IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS EASTERN DIVISION

BAXTER INTERNATIONAL, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Case No. 17 C 7576
	)	
BECTON, DICKINSON AND COMPANY,	)	Judge Joan H. Lefkow
	)	
Defendant.	)	

OPINION AND ORDER

Before the court are several motions: Becton, Dickinson and Company (BD) moves for summary judgment under Federal Rule of Civil Procedure 56 as to noninfringement of the '192 Patent (dkt. 353), noninfringement of the '237 Patent (dkt. 396), and willfulness and damages regarding both patents (dkt. 375); and moves to strike certain portions of Kimberly J. Schenk's (dkt. 367) and Karl R. Leinsing's (dkt. 402) expert opinions. Baxter International, Inc. also moves for partial summary judgment on BD's counterclaim for invalidity for obviousness. (Dkt. 358). For the following reasons, BD's motions for summary judgment as to noninfringement for the '192 Patent and '237 Patent are granted, and the remaining motions denied as moot.

BACKGROUND

Baxter brought a patent infringement action against BD over a certain device in its "PhaSeal System." The PhaSeal System is a suite of components that transfer drugs or can be combined to transfer drugs in a closed system. Baxter alleges that the combination of two of those components, the "Protector" and the "Injector," form a device that infringes on three of its patents, each entitled "Sliding Reconstitution Device With Seal," U.S. Patent Nos. 5,989,237 ('237 Patent), 6,159,192 ('192 Patent), and 6,852,103 ('103 Patent).

Baxter proceeds on claims for direct and indirect infringement of Claims 1 and 15 of the '237 Patent under 35 U.S.C. § 271(a), and direct infringement of Claims 1 and 2 of the '192 Patent, a method patent, under 35 U.S.C. § 271(a) and contributory infringement under 35 U.S.C. § 271(c). Baxter also alleges that BD's infringement was willful, meriting treble damages under 35 U.S.C. § 284.[1]

BD raised several affirmative defenses and counterclaims, including a counterclaim for a declaratory judgment that the '237 Patent and '192 Patent are invalid on obviousness grounds under 35 U.S.C. § 103.

BD now moves for summary judgment, arguing that there is insufficient evidence for a reasonable jury to conclude that the PhaSeal System infringes on the '192 Patent or '237 Patent. BD also moved for summary judgment on damages claims for willful infringement as to the '192 Patent and '237 Patent and damages claims based on conduct predating the October 19, 2017 filing date of this action as to the '237 Patent. Along with its summary judgment motions, BD moves to exclude portions of Baxter's expert opinions from Kimberly J. Schenk on damages and Karl R. Leinsing on infringement.

Baxter also moves for partial summary judgment on BD's counterclaims for invalidity of the '192 Patent and '237 Patent on obviousness grounds.

ANALYSIS

BD is entitled to summary judgment on Baxter's infringement claims for the '192 Patent and '237 Patent. As to the '192 Patent, *see infra* § II, the evidence is insufficient to support a joint direct infringement theory based on BD's alleged control over PhaSeal System users; it is undisputed that the PhaSeal System has a substantial noninfringing use, and so there is no

[1] BD was granted summary judgment on the '103 Patent claims in an earlier order.

contributory infringement; and users of the PhaSeal System who follow BD's printed instructions for the system do not perform the method described in the '192 Patent. As for the '237 Patent, *see infra* § III, the undisputed evidence shows that the PhaSeal System does not infringe because it does not perform at least one of the means-plus-function claim limitations.

Given the outcome on the merits of Baxter's remaining infringement claims, BD's motion for summary judgment on willfulness and damages, as well as Baxter's motion for summary judgment on BD's obviousness counterclaim, along with both parties' *Daubert* motions are denied as moot.

I. Summary judgment standards

Summary judgment is proper when "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The movant must show that there is no genuine dispute of fact preventing the entry of judgment in its favor as a matter of law. *See Celotex Corp.* v. *Catrett*, 477 U.S. 317, 323 (1986). To avoid summary judgment, the non-movant must do more than raise "some metaphysical doubt as to the material facts." *See Matsushita Elec. Indus. Co.* v. *Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). Rather, he "must present affirmative evidence in order to defeat a properly supported motion for summary judgment." *Anderson* v. *Liberty Lobby, Inc.*, 477 U.S. 242, 257 (1986). To create a genuine dispute, the evidence must be "such that a reasonable jury could return a verdict for the [non-movant]." *Id.* at 248. The court views all facts in the light most favorable to the nonmovant and draws all reasonable inferences in its favor. *Matsushita Elec. Indus. Co.*, 475 U.S. at 587.

II. BD's motion for summary judgment on the '192 Patent claims

BD argues that it is entitled to judgment as a matter of law on several bases. It first argues that there is insufficient evidence for a reasonably jury to find it liable for infringing the method

patent based on its customers' use of the accused device under a joint direct infringement theory. Second, it argues that the accused device is capable of substantial noninfringing use and thus it cannot be liable for contributory infringement. Third, BD argues that its printed instructions for the PhaSeal System do not describe the performance of one of the steps of the method patent, precluding a finding of infringement. Explained below, summary judgment is appropriate on each basis.

