NOT FOR PUBLICATION

**UNITED STATES DISTRICT COURT**
**DISTRICT OF NEW JERSEY**

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| **MILLIPORE CORPORATION, et al.** | : | **Civil Action No. 11-1453 (ES)** |
| **Plaintiffs,** | : | **OPINION** |
| **W.L. GORE & ASSOCIATES, INC.,** | : | |
| **Defendant.** | : | |

**SALAS, District Judge**

## I. Introduction

Plaintiffs Millipore Corporation, Millipore AB, and Millipore SAS (collectively "Millipore") sued defendant W.L. Gore & Associates, Inc. ("Gore") for infringement of Claim 1 of United States Patent No. 6,779,575 ("'575 Patent"), reissued as United States Reissue No. RE41,169 ("'169 Reissue"). Currently before the Court is Millipore's Motion for a Preliminary Injunction filed on March 15, 2011. The Court has reviewed the parties' submissions and heard oral argument on the instant motion on September 27, 2011. For the reasons set forth below, the Court denies Millipore's Motion for a Preliminary Injunction.

## II. Background

The patent at issue in this litigation is the '575 Patent issued on August 24, 2004, and subsequently reissued on March 30, 2010 as the '169 Reissue. The patent claims a device, titled "Sealing Appliance," that was invented to assist in satisfying all of the requirements for

contamination-free transport of sample containers, which are filled with a medium, and then taken to a laboratory for analysis. ('169 Reissue, Col. 1, lines 55-60).

The parties to this litigation are Millipore and Gore. These companies compete to provide sampling systems, and their corresponding sealing appliances, to the pharmaceutical industry. Millipore filed the instant Complaint, accompanied by a Motion for a Preliminary Injunction, for two reasons. First, Millipore seeks to enjoin Gore from further infringement of the '169 Reissue. Second, Millipore contends that Gore is ignoring the provisions of a Consent Judgment Order ("Consent Order") to which it is bound.

The procedural and factual background to the present litigation are complex. Therefore, before the Court turns to its analysis of the underlying issues presented in Millipore's Motion, the Court will briefly discuss the underlying facts which have led to the instant litigation. The Court first will discuss the prior action that involved Millipore and Gore's predecessors-in-interest. Next, the Court will discuss the parties and their respective sealing appliances, which form the basis of this litigation. Finally, the Court will discuss Millipore's Complaint and Motion for a Preliminary Injunction.

**A. The Original Action**

On October 28, 2005, NovaSeptum AB, NovAseptic AB, and NovAseptic America, Inc. (collectively "NovaSeptum") filed a complaint in the District of New Jersey against Amesil, Inc. ("Amesil") to enforce the '575 Patent against Amesil's infringing product—a cutting and crimping device titled the ACP-9000. (Compl. ¶ 15). The case was captioned *NovaSeptum AB, et al. v. Amesil, Inc.*, Civil Action No. 05-5175 (DMC), and will be referred to herein as the "Original Action." The parties ultimately resolved the litigation and entered into a settlement agreement in early February 2007. (*Id.* ¶ 16).

On February 28, 2007, the court entered a Consent Order memorializing a majority of the terms of the parties' Settlement Agreement. (*See* Civil Action No. 05-5175 (DMC), Docket Entry No. 22). Of particular importance to the instant Motion, are Paragraphs 3, 8, and 9 of the Consent Order. Paragraph 3 provides, in relevant part, "Amesil's manufacture, use, sale, offer for sale, and/or importation into the United States of its ACP-9000 device constitutes infringement of Claim 1." Paragraph 8 provides, in relevant part, "Amesil . . . [is] hereby permanently restrained and enjoined, for the life of the Patent-in-Suit from making, having made, using, selling, or offering to sell or importing into the United States of America the ACP-9000 . . . , or any of the preferred embodiments disclosed in the '575 patent, or any substantially similar functional imitations of the jaw components of the foregoing without first obtaining a license from NovaSeptum." Paragraph 9 provides, in relevant part, that "NovaSeptum represents, warrants, and agrees that the manufacture, use, sale, offer for sale, and/or importation into the United States of America, of the Amesil anvil-type crimper tool device . . . and any device that is substantially similar to the anvil-type crimper, does not and will not constitute infringement of any claims of the '575 Patent or any reissue thereof." Finally, although not memorialized in the Consent Order, Paragraph 10 of the Settlement Agreement is also relevant to the motion pending before this Court. Paragraph 10 provides:

> Amesil agrees . . . it will not manufacture, have made use, or import into the United States of America, any crimper tool device that in a single operative step employs (a) at least one bar extending along a straight line from one side of the crimper jaws to the other side to crimp a separate metal or plastically deformable crimp sleeve, and (b) a substantially straight cutting edge to partially or fully cut the crimp sleeve into at least two sections.

(Settlement Agreement between NovaSeptum AB, NovAseptic AB and NovAseptic America Inc. and Amesil, Inc., dated February 2007). Following the entry of the Consent Order, the case was closed.

On February 28, 2007, the same day the Consent Order was entered, Gore publicly announced its acquisition of Amesil. Although Gore referred to the transaction as an acquisition, the legal transaction was technically an asset purchase wherein Gore acquired certain assets from Amesil. *See NovaSeptum AB v. Amesil, Inc.*, No. 05-5175, 2010 U.S. Dist. LEXIS 138513, at *4 (D.N.J. Dec. 29, 2010). One of the assets Gore acquired from Amesil was an anvil-type crimping device. *Id.* at *5. Gore maintains that this crimping device was approved in Paragraph 9 of the Consent Order. *Ibid.*

Sometime later in April 2009, Laurent Leard ("Mr. Leard"), Global Senior Product Manager at Millipore, was examining Gore's website when he stumbled upon a product that caught his attention. Mr. Leard downloaded a datasheet containing the product specification from Gore's website. (Leard Decl. ¶ 26). The datasheet depicted the Gore Crimp and Cut tool that was currently available and/or being sold by Gore. (*Ibid.*). Notably, Millipore did not take immediate action.

