as rising and falling together, while accounting for the lower pleading burden under DTPA." *Peloton Interactive v. Icon Heath & Fitness*, Civil Action No. 20-662-RGA, 2021 U.S. Dist. LEXIS 101436, at *21 (D. Del. May 28, 2021).

IV. THE PATENT CLAIM SHOULD BE DISMISSED

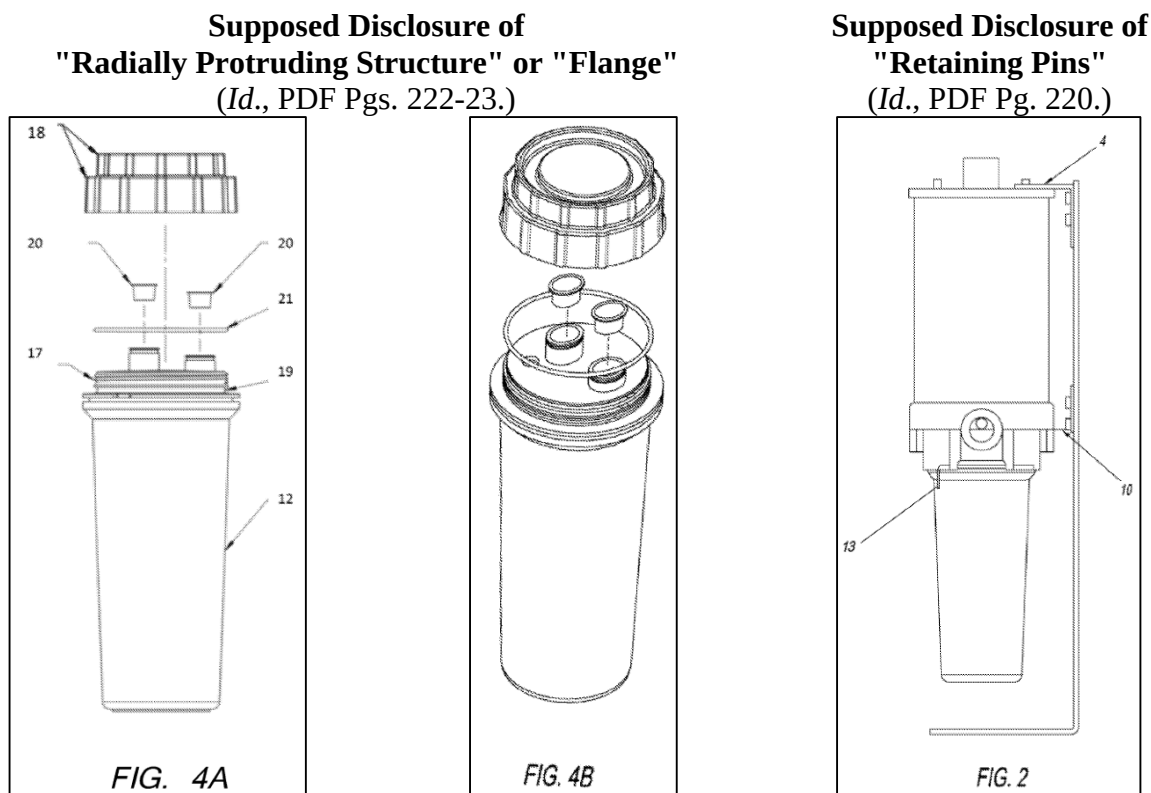
Solmetex's patent infringement claim should be dismissed. The prosecution history—which is part of the record on the pleadings—demonstrates that the '175 patent is not entitled to a priority date earlier than its October 13, 2022 filing date.² Accordingly, accepting as true Solmetex's allegations that (1) both Solmetex's and DRNA's cartridges practice the claims of the '175 patent; and (2) both cartridges were on the market more than a year *before* the '175 patent was filed, the '175 patent is invalid under the on-sale bar pursuant to 35 U.S.C. § 102(a).