Then, on April 2, 2010, Millipore's Counsel sent Gore a cease and desist letter. (Compl. ¶ 28). The letter advised Gore that the Crimp and Cut tool currently being offered for sale on its website was covered by Paragraph 8 of the Consent Order, and was "no more than colorably different than the ACP-9000." (*See* April 1, 2010 Letter from Susan G. L. Glovsky, Attached as Exhibit A to Millipore's Reply to Gore's Opposition to Application for Preliminary Injunction ("Pl. Reply Br.") at 1). Millipore requested that Gore cease all sales of the Crimp and Cut tools, remove the products from its website, and provide an accounting of sales to Millipore. (*Ibid.*). If

Gore chose not to comply with the request, Millipore demanded a sample of the Crimp and Cut tool. (*Id.* at 2).

On April 7, 2010, Gore responded to Millipore's letter request. Gore, through its Counsel, stated "[i]t is difficult to understand how you could have asserted that the Gore product is an imitation of the Amesil product and threatened Gore with a contempt action without first obtaining a sample and comparing it to the Amesil product in *Novaseptum v. Amesil* and the claims of the . . . ['169 Reissue]." (April 7, 2010 Letter from James W. Poradek, attached as Exhibit B to Pl. Reply Br. at 1). Nevertheless, Gore provided Millipore with a sample of its Crimp and Cut tools—the ACS-9073 and GS00020. (*Ibid.*).

On May 12, 2010, NovaSeptum filed a motion to, *inter alia*, reopen the Original Action to hold Gore in contempt for violating the court's Consent Order, as well as substitute Millipore for NovaSeptum. (Compl. ¶ 34). The court substituted Millipore for NovaSeptum, and found that although Gore was bound by the Consent Order as Amesil's successor-in-interest, "substantial open issues existed that created a fair ground of doubt as to whether the Consent Order was violated." *NovaSeptum AB*, 2010 U.S. Dist. LEXIS 138513, at *17, 21. The court, therefore, denied Millipore's motion for contempt.

**B. The Parties and Their Sealing Appliances**

**1. Millipore and Its Sealing Appliance, the NovaSeal Crimping Device**

Millipore's business includes manufacturing, selling, and offering for sale sampling devices for the pharmaceutical industry. (Pl. Moving Br. at 2). Customers purchase sealing appliances as part of their purchase of the NovaSeptum sampling system. (*Id.* at 5). Thereafter, customers purchase replacement sealing appliances as needed. (*Ibid.*).

The sealing appliance of the ’169 Reissue “is intended for contamination-free sealing and cutting of hoses that [connect a] conveying means [to] collecting vessels which are connected to the process container, so that the collecting vessels, after being filled with a medium from the process container, can be moved without any risk of contamination to a laboratory for analysis or sampling of the medium.” (’169 Reissue, Col. 1, lines 32-42).

The process of using a sealing appliance of the ’169 Reissue can be summarized as follows: a small amount of liquid is taken from a vessel containing a pharmaceutical beverage (*e.g.*, a liquid often containing potentially harmful compounds); the liquid is transferred through a hose to an empty sample container or bag for testing; once the sample is transferred, the vessel containing the beverage and sample container must be separated with a clean separation method, that is a method which ensures that the contents of the containers are not contaminated, and that the operator using the sealing appliance is not exposed to potentially harmful compounds. (Leard Decl. ¶ 15-16).

The Sealing Appliance of the ’169 Reissue achieves this clean separation. Specifically, the hose that connects the vessel containing the beverage and the sample container is placed between the jaws of the Sealing Appliance. When actuated, Millipore’s Sealing Appliance uses straight bars (located on the upper jaw) to reinforce the sealing of the hose, and to fix a sleeve on the hose, and a cutting means, which has a substantially straight cutting edge, to make a cutting indication in the hose and sleeve for the necessary separation. (’169 Reissue, Col. 4, lines 51-62).

Sealing Appliances disclosed in the ’169 Reissue are an important part of Millipore’s sampling business. (Pl. Moving Br. at 3). Millipore’s Sealing Appliances are extremely advantageous in the manner they achieve the necessary clean separation of two containers.

(*Ibid.*). In addition, the Sealing Appliances of the '169 Reissue provide a superior alternative to the traditional methods of separating hoses. (Leard Decl. ¶ 20). Specifically, the benefits associated with the technology of the '169 Reissue are threefold: (1) it is more cost effective; (2) a crimped metal sleeve will not open; and (3) a source of energy (*e.g.*, heat or steam) is not required. (*Ibid.*). As a result, Millipore has achieved commercial success in this industry. (Pl. Moving Br. at 3).

**2. Gore and the GS00020, GS00021, and ACS-9073**

Gore manufactures, sells, and offers for sale sampling devices for the pharmaceutical industry. (Pl. Moving Br. at 6). Gore is a direct competitor of Millipore, and Gore's Crimp and Cut tools directly compete with Millipore's NovaSeal Crimping Solution products. (*Ibid.*).

On February 28, 2007, Gore purchased an anvil-type crimping device from Amesil, which Gore maintains was approved in Paragraph 9 of the Consent Order. *NovaSeptum AB*, 2010 U.S. Dist. LEXIS 138513, at *5. Several months later, Gore modified the crimping tool. *Ibid.* Gore's goal was to "preserve the two-step [crimping and cutting] process but incorporate the ability to perform both steps in a single device." *Ibid.* Thus, Gore sought to have the crimping and cutting processes occur in two separate steps. To accomplish that goal, Gore attached a cutting blade to a stainless steel lever, and then attached the lever to the anvil-type crimping tool. *Ibid.*

Gore asserts that the modified device retains the two-step process approved by the Settlement Agreement. Initially, the modified device was manufactured and sold under the

product number ACS-9073.[1] Gore now sells a similar device bearing product numbers GS00020 and GS00021.[2] *Ibid.*

### C. Millipore's Complaint and Motion for Preliminary Injunction

Millipore filed the instant Complaint on March 15, 2011, and moved simultaneously for a preliminary injunction. (*See* Docket Entry Nos. 1 and 4). The matter was reassigned to this Court on July 14, 2011. (*See* Docket Entry No. 23).

Millipore's Complaint contains two causes of action. In Count I, Millipore alleges that Gore is making, using, selling, offering for sale, or importing into the United States of America a crimping device that has infringed and is infringing one or more claims of the '575 Patent and '169 Reissue. (Compl. ¶ 46).

In Count II, Millipore alleges that Gore, as Amesil's successor-in-interest, has breached the Consent Order and Settlement Agreement. Specifically, Millipore alleges that Gore is making, using, selling, offering to sell, or importing into the United States of America crimping devices that are "substantially similar to the ACP-9000 or a preferred embodiment disclosed in the '575 Patent and '169 Reissue," which violates Paragraph 8 of the Consent Order. (*Id.* ¶¶ 22, 53). Finally, Millipore believes that Gore is making, using, and selling crimping devices that can be used in a manner proscribed by the Settlement Agreement. (*Id.* ¶ 55).

In light of the above, Millipore requests that Gore be enjoined from further infringement of the '169 Reissue. Millipore believes that if Gore is not enjoined it will suffer irreparable harm which would not be fully compensable by money damages.

[1] Gore asserts that it no longer sells the ACS-9073.

[2] The GS00021 is in all material ways identical to the GS00020. The only difference is cosmetic—the GS00021 is nickel-plated. Thus, a reference to the GS00020 incorporates the GS00021.

## III. Standard of Review

Preliminary injunctions are extraordinary remedies that are not routinely granted. *Titan Tire Corp. v. Case New Holland, Inc.*, 566 F.3d 1372, 1375 (Fed. Cir. 2009). The decision to grant a preliminary injunction is within the sound discretion of this Court. *Abbott Labs. v. Andrx Pharms., Inc.*, 452 F.3d 1331, 1334 (Fed. Cir. 2006). In determining whether the extraordinary remedy of injunctive relief should issue, the Court examines the following four factors:

> (1) whether the movant has shown a reasonable probability of success on the merits;
> (2) whether the movant will be irreparably harmed by denial of the injunctive relief;
> (3) whether the threatened injury to the movant if an injunction is not granted outweighs the threatened harm to the non-movant if the injunction is granted; and
> (4) the impact of a preliminary injunction on the public interest.

*Ibid.*

The movant bears the burden to demonstrate that a preliminary injunction should be granted. *See ibid.* ("the moving party . . . ha[s] to establish its right to a preliminary injunction . . . ."). Although the Court must generally weigh all four of these factors, "a movant cannot be granted a preliminary injunction unless it established both of the first two factors, *i.e.*, likelihood of success on the merits and irreparable harm." *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350 (Fed. Cir. 2001) (internal citation omitted).

## IV. Legal Discussion

### A. Patent Infringement

#### 1. Likelihood of Success on the Merits

"[B]ecause of the extraordinary nature of the relief, the *patentee* carries the burden of showing likelihood of success on the merits with respect to the patent's . . . infringement." *Nutrition 21 v. United States*, 930 F.2d 867, 869 (Fed. Cir. 1991) (emphasis in original). Thus,

Millipore must demonstrate that it will likely prove infringement, and that it will likely withstand Gore's challenges, if any, to the alleged infringement of the patent. *Titan Tire Corp.*, 566 F.3d at 1376. A preliminary injunction should not issue if Gore is able to raise a substantial question regarding infringement. *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1050 (Fed. Cir. 2010).

A patent infringement analysis requires two steps. *Hilgraeve Corp. v. Symantec Corp.*, 265 F.3d 1336, 1341 (Fed. Cir. 2001); *Oakley, Inc. v. Sunglass Hut Int'l*, 316 F.3d 1331, 1339 (Fed. Cir. 2003) ("An assessment of the likelihood of infringement . . . *requires* a two-step analysis.") (emphasis added). First, "the court . . . must . . . determine the meaning and scope of the claims." *Gillette Co. v. Energizer Holdings, Inc.*, 405 F.3d 1367, 1370 (Fed. Cir. 2005); *Amazon.com, Inc.*, 239 F.3d at 1351 ("A claim must be construed before . . . deciding infringement).[3] Second, the claim as properly construed must be compared to the alleged infringing device. *Hilgraeve Corp.*, 265 F. 3d at 1341 (internal citation and quotation omitted).

In construing claims, the analytical focus must begin and remain centered on the language of the claim itself. *Gillette Co.*, 405 F.3d at 1370; *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) ("the claims are of primary importance [ ] in the effort to ascertain precisely what it is that is patented") (internal citation and quotation omitted). A proper claim construction requires an examination of the intrinsic evidence of record. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). The intrinsic evidence, "*i.e.*, the patent itself, including the claims, the specification and, if in evidence, the prosecution history . . . is the most significant source of the legally operative meaning of disputed claim language." *Ibid.* Nevertheless, when the court is unable to perform step one of the infringement analysis, the court cannot, nor should it, compare the alleged infringing device to an improperly construed claim. *See Amazon.com, Inc.*, 239 F.3d at 1351 ("The court must properly interpret the claims, because

[3] It is the first step, commonly known as claim construction, that is at issue here.

an improper claim construction may distort the infringement . . . analyses."); *see also Fair Isaac Corp. v. Int'l Bus. Mach. Corp.*, No. 05-2081, 2006 WL 1283852 (D. Minn. May 9, 2006); *Docusign, Inc. v. Sertifi, Inc.*, 468 F. Supp. 2d 1305 (W.D. Wash. Oct. 19, 2006).