A. The '175 Patent Is Not Entitled to Priority Before Its Filing Date

The '175 patent cannot plausibly claim priority before its October 13, 2022 filing date, because the applications that the '175 patent claims priority to—whose specifications lack the new material added during prosecution of the '175 patent—do not actually or inherently disclose the "radially protruding structure for engaging the at least one retaining pin" recited (with minor variation) in all three independent claims. *See PowerOasis*, 522 F.3d at 1306 ("It is elementary patent law that a patent application is entitled to the benefit of the filing date of an earlier filed application only if the disclosure of the earlier application provides support for the claims of the later application, as required by 35 U.S.C. § 112.")

² More specifically, the '175 patent is not entitled to priority before the new material was added to the specification on February 7, 2023, and March 16, 2023. (Ex. 2, PDF pp. 118-53.) However, because the Complaint establishes that the Solmetex Collection Container and DRNA Cartridge 2 were sold in the United States prior to any of these dates, the precise priority date is not pertinent to the resolution of this motion.

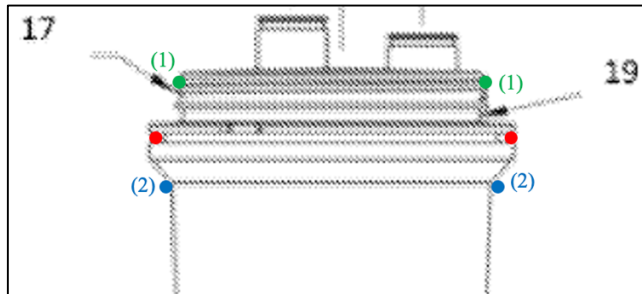
Prior to the addition of the new materials during prosecution of the '175 patent, the sole disclosure that could conceivably relate to the claimed "radially protruding structure" was the predecessor versions of Fig. 4A (which include no corresponding description of a "radially protruding structure") and Fig. 4B (which include no corresponding description at all). (Ex. 2, PDF pp. 222-23.) And the sole disclosure that could conceivably relate to the claimed "retaining pins" was Fig. 2 and a single corresponding sentence in the specification stating that "[t]he system is provided with . . . removable retaining pins 13 to ensure the recycling container does not detach from the air-water separation tank when there is no vacuum in the system." (*Id.*, PDF pp. 213, 220.) This universe of material—which must alone establish any priority claim before the October 13, 2022 filing date of the '175 patent—is reproduced below for reference:



But these materials do not disclose the combination of a "radially protruding structure for engaging the at least one retaining pin." Indeed, the supposed "radially protruding structure" and the "retaining pin" are ***never depicted together***. Rather, the former is purportedly depicted (by a

thin, barely-visible, unlabeled line of pixels) only in Figs. 4A and 4B, while the latter is depicted (though barely-visible and largely obscured) only in Fig. 2. Similarly, in the written description, these structures are *never described together* and, more to the point, these structures are certainly *never described as cooperating to secure the container in place*, as the claims require.

Nor do these materials inherently disclose the claimed combination of a "radially protruding structure for engaging the at least one retaining pin." For a disclosure to be inherent, "the missing descriptive matter *must necessarily be present* in the [original] application's specification." *Tronzo*, 156 F.3d at 1159 (emphasis added). But here, the "retaining pins" need not necessarily engage with the purported "radially protruding structure" to secure the container in place. Indeed, particularly given that the shape of the retaining pins was not specified in the priority specification or legibly depicted in Fig. 2, the pins could mate with any number of other conceivable structures on the container, including a depression or hole. But even accepting Solmetex's assertion in the prosecution history that the retaining pins are L-shaped (Ex. 2, PDF p. 98), they would not need to mate with the radially protruding structure (red below) to secure the container. For instance, pins could be inserted either (1) in the threading of the upper cylindrical portion (green below); or (2) below the top structure of the container entirely (blue below).



(175 Patent, Fig. 4A (cropped; annotations added to show potential pin engagement sites).)