Keeping these legal principles in mind, the Court turns to Claim 1 of the '169 Reissue,[4] which provides:

> An appliance for mechanical sealing of hollow hoses (2) of elastic material with a sealing means (3) which is made of plastically deformable material and which is applied to the hose, said appliance (1) having two jaws (8, 9), at least one of the jaws is movable towards and away from the other jaw and the jaws crimp the sealing means (3) against the hose (2) to seal the same, characterised [sic] in that the sealing means (3) has the form of a sleeve (4) which is slipped on to the hose (2), that at least one of the jaws (8 or 9) has at least one straight bar (11) having a projecting end which projects towards the other jaw (9 or 8) and which, when at least one of the jaws is moving towards the other jaw, makes an indentation (12) in the sleeve (4) and the hose (2) to reinforce the sealing thereof as well as the fixing of the sleeve on the hose, that at least one of the jaws (8 or 9) has a cutting means (13), which projects towards the other jaw (9 or 8) and which when at least one of the jaws (8 or 9) is moving towards the other jaw, makes a cutting indication (14) in the sleeve (4) and the hose (2) to allow a sealing cutting of the hose (2), and that the cutting means (13) has the form of a substantially straight cutting edge (15) which projects to a greater extent than the projecting end of said at least one bar (11).

('169 Reissue, Claim 1, Col. 4, lines 42-64).

Since Claim 1 contains a number of terms which must be construed by the Court, it is imperative that the parties provide the Court with guidance in this step of the analysis. As such, the Court next turns to Millipore and Gore for guidance. Specifically, the Court looks to Millipore and Gore to identify terms to be construed so that the Court can intelligently determine the meaning and scope of Claim 1, as required by step one of the infringement analysis. *See*

[4] Only Claim 1 of the '169 Reissue is at issue in Millipore's motion for a preliminary injunction.

*Gillette Co.*, 405 F.3d at 1370 ("the court . . . *must* first determine the meaning and scope of the claim[ ]."") (emphasis added).

Millipore's Moving Brief, however, does not assist the Court in determining the meaning and scope of Claim 1. To be clear, Millipore neither offered terms for claim construction, nor did Millipore attribute any meaning to the terms of Claim 1. (*See* Pl. Moving Br. at 9-15).[5] Instead, Millipore opened its briefing by concluding that Gore's devices met all the limitations of Claim 1of the '169 Reissue. (*See id.* at 9). Thus, Millipore proceeded directly to step two of the infringement analysis and compared the alleged infringing device to Claim 1. (*See id.* at 10-15).

In conducting its infringement analysis, Millipore offers two theories of how Gore's devices infringe Claim 1 of the '169 Reissue. Under Millipore's first theory, a hose with a deformable sleeve is placed between the jaws of Gore's device. (*Id.* at 10). The blue handles are then fully squeezed; the separate lever is not depressed. (*Ibid.*). Millipore contends that when the device is actuated in this manner, the straight bars located on the upper jaw make indentations in the hose and sleeve, while the cutting edge,[6] located on the upper jaw of the device, makes a sealing cutting indication in the sleeve and hose. (*Ibid.*). Millipore's second theory of infringement is as follows: a hollow hose and sleeve are placed between the jaws of the GS00020; the blue handles are squeezed until they click once; then, in one motion, the blue handles and the separate lever are depressed simultaneously. (*Id.* at 13). Under this theory, the straight bars of the upper jaw create indentations in the hose and sleeve, and the cutting edge of the separate lever makes a cutting indication in the hose and sleeve that goes fully through both, resulting in two pieces. (*Ibid.*).

[5] The closest Millipore gets to attributing meaning to terms of Claim 1, is when it states that "a cutting indication can be such that the sleeve and the hose are not cut or broken directly when sealing by means of the appliance . . . but at an optional point in time after that." (*Id.* at 10, 11).

[6] Gore refers to this piece as its central crimping bar.

In response, Gore argues that Millipore's application is fatally flawed from the start because Millipore failed to conduct the required claim construction analysis. (Def. Opp. Br. at 5). According to Gore, when a plaintiff attempts to skip step one of the analysis, *i.e.*, claim construction, courts do not hesitate to deny motions for injunctive relief. (*Ibid.*).

Gore next identified the following claim terms to be construed for purposes of assessing the scope and meaning of Claim 1: (1) "cutting means"; (2) "substantially straight"; (3) "cutting edge"; (4) "indentation"; (5) "cutting indication"; (6) "sealing cutting"; and (7) "has." Gore also offered proposed constructions for the majority of these terms. Specifically, Gore proposes that to be considered a "cutting means," there must be a cutting edge that makes at least a partial cut in the sleeve and hose.[7] (Def. Opp. Br. at 15). Gore asserts that "cutting edge" should be construed to mean an edge that makes a partial cut in the sleeve and tube. (*Id.* at 16-18). Gore also appears to argue that the claim term "indentation" should be construed to mean the compression or deformation of a metal sleeve, *i*.e., not a partial cut. (*Id.* at 13). Gore contends that "cutting indication" should be construed to mean a partial cut in the sleeve and tube. (*Id.* at 18). Gore defines "sealing cutting" as a cutting where the initial seal created by the crimp is maintained during and after the tube is cut. (*Id.* at 19). Finally, Gore proposes that "has" should be construed as "attached to" or "is part of the structure of." (*Id.* at 21).

Gore then compared its GS00020 device to Claim 1, and explained why infringement does not occur under either of Millipore's two theories. Gore argues that infringement does not occur under Millipore's first theory of infringement for the following reasons. First, Gore claims that its central crimping bar is not a "cutting means" with a "substantially straight" "cutting edge." (*Id.* at 16-18). Rather, its central crimping bar is a flat-faced structure, *i.e.*, it is not

[7] The Court notes that Gore provided the Court with a detailed analysis of Claim 1, which included a discussion of the patent specification, prosecution history of the patent, and prior settlement agreement, in attempting to explain why the "central crimping bar" of its device is not a "cutting means." (*See id.* at 8-15).

substantially straight. In addition, the central crimping bar does not contain a "cutting edge" as required by Claim 1; instead, the central crimping bar crimps or indents the sleeve and hose together. (*Ibid.*). Second, Gore argues that its central crimping bar is not a cutting means because it creates an "indentation," not a "cutting indication" which Gore defines as a partial cut in the sleeve and tube. (*Id.* at 18). Third, Gore argues that a "sealing cutting" would not be achieved because the process of bending the sleeve and hose back and forth involves considerable force, and it is unclear whether a seal would be maintained between the two sides of the crimped hose and sleeve. (*Id.* at 18-19).

Gore also argues that infringement does not occur under Millipore's second theory because its device "has" a cutting edge that is attached to a separate lever, not to one of the jaws as required by Claim 1. (*Id.* at 21). Furthermore, Gore argues that the "cutting edge" attached to the separate blade has a "tapered-cutting edge," which is angled, not "substantially straight." (*Id.* at 20, 24).

Millipore's Reply Brief offers proposed constructions for several, but not all, of the claim terms raised in Gore's opposition brief. These claim terms include: (1) cutting means;[8] (2) cutting indication; and (3) straight. Millipore contends that a "cutting means" need not actually cut; instead, it is only required to leave a cutting indication. (Pl. Reply Br. at 4). Millipore believes that "cutting indication" should be construed to mean allowing for the sealing cutting of the hose either by the cutting means itself, or allowing something else, such as manual bending action. (*Ibid.*). Finally, Millipore, without citation, defines "straight" as a direct line between two points, even if at an angle. (*Id.* at 7-8).

[8] The Court has thoroughly reviewed Millipore's submissions. However, it is not clear what Counsel would like cutting edge to be construed to mean. For example, Millipore asserts that the "fixed cutting means makes a cutting indication." It appears that Millipore does not specifically discuss the "cutting edge."

Based upon these proposed constructions, Millipore argues that infringement occurs under both of its theories. Millipore concludes that infringement occurs under its first theory because the "fixed cutting means satisfies the claimed cutting means." (*Id.* at 7). Under its second theory of infringement, Millipore claims that Gore's "position that the edge of its cutting means is not *straight* because it is tapered . . . is contrary to the plain meaning of *straight*. (*Id.* at 7-8) (emphasis added). Millipore also summarily rejects Gore's proposed definition of "has," but fails to provide its own definition for this term.[9] To that end, Millipore concludes that infringement occurs because the "movable cutting means satisfies the claimed cutting means." (*Id.* at 9).

In light of the arguments outlined above, the Court must now determine whether it can perform step one of the infringement analysis and determine the meaning and scope of Claim 1 based upon what has been submitted by the parties. In making this determination, the Court is guided by the holdings of *Nazomi*,[10] *Fair Isaac*, and *Docusign*.

In *Nazomi*, the Federal Circuit noted that in order to perform its review of a district court's claim construction, the district court's order must provide "sufficient findings and reasoning to permit meaningful appellate scrutiny." *Nazomi Commc'ns, Inc.*, 403 F.3d at 1371 (internal citation omitted). Thus, prudence dictates that the parties provide the district court with as much detail as possible supporting their claim construction positions, so that the court is fully informed before it issues an order.

In *Fair Isaac*, the court denied plaintiff's request for a preliminary injunction because it was unable to construe the claims at issue. Specifically, Fair Isaac bypassed step one of the claim construction analysis and concluded that the defendant's alleged infringing product met all

[9] Millipore concludes that "[a]t least one of the jaws of Gore's device 'has' a cutting means based on the plain meaning of this phrase." *Id.* at 8. Millipore does not, however, state what the plain meaning of "has" is.

[10] *See Nazomi Commc'ns, Inc. v. Arm Holdings, PLC*, 403 F.3d 1364 (Fed. Cir. 2005).

the limitations of the claim at issue, without offering any terms that required construction. Fair Isaac also failed to "attribute any meaning to the terms of the claim." *Fair Isaac*, 2006 WL 1283852, at *6. The court concluded that Fair Isaacs's claim construction and infringement analysis were incomplete. *Id.* at *7.

In *Docusign*, the court concluded that it was unable to compare the claims to the accused device. 468 F. Supp. 2d at 1309. The movant there failed to present sufficient evidence based upon the specification and prosecution history to construe the claims. *Ibid.* Thus, the court declined to undertake a *sua sponte* analysis of the specification without any direction from the parties. *Id.* at 1308.

The principles announced in *Nazomi*, *Fair Isaac*, and *Docusign* are applicable to the matter pending before this Court. To that end, the Court cannot, nor should it, determine the scope and meaning of Claim 1 for the following three reasons.

First, the parties' submissions have failed to provide the Court with sufficient detail relating to their claim construction positions. Millipore's attempt to supplement its prior submissions during the Preliminary Injunction Hearing, *vis-à-vis* newly minted arguments, will be disregarded for purposes of this motion.[11] Judge Hayden most elegantly explained the rationale underlying this position:

> The Court notes that in its reply brief, defendant breaks a cardinal rule of motion practice by raising an argument . . . that it failed to raise in its moving papers. The purpose of the reply brief is to respond to the opposition brief or explain a position that the respondent has refuted. Because the local rules do not permit sur-

[11] The majority, if not all, of Millipore's newly minted arguments concern proposed constructions for claim terms that were not previously argued in Millipore's prior submissions. Millipore also provided the Court with a document titled, "Millipore's Preliminary Claim Constructions" at the conclusion of the Preliminary Injunction Hearing. Although not dispositive, the Court believes it is worth noting that several of the claim terms for which Millipore provides proposed constructions, Millipore did not include in either of its submissions to the Court in support of its motion for a preliminary injunction (*e.g.*, "has" and "substantially straight").

> reply briefs, the non-moving party cannot respond to newly minted arguments contained in reply briefs.

*Dana Transport, Inc. v. Abelco Finance, LLC*, No. 04-2781, 2005 U.S. Dist. LEXIS 18086, at *16 (D.N.J. Aug. 17, 2005) (internal citations omitted).[12]

*Dana Transport* also guides the Court. Specifically, if raising a "newly minted argument" is frowned upon in a reply brief, surely a "newly minted argument" raised for the first time during oral argument is even more problematic. Although the Court appreciates Counsel's efforts to present sufficient evidence for the Court's consideration, Millipore's arguments raised for the first time at oral argument will be disregarded. (*See* Preliminary Injunction Hr'g Tr. at 21-23; 111:16-23; 129:1-3; 130-133:16). Consequently, a court order, at this point, would be devoid of sufficient findings and reasoning. *Nazomi Commc'ns, Inc.*, 403 F.3d at 1371.