And of course, Solmetex effectively admitted during prosecution that the priority

specification did not disclose the claimed features. As detailed above, the examiner rejected all pending claims under 35 U.S.C. § 112 for lack of enablement because the specification "fail[ed] to sufficiently disclose and describe the 'radially protruding structures' and the 'pair of pin engaging surfaces' (claims 13, 25, 31), the 'flange' (claims 20, 21, 28, 29)," and "the 'pins' 13 [were] not sufficiently disclosed." (Ex. 2, p. 158.) Solmetex could have argued against this rejection without amendment. Instead, it chose to add the new material at issue here, tacitly admitting that the specification was deficient. (*See id.*, PDF pp. 60, 149.) Solmetex cannot now claim those additions were unnecessary because the limitation was disclosed all along. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1317 (Fed. Cir. 2005) ("Like the specification, the prosecution history provides evidence of how the PTO and the inventor understood the patent.")

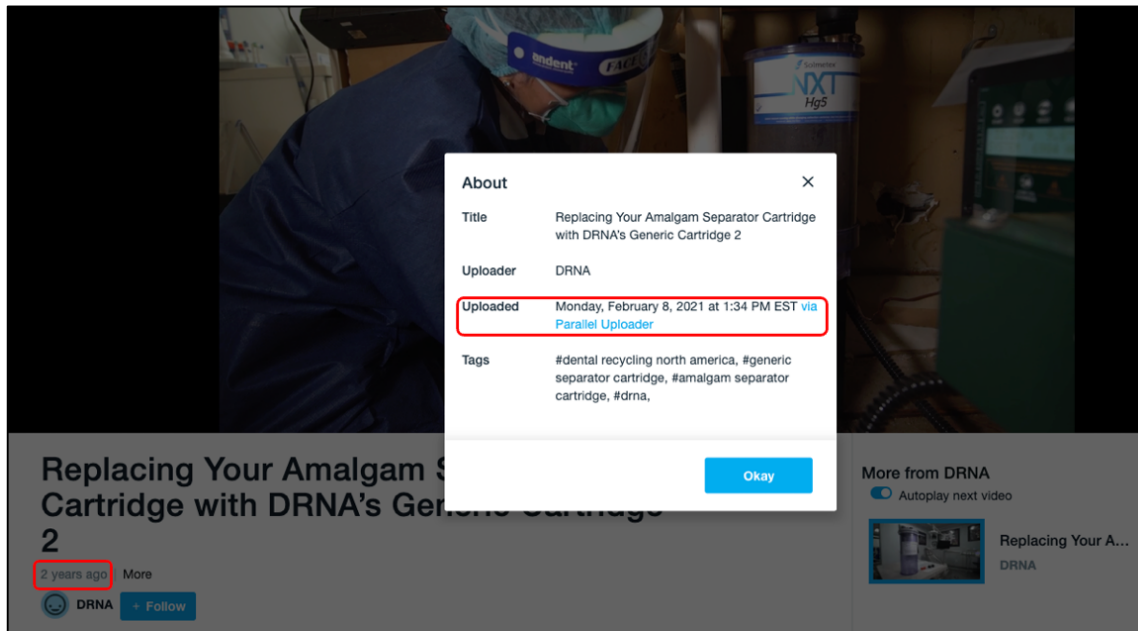
Bottom line: this is not a case where the patentee simply claimed preexisting disclosure using new language. There was no disclosure of the claimed "radially protruding structure for engaging the at least one retaining pin" before Solmetex's addition of new material. Accordingly, the claims of the '175 patent—all of which incorporate this limitation—are entitled to, at best, a priority date of October 13, 2022. *See In re NTP, Inc.*, 654 F.3d 1268, 1276 (Fed. Cir. 2011) ("[Patent claims] are not entitled to an earlier priority date merely because the patentee claims priority.")

B. Prior Sales of the Allegedly Infringing DRNA and Allegedly Embodying Solmetex Products Invalidate the '175 Patent

Accepting as true Solmetex's allegations that the accused DRNA Cartridge 2 and allegedly embodying Solmetex Collection Container practice the claims of the '175 patent, their alleged sale prior to October 13, 2022 would invalidate the '175 patent.

First, Solmetex's Complaint cites to a Vimeo video embedded on a DRNA web page depicting the allegedly infringing Cartridge 2 product. (Compl., ¶ 27.) But the linked web page

for this video states on its face that it was "Uploaded" approximately "2 years ago" on "Monday, February 8, 2021." (See Exs. 3-4 (cited by Compl., ¶ 27).)³



Assuming the truth of Solmetex's allegation that the DRNA Cartridge 2 is infringing (Compl., ¶ 63), its sale before the earliest possible October 13, 2022 priority date would invalidate the '175 patent. *Peters v. Active Mfg. Co.*, 129 U.S. 530, 537 (1889) ("That which infringes, if later, would anticipate, if earlier.") Accordingly, Solmetex has pleaded itself out of court.

Second, and additionally, Solmetex's complaint attaches as Exhibit B an "Installation and Operations Manual" for its NXT Hg5 amalgam separator and Collection Cartridge. (Compl., Ex. B.) That manual is dated March 2019, indicating that the Solmetex Collection Cartridge was sold more than three years before the October 13, 2022 application.

³ See *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997) ("[A] document integral to or explicitly relied on in the complaint may be considered without converting the motion to dismiss into one for summary judgment."). The Court is also entitled to consider "matters incorporated by reference . . . to the claim, items subject to judicial notice, matters of public record, orders, items appearing in the record of the case and exhibits attached to the complaint whose authenticity is unquestioned." *Esaka v. Nanticoke Health Servs.*, 752 F. Supp. 2d 476, 480 (D. Del. 2010).



(Compl, Ex. B, at 9.) Assuming the truth of Solmetex's allegation that "Collection Container practices one or more claims of the '175 Patent" (*see* Compl., ¶ 24), its sale before the earliest possible October 13, 2022 priority date would invalidate the '175 patent. *See Mayer*, 605 F.3d at 229; 35 U.S.C. § 102(a)-(b) (defining prior art to include public use or sale of a product more than a year before the filing date even if the product was by the inventor). Again, Solmetex has pled itself out of Court, and its Complaint should be dismissed.

V. THE FALSE ADVERTISING CLAIMS SHOULD BE DISMISSED

Solmetex's claims for false advertising under the Lanham Act and in violation of the DTPA should, like its spurious claim for patent infringement, be dismissed out of hand. Solmetex's false advertising claims are fundamentally deficient because Solmetex does not adequately allege that any identified statement by DRNA is false or misleading. A false advertising plaintiff must plead that the defendant's statements "were, in context, literally false or that they were misleading and that the relevant public 'was, in fact, misled.'" *Accenture Glob. Servs. GmbH v. Guidewire Software Inc.*, 581 F. Supp. 2d 654, 666 (D. Del. 2008) (citation omitted). Solmetex fails to meet this bar for any of the statements that it raises.

A. Solmetex's Allegations on DRNA's Performance-Related Statements Fail

Solmetex attacks DRNA's statement that customers that "opt[] for DRNA's products" will "access cost-effective solutions that support compliance and perform as well as the more costly, big name brands" (Compl., ¶ 32), claiming that this is false because the Cartridge 2 does "not 'perform as well as' Solmetex's NXT Hg5 Collection Container in several respects." (*Id.*) This is