Second, the factual scenario presented here is analogous to what occurred in *Fair Isaac*. Specifically, Millipore's moving brief, like Fair Isaac's, neither offered terms for construction nor attributed any meaning to the terms of Claim 1. Instead, Millipore elected to begin its analysis under the heading, "The Gore Devices Literally Infringe Claim 1 of the 169 Reissue," and then attempted to identify where each claim limitation was present in Gore's devices. (Pl. Moving Br. at 9-15). In fact, the majority of Millipore's argument is directed at providing the Court with a detailed account of how Gore's devices infringe Claim 1 of the patent.[13]

[12] The Court notes that because the Local Patent Rules do not address the permissibility of filing sur-reply briefs, the Local Civil Rules apply, which means that sur-reply briefs are not permitted in patent cases without the permission of the Judge or Magistrate Judge to whom the case is assigned. *See* L. Pat. R. 1.2 ("The Local Civil Rules of this Court shall apply to such actions, except to the extent that they are inconsistent with these Local Patent Rules.").

[13] Millipore also fails to discuss the prosecution history of the patent. The only time Millipore touches upon the patent's prosecution history is when it attempts to refute Gore's analysis of how NovaSeptum obtained the patent.

Millipore also failed to offer a proposed construction for several claim terms after Gore raised proposed constructions in its opposition brief.[14] These terms are: "substantially straight;" "indentation"; and "has." Without Millipore's proposed construction of these terms the Court cannot perform step one of the infringement analysis. Therefore, the Court cannot proceed to step two and determine whether Gore's Crimp and Cutting devices infringe under either of Millipore's theories.

For example, the Court is unable to determine infringement under Millipore's first theory because it is unclear whether Gore's purported crimping bar is a "cutting means." According to Claim 1, the requirements of a cutting means are: (1) a cutting indication; (2) a substantially straight cutting edge; and (3) a sealing cutting. To reiterate, Millipore does not propose a construction for the claim term indentation, and thus the distinction between a "cutting indication" and "indentation" is unclear. Furthermore, the Court is uncertain whether Gore's crimping device possesses a "substantially straight" "cutting edge" because there has not been a proposed construction of the term "substantially straight."[15]

The Court similarly is unable to perform step one of the infringement analysis in connection with Millipore's second infringement theory for the following reasons. First, the Court cannot determine whether one of the jaws "has" a cutting means, as required by Claim 1. (*See* '169 Reissue, Column 4, lines 56-57). Second, the Court is unable to determine whether the

[14] Millipore's reliance on *O2 Micro Int'l Ltd. v. Beyond Innovation Tech.Co.* is unavailing. 521 F.3d 1351. In *O2 Micro*, the Federal Circuit held "[c]laim construction is a matter of resolution of disputed meanings and technical scope, to clarify and when necessary to explain what the patentee covered by the claims, for use in the determination of infringement. When the parties present a fundamental dispute regarding the scope of a claim term, it is the court's duty to resolve it." *Id.* at 1362 (internal citations omitted). Thus, the holding of *O2 Micro* undermines Millipore's argument here because there was a clear dispute regarding the meaning and scope of claim terms as outlined above.

[15] In fact, Millipore actually states that "Gore does not dispute that its fixed cutting means is straight." (Pl. Reply Br. at 3). Perhaps that is the reason why Millipore failed to offer a proposed construction of "substantially straight." Nevertheless, Millipore's position is incorrect because Gore argues that its central crimping bar has a flat-face that is *not* substantially straight. (emphasis added).

cutting edge of Gore's device is "substantially straight." Millipore's assertion that "a direct line between two points, even if at an angle, is straight" is misguided because the claim term at issue is "substantially straight," not "straight." Millipore also fails to explain if straight and "substantially straight" should be construed in the same manner. Thus, the Court is left to wonder whether "substantially straight" is a direct line between two points, even if at an angle.

Finally, this Court will not, nor is it required to under Federal Circuit law, construe claims "in a vacuum." *Kyocera Wireless Corp. v. ITC*, 545 F.3d 1340, 1347 (Fed. Cir. 2008). Moreover, the Court declines to undertake a *sua sponte* analysis of claim terms to determine the scope and meaning of Claim 1 because courts should avoid improper claim construction, which would, in the end, distort the infringement analysis. *See Amazon.com, Inc.*, 239 F.3d at 1351 ("The court must properly interpret the claims, because an improper claim construction may distort the infringement . . . analyses."); *see also Am. Piledriving Equip., Inc. v. Geoquip, Inc.*, 637 F.3d 1324, 1331 (Fed. Cir. 2011) ("It is well settled that the role of a district court in construing claims is not to redefine claim recitations or to read limitations into the claims . . . ." ).

In light of the above, the Court cannot, at this juncture, properly determine the scope and meaning of Claim 1. Consequently, the Court is unable to compare Claim 1 to the alleged infringing device, and is therefore unable to determine whether infringement has occurred. Accordingly, the Court finds that Millipore has failed to carry its burden of showing likelihood of success on the merits.

**2. Irreparable Harm**

Millipore must provide a clear showing that in the absence of injunctive relief it will suffer irreparable harm. *Nutrition 21*, 930 F.2d at 870-71 (Fed. Cir. 1991). The Supreme Court has emphasized that irreparable harm must be established as a separate element, independent of

any showing of likelihood of success; irreparable harm can no longer be presumed. *Winter v. Natural Resources Defense Counsel, Inc.*, 555 U.S. 7, 22 (2008); *eBay Inc. v. MercExchange L.L.C.*, 547 U.S. 388 (2006).[16]

In an attempt to meet its burden, Millipore argues that it has established irreparable harm because should Gore not be enjoined Millipore will (1) suffer a loss of its market share; (2) likely lose customers and business opportunities; (3) suffer irreparable harm to the good will of its customers that it has built up over many years; and (4) perhaps consider decreasing the price of its sampling system. (Pl. Moving Br. at 19-22).