misguided for several reasons. First, in focusing on this comparison of the performances of the Cartridge 2 and the NXT Hg5 Cartridge, Solmetex ignores that generic comparisons to competing products unconnected to specific product features are classic examples of "puffery," or advertising "'that is not deceptive for no one would rely on its exaggerated claims.'" *United States Healthcare, Inc. v. Blue Cross of Greater Phila.*, 898 F.2d 914, 922 (3d Cir. 1990) (advertisements that stated plaintiff's health plans were "better than HMO" were "most innocuous kind of 'puffing'" and not actionable) (citation omitted). The statement that DRNA's "products" "perform as well"—omitting any metrics, and not even (1) specifying how "performance" could be measured, (2) indicating which DRNA product is being described, or (3) naming the product(s) against which the DRNA product is being compared—is textbook puffery. *See id.*; *see also, e.g., Liqwd, Inc. v. L'Oréal United States*, No. 17-14-JFB-SRF, 2019 U.S. Dist. LEXIS 233247, at *28 (D. Del. June 25, 2019) (granting summary judgment for claims based on statements "regarding L'Oréal's products not performing as well as Olaplex's products," noting that "[w]ere we to find these words to be facts, the entire business community will be involved in multiple law suits over what amounts to puffing").

Next, Solmetex's allegations do not support a plausible inference that the claim is false, i.e., that the Cartridge 2 does **not** perform as well as the NXT Hg5 Collection Container. Solmetex alleges on "information and belief" that DRNA has "received complaints from its customers that they experienced leaking from the NXT Hg5 System when used with the Accused Instrumentality." (Compl., ¶ 34.) Solmetex ignores, however, that a plaintiff may rely on information-and-belief allegations only where "'essential information lies uniquely within another party's control.'" *Brinkmeier v. BIC Corp.*, 733 F. Supp. 2d 552, 559 (D. Del. 2010) (citation omitted). And, even in such situations, plaintiffs have an obligation to "accompany

their legal theory with factual allegations that make their theoretically viable claim plausible." *Id.* (quoting *Burlington Coat Factory*, 114 F.3d at 1418). Solmetex does not do so here. The only support for this allegation is that the Cartridge 2 is designed with ports at the same height, which supposedly "lead[s] to leaks due to insufficient sealing." (Compl., ¶ 33.) But this claim—in essence, that the Cartridge 2 is different and therefore worse—is bare of any factual specifics, such as any indication that Solmetex tested the performance of the Cartridge 2, let alone allegations of the results of such tests. This fails. *See, e.g., Tortilla Factory, Ltd. Liab. Co. v. Rowdy Mermaid Kombucha Ltd. Liab. Co.*, No. CV 18-2984-R, 2018 U.S. Dist. LEXIS 229954, at *5 (C.D. Cal. Sep. 11, 2018) (plaintiff had not adequately pled falsity of product labels under Rule 9(b) standard where plaintiff had relied on information and belief allegations and its "own experience" manufacturing product rather than testing defendant's product); *see also, e.g., Burke v. Weight Watchers Int'l, Inc.*, 983 F. Supp. 2d 478, 480, 483 (D.N.J. 2013) (state law false advertising claims regarding product calorie count inadequate where plaintiff cited "independent laboratory tests" of products but not "which tests").

Solmetex's information-and-belief allegations that DRNA has received "complaints from customers, indicating that the NXT Hg5 System has backed up when using the" Cartridge 2s and "DRNA customers have informed DRNA that the [Cartridge 2] does not, in fact, perform as well as Solmetex's NXT Hg5 Collection Container" (Compl., ¶¶ 37, 39) are no better supported. There is no basis whatsoever provided for the latter allegation, and the former depends entirely on a vague allegation that Solmetex received complaints about back-ups from its own customers supposedly using Cartridge 2s in lieu of the NXT Hg5 Collection Container. (*See id.*, ¶ 36.) But Solmetex offers no reason to suppose that these alleged complaints are actually indicative of Cartridge 2 performance issues. It does not allege, for example, that it does not receive

complaints regarding back-ups from its customers using the NXT Hg5 Collection Container, nor does it offer any details about these complaints—such as the number of them received—from which it may be inferred that they were evidence of a pervasive performance issue (let alone a performance issue traceable to the Cartridge 2 and not Solmetex's own system).

B. Solmetex Does Not Plausibly Allege That the Testing-Related Statements Are False

Solmetex next challenges DRNA's statements that the Cartridge 2 has been "[s]uccessfully tested to ISO 11143:2008 standard" and "tested to ISO 11143:2008 standard" (the "Testing Statements"), contending that they are "literally false" because the Cartridge 2 allegedly does not "comply with the requirements of the ISO 11143:2008 standard." It claims that Section 12.4 of the ISO 11143:2008 standard supposedly requires marking a cartridge with the model number of the corresponding unit, and the Cartridge 2 omits a model number. (Compl., ¶ 43.) To repeat the argument—contrasting DRNA's statement about "testing to" the standard and Solmetex's argument about "complying with the requirements of" the standard—is to highlight its flaws, as Solmetex offers no basis from which it may be inferred that consumers understand a statement that a product is "tested" to or against a certain standard to mean that a product complies with other requirements of the standard that self-evidently have nothing to do with product testing, such as the model marking requirement. *J & M Turner, Inc. v. Applied Bolting Tech. Prods.*, No. 95-2179, 1996 U.S. Dist. LEXIS 788, at *37 (E.D. Pa. Jan. 31, 1996) (plaintiff had failed to demonstrate likelihood of success on the merits of claims based on supposedly false statements that product was "made to" industry standard where standard was "ambiguous"); see also, e.g., *Wayne-Dalton Corp. v. Amarr Co.*, No. 5:06CV01768, 2008 U.S. Dist. LEXIS 143540, at *15 (N.D. Ohio Jan. 23, 2008) (granting motion for summary judgment on false advertising claims where plaintiff failed to show consumers understood advertisement to indicate compliance with particular industry standard, and standard was moreover ambiguous).

Solmetex relies next on information-and-belief pleading to argue that the Testing Statements are also misleading because "they suggest to consumers that the [Cartridge 2] has been 'certified' to the ISO 11143:2008 standard" (Compl., ¶ 52), but Solmetex again fails to draw any connection between the actual language it challenges—that the product has been "tested to" the standard—and the supposed "truth" that it has not been "certified to" the standard. Indeed, Solmetex acknowledges that "DRNA's website does not specifically represent that the [Cartridge 2] is ISO11143 'certified' or that it has a 'certification' under ISO11143," and thus appears to recognize, as it must, a distinction between testing and certification. (Compl., ¶ 49.) *See, e.g., Warren Tech. v. UL LLC*, 962 F.3d 1324, 1328-29 (11th Cir. 2020) (distinguishing between claims of certification by third party and claims of meeting standards promulgated by third party in affirming dismissal of false advertising claims).

Its additional information-and-belief allegations do not bridge this gap, as Solmetex's only basis for its allegation that the Cartridge 2 has not been tested by an accredited laboratory is that DRNA supposedly does not mark the Cartridge 2 with a mark from NSF International ("NSF"), an accredited testing laboratory, and NSF supposedly "requires that certified products bear the 'NSF' mark or be otherwise represented as certified." (Compl. ¶ 45.) But here, Solmetex engages in sleight-of-hand, as the NSF rule that it references describes NSF's optional marketing program, whereby companies may opt for NSF "certification," not just testing services, so that they may advertise their products as certified *by NSF*, not as certified *to* the ISO11143 standard.⁴ Solmetex's misdirection is particularly obnoxious given that DRNA sued it

⁴ *See* "NSF Engineering Lab," available at <https://www.nsf.org/lab-testing/engineering-lab> (accessed August 1, 2023) (describing NSF testing services); *compare to* "The NSF Mark," available at <https://www.nsf.org/about-nsf/nsf-mark> (accessed July 24, 2023) (describing NSF marking program); *see also* "NSF Certified vs. Tested to NSF Standards," available at

for falsely claiming that DRNA products were not NSF-tested, and Solmetex defended against those claims by arguing that it had actually correctly claimed that the DRNA products were not NSF-certified.⁵ Solmetex is thus obviously on notice of the distinction between NSF testing and NSF certification, and its conflation of the two here cannot meet its pleading burden.