In response, Gore argues that Millipore has failed to demonstrate that it will suffer irreparable harm. Initially, Gore states that Millipore has, without reason, delayed in bringing this motion for more than two years, which precludes a finding of irreparable harm. Gore next contends that Millipore's purported harms in the forms of lost sales, lost market share, possible price erosion, and possible loss of customer good will are speculative, and thus not cognizable harms. Furthermore, Gore asserts that lost market share and price erosion are economic harms that can be compensated by money damages. Finally, Gore claims that lost sales standing alone are insufficient to prove irreparable harm, but regardless of that fact, Gore argues that Millipore actually concedes that it has suffered no actual lost sales to Gore.

During oral argument Mr. Leard provided testimony relating to information contained in his March 9, 2011 Declaration. The majority, if not all of Mr. Leard's testimony, focused on the sealing appliance industry, and Mr. Leard's interaction with end users (*i.e.*, customers) during the period in which Gore's products have been on the market. Of particular importance to the Court

[16] The Federal Circuit recently adopted the Supreme Court's view that irreparable harm can no longer be presumed. *See Robert Bosch, LLC v. Pylon Mfg. Corp.*, No. 2011-1096, 2011 U.S. App. LEXIS 20700, at *13 (Fed. Cir. Oct. 13, 2011) ("We take this opportunity to put the question to rest and confirm that *eBay* jettisoned the presumption of irreparable harm as it applies to determining the appropriateness of injunctive relief.").

is the testimony elicited in connection with irreparable harm. Specifically, the Court finds the following testimony relevant to its analysis in determining whether Millipore has made a clear showing that in the absence of injunctive relief it will suffer irreparable harm. First, Mr. Leard stated that he has no formal evidence that a single Gore Crimp and Cut tool device has been sold. (Preliminary Injunction Hr'g Tr. at 85:21-23; 92:20-24; 95:17-20, Sep. 27, 2011).[17] Second, Mr. Leard stated that of the ten percent of the customers that converted from the traditional method, "almost all of them" are currently using the NovaSeal product, *i.e.*, Millipore has not lost a sale to Gore. (*Id.* at 94). Third, Mr. Leard had no information that Millipore's market share has been compromised because of Gore's Crimp and Cut device. (*Ibid.*). Finally, Mr. Leard confirmed that Millipore had not reduced its prices. (*Id.* at 139).

In light of the above, the Court finds that Millipore has failed to establish that in the absence of injunctive relief it will suffer irreparable harm. First, the Court finds Millipore's argument relating to loss of good will to be unpersuasive. Millipore states that it will lose its customers' good will when it prevails in this litigation because it will be in the unenviable position of having Gore's customers switch products. This argument is too speculative for this Court to accept. Indeed, if Millipore eventually prevails in this litigation, customers in general, and Gore's former customers in particular, will need to purchase sampling systems and sealing devices from a new manufacturer. Considering the relatively small size of this niche market, in conjunction with Millipore's self-proclaimed superior product, the manufacturer selected by these customers could be Millipore.[18]

Second, the Federal Circuit, as well as courts in this district, have declared that the types of harms advanced by Millipore—loss of market share, lost sales, and price erosion—are not

[17] Mr. Leard indicated that of the 350 customers that Millipore services, he knows of only one customer that has actually switched to Gore's product. (*See id.* at 90:3-17).
[18] Millipore conceded this point during oral argument. (*See id.* at 28:1-4).

irreparable, and thus cannot form the basis for granting injunctive relief. *Nutrition 21*, 930 F.2d at 871 ("[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." ); *Eli Lilly & Co. v. Am. Cyanamid Co.*, 82 F.3d 1568, 1578 (Fed. Cir. 1996) ("Such a rule would convert the 'extraordinary' relief of a preliminary injunction into a standard remedy available whenever the plaintiff has shown a likelihood of success on the merits."); *Altana Pharma AG v. Teva Pharms. USA, Inc.*, 532 F. Supp. 2d 666, 682 (D.N.J. 2007) (finding plaintiffs have not established irreparable harm despite contending loss of revenue, price erosion, decrease in market share), *aff'd*, 566 F.3d 999 (Fed. Cir. 2009); *Novartis Corp. v. Teva Pharms. USA, Inc.*, No. 04-4473, 2007 U.S. Dist. LEXIS 42163, 2007 WL 1695689, at *26-28 (D.N.J. June 11, 2007) (finding that plaintiff failed to establish irreparable harm because damages were calculable, Teva had the ability to pay any damages award, and the possibility of loss of market share and price erosion do not constitute irreparable harm); *In re Gabapentin Patent Litig.*, Nos. 00-2931, 01-1537 (D.N.J. Aug. 20, 2004), Transcript at 12-14 ("Loss of market share, or price erosion, lost sales, and even lost market opportunities in my view can be reduced to dollars, not easily but feasibly.") (quoted in *Altana*, 532 F. Supp. 2d at 683-84); *Sanofi-Aventis Deutschland GmbH v. Glenmark Pharms. Inc., U.S.A.*, No. 07-5855, 2010 U.S. Dist. LEXIS 56019, at *47 (loss of market share and price erosion are economic harms that can be compensated by way of money damages).[19] Notwithstanding these decisions, Millipore has

[19] The Court is cognizant of the cases cited by Millipore. *See Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341 (Fed. Cir. 2008); *Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 237 F.3d 1359 (Fed. Cir. 2001); and *Bio-Technology Gen. Corp. v. Genetech, Inc.*, 80 F.3d 1553 (Fed. Cir. 1996). The Court does not, however, believe that the decisions reached there, conflict with the decision reached here. Specifically, in those cases, the Federal Circuit indicated that the district court *did not clearly err* in finding that the Plaintiff established irreparable harm by arguing some of the same types of harm alleged here, *i.e.*, loss of market share, price erosion, and lost sales. To that end, it becomes clear that the Federal Circuit's decisions in *Sandoz*, *Boehringher*, and *Genetech* stand for the proposition that the Federal Circuit reviews a district court's findings with deference and only overturns a district court's exercise of discretion with respect to irreparable harm if it was clearly erroneous. *See Novartis Corp. v.*

not presented the Court with any evidence that it has or will suffer lost sales, price erosion, and lost market share. In fact, Mr. Leard confirmed that Millipore has not lost sales to Gore; Millipore has not lowered the price of its product; and Millipore's market share has not been compromised despite the fact that Gore's Crimp and Cut devices have been on the market since at least as early as April 2009.[20]

For these reasons, Millipore has failed to provide a clear showing that it will suffer irreparable harm in the absence of injunctive relief.

**3. Balance of Hardships and Public Interest**

Because Millipore has not demonstrated either a likelihood of success on the merits or irreparable harm, the balance of hardships weighs in favor of Gore.

The public interest also weighs in favor of Gore. This Court believes that a company that builds a business based on infringing products can blame no one other than itself should a court enjoin it from further infringement. *See Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1383 (Fed. Cir. 2006). However, "competitors are entitled to review the public record, apply the established rules of claim construction, ascertain the scope of the patentee's claimed invention and, thus, design around the claimed invention." *Vitronics Corp.*, 90 F.3d at 1583. Millipore, at this preliminary stage, has not demonstrated that Gore infringed Claim 1 of the '169 Reissue. Thus, the Court concludes that the public interest also weighs in favor of Gore.

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*Teva Pharm. USA, Inc.*, Nos. 04-4473, 06-1130, 2007 U.S. Dist. LEXIS 42163, 2007 WL 1695689, at *27 (D.N.J. June 11, 2007) ("Although there might exist many examples of courts granting preliminary injunctions where these factors [lost sales, market share, and price erosion] were present, it does not necessarily follow that the possibility of such factors in such matters *demanded* a preliminary injunction. Similarly the possibility of these factors in the instant matter does not alone demand a preliminary injunction, especially where such losses, by all measure, appear to be calculable.") (emphasis in original).

[20] The Court also notes that Mr. Leard's Declaration further supports the Court's finding that Millipore has failed to establish that it will suffer irreparable harm if a preliminary injunction is not issued. As to lost sales, Millipore has asserted that it is not aware of any significant sales that have been lost to Gore. (Leard Decl. ¶ 36). With respect to price erosion, Millipore concedes that it will only consider lowering its prices as a "last resort." (*Ibid.*). Finally, Millipore emphasizes that, while competing with Gore, it nevertheless "enjoys tremendous commercial success with the sales of its NovaSeal Crimping Solution," which requires Millipore's Sealing Appliance. (*Id.* ¶ 25).

**B. Consent Order**

Millipore also claims that Gore has failed to abide by the conditions of the Consent Order, specifically Paragraph 8. Namely, Millipore argues that the GS00020 is substantially similar to a preferred embodiment disclosed in the '575 Patent and '169 Reissue, and is also substantially similar to the ACP-9000. (Pl. Moving Br. at 15-19).

In countering Millipore's argument, Gore asserts that the 2007 Settlement Agreement between NovaSeptum and Amesil is instructive. First, Gore contends that pursuant to paragraph 10 of the Settlement Agreement, Amesil agreed not to manufacture "any crimper tool device that in a single operative step employ[ed] (a) at least one bar extending along a straight line from one side of the crimper jaws to the other side to crimp a metal . . . sleeve, and (b) a substantially straight cutting edge to partially or fully cut the crimp sleeve into at least two sections." (Def. Opp. Br. at 14). Second, Gore argues that the GS00020 is different than the ACP-9000. Specifically, the ACP-9000 utilizes a one-step process to crimp and cut hollow hoses. (Preliminary Injunction Hr'g Tr. at 46:19-24). To that end, Gore believes that its device, which utilizes a two-step process to crimp and cut, is unlike the ACP-9000, and is more akin to the device that NovaSeptum agreed did not infringe the '169 Reissue in Paragraph 9 of the Consent Order. (Def. Opp. Br. at 15).

The Court finds that it cannot, at this preliminary stage, determine whether Gore has violated the Consent Order for the following reasons. First, Millipore's conclusion that the GS00020 is substantially similar to a preferred embodiment disclosed in the '575 Patent and '169 Reissue is based upon flawed reasoning. Specifically, Millipore's conclusion is based upon the same analysis it used in attempting to demonstrate infringement. (*See* Pl. Moving Br. at 16-17). However, as this Court has already explained above, Millipore's analysis is premature because

Claim 1 has not been properly construed. A proper construction of Claim 1 is required before this Court can determine whether the GS00020 is substantially similar to a preferred embodiment disclosed in the '575 Patent and '169 Reissue. Moreover, Millipore failed to carry its burden in providing the Court with sufficient information to determine the scope and meaning of Claim 1. For those reasons, the Court cannot, nor will it, evaluate Millipore's argument in the abstract.

Second, the Court cannot determine at this point whether the GS00020 possesses "substantially similar functional imitations of the jaw components of the ACP-9000."[21] (*See* Consent Order ¶ 8). That said, the Court identifies some of the differences between the GS00020 and the ACP-9000 as follows: (1) the straight bars of the GS00020 are located on the upper jaw; (2) the cutting means of the ACP-9000 is on the lower jaw; (3) a separate lever has been attached to the GS00020, *i.e.*, the GS00020 has three levers; (4) the cutting means that appears to be attached to this lever does not project from the lower jaw unless this lever is depressed; (5) the cutting edge of the ACP-9000 appears to work in conjunction with a recess on the opposite jaw; and (6) Gore has added an additional piece to the upper jaw of the GS00020—which Gore identifies as its central crimping bar, and Millipore identifies as an additional cutting means.[22] Although these differences are not dispositive, it is still unclear at this preliminary stage, whether the alterations made to the GS00020 essentially changed the nature of the device or its function.

[21] At the outset, the Court notes that both Millipore and Gore's submissions contain, at most, a minimal discussion of this issue.

[22] During oral argument, Counsel from Millipore provided the Court with the ACP-9000. Upon examination, both the Court and Counsel agreed that the GS00020 and ACP-9000 are visually different, and that the GS00020 has a sharper cutting edge than the ACP-9000.

## V. Conclusion

For the reasons set forth above, Millipore's Motion for a Preliminary Injunction (Docket Entry No. 4) is denied.

*s/Esther Salas*
**Esther Salas, U.S.D.J.**