And even setting that distinction aside and assuming that the Cartridge 2 did not undergo NSF testing, Solmetex's reliance on the lack of an NSF mark is nonetheless still deficient, because Solmetex fails to render plausible the inference that the Cartridge 2 not undergoing testing by the NSF means that it did not undergo testing by *any* accredited laboratory. Solmetex does not allege, for example, that the NSF is the only accredited laboratory in existence or even in the United States that can provide testing to the ISO 11143:2008 standard. Even under the Rule 12 standard, the leap of logic that Solmetex wishes to make—that a lack of testing by one means a lack of testing by all—is simply too far.

C. Solmetex Does Not Allege the Falsity of the Regulatory Compliance- and Compatibility-Related Statements

Solmetex also challenges DRNA's statement that its "amalgam separators satisfy all local, state, and federal regulations" (Compl., ¶ 53), relying first on its claim that the Cartridge 2 has not been tested by an accredited facility, which argument fails as described above. It further asserts that the statement is literally false because the Cartridge 2 supposedly does not comply with the model-marking requirement of ISO 11143:2008. Solmetex neglects, however, that ISO 11143:2008 is not a "local, state, [or] federal regulation," but instead a "voluntary international

<https://www.nsf.org/blog/consumer/nsf-certified-vs-tested-to-nsf-standards> (accessed August 6, 2023) (distinguishing between certification and testing to standard).

⁵ See *Solmetex, LLC v. Dental Recycling of N. Am., Inc.*, No. 17-cv-860 (JSR), 2017 U.S. Dist. LEXIS 102451, at *8-9 (S.D.N.Y. June 26, 2017) ("Specifically, while the amended counterclaims allege that Solmetex wrote that DRNA's device had not been 'successfully tested to ISO [standards],' the January Letter in fact states (correctly) that DRNA's device had not been certified by NSF International[.]").

standard," and that compliance with ISO standards "is not mandatory." *Wazana Bros. Int'l, Inc. v. Int'l Laser Grp., Inc.*, No. CV 12-1850 PA (PJWx), 2013 U.S. Dist. LEXIS 199936, at *7 n.1 (C.D. Cal. Mar. 25, 2013).⁶ Solmetex further cites an EPA regulation directing that if an amalgam separator is malfunctioning, it must be "repaired consistent with manufacturer instructions or replaced," and claims that the manufacturer instructions for repairing its NXT Hg5 separator do not apply to the Cartridge 2, rendering the Cartridge 2 non-compliant with this regulation. (*See* Compl., ¶¶ 54-58 (citing 40 C.F.R. § 441.30(a)(1)(v).) But Solmetex ignores that the EPA regulation calls for repair consistent with instructions **or replacement**, *see id.*, and makes no allegation that the Cartridge 2 cannot be replaced.

Solmetex finally attacks DRNA's statement that the Cartridge 2 is "compatible with" Solmetex's NXT Hg5 system (*see* Compl. ¶ 58), but its arguments as to falsity are a retread of its other allegations: that the Cartridge 2 is not ISO11143 certified and "would not comply with all federal, state, and/or local regulations" and that it is "much more susceptible to leaking and clogging." (*Id.*, ¶ 59.) Its arguments fail here just as they fail in the contexts described above, *viz.*, Solmetex does not adequately establish any one of these premises.

VI. CONCLUSION

For the foregoing reasons, DRNA respectfully submits that the Complaint should be dismissed with prejudice.

⁶ To the extent that Solmetex might argue that Section 441.30, the relevant EPA regulation, incorporates the ISO standard, it overlooks that this regulation also permits separators that are compliant with ANSI/ADA Specification 108 or subsequent versions of that or the ISO standard, *see* 40 C.F.R. § 441.30(a)(1)(i), and Solmetex does not allege a lack of compliance with those standards. Accordingly, Solmetex fails to establish a lack of compliance with applicable regulations and thus fails to establish falsity.

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