A. The undisputed facts regarding the '192 Patent[2]

1. The '192 Patent

Baxter alleges that the PhaSeal System infringes claims 1 and 2 of the 192 Patent, a method for a "Sliding Reconstitution Device with Seal." (DSOF ¶¶3–6, 18.). Claim 1 of the '192 Patent is the only asserted independent claim:

> A method of connecting a reconstitution device to a drug container having a top and a closure, the method comprising the steps of:
>
> providing a reconstitution device having first and second ends, the second end having a receiving chamber dimensioned to receive the top of the container for fixedly attaching the device to the container, the device having a central channel housing a piercing member, the device further having first and second sleeve members capable of sliding axially with respect to one another from an inactivated position where the piercing member is outside the receiving chamber to an activated position where a portion of the piercing member is positioned inside the receiving chamber; and
>
> inserting the top of the container into the receiving chamber of the device and fixedly attaching the container therein when the device is in the inactivated position.

[2] As with the prior order on summary judgment (dkt. 275 at 1 n.2), the court will address many but not all factual assertions in the parties' submissions. *See Omnicare, Inc.* v. *UnitedHealth Grp., Inc.*, 629 F.3d 697, 704 (7th Cir. 2011). Any objections to factual assertions were considered and only properly supported factual assertions are included here. This decision cites BD's undisputed asserted facts as "DSOF ¶_," Baxter's undisputed additional asserted facts as "PSOAF ¶_," and responses or objections to an asserted fact are indicated with an additional "R," as in "RDSOF" or "RPSOAF."

(DSOF ¶5.) Claim 2 is "[t]he method of claim 1 wherein the step of inserting the top of the container into the chamber is done manually." (DSOF ¶6.)

The court previously construed "reconstitution device" to mean "[a] device for placing a powdered drug in a drug already in liquid form, as well as, further diluting a liquid drug." (Dkt. 308 at 1.) "Fixedly attaching" was construed as "[a]ttaching such that in order to remove the container from the reconstitution device one would have to exert a force considerably in excess of that normally used to operate the device, such that the force likely would break, detach, or noticeably deform the device in the process." (Id.) "Inactivated position" was construed as "[p]osition in which the piercing member does not establish fluid communication with the drug container." (*Id.* at 3.) "[A]ctivated position" was construed as "[p]osition in which the piercing member establishes fluid communication with the drug container." (*Id.*)

2. The accused reconstitution device

The PhaSeal System is a system designed to safely transfer hazardous drugs, in powder or liquid form, between syringes and drug vials by creating a closed system that prevents the drugs from being exposed to the user or contaminants. (DSOF ¶¶9, 23.) The system allows products to "mate" through a sealed bayonet connection in which a male part connects with a female part and then a cannula (needle) pierces through membranes between the male and female parts, thereby forming a sealed connection. (DSOF ¶¶13, 23, 33.)

Baxter alleges that two components of the PhaSeal System, the Protector and Injector Luer Lock (Injector), when engaged together, form an infringing device. (*See* DSOF ¶¶3, 18, 23.) The Protector is pictured on the left and Injector on the right:

(DSOF ¶23; *see also* DSOF ¶8.) When combined, the accused device in its "inactivated position" is displayed on the left, while its "activated position" is on the right:

(DSOF ¶23.)

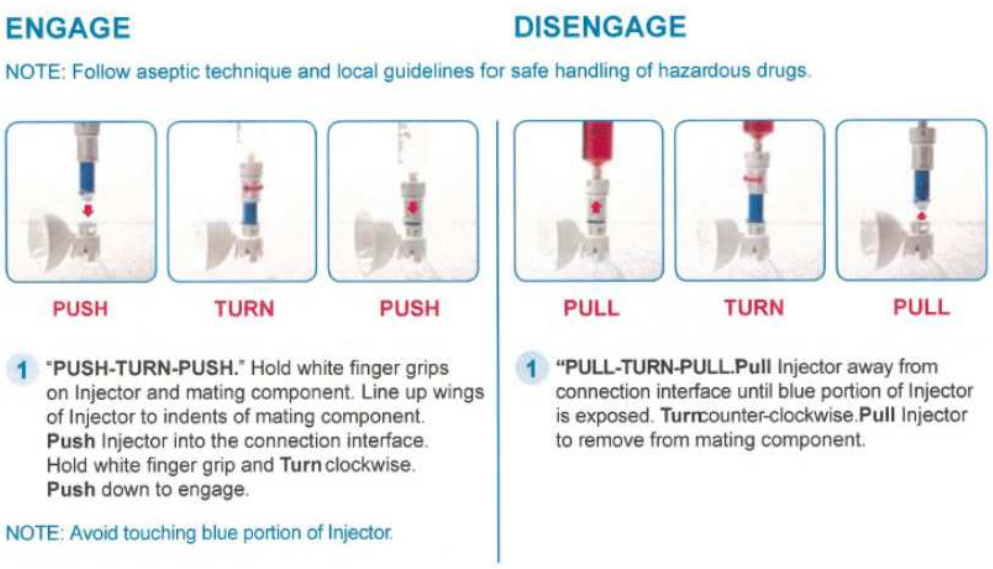
Contained in a BD PhaSeal System Procedures brochure are instructions for how users "might implement the BD PhaSeal™ System components into [their] procedures," but the brochure also states that "it is not intended as a substitute for local guidelines, regulation or [their] facility's policies." (DSOF ¶10.) The brochure further counsels that users should "[a]lways follow aseptic technique and adhere to local guidelines, regulations and [their] facility's policies for the safe handling of hazardous drugs." (*Id.*) In several other places in the brochure it states, "NOTE: Follow aseptic technique and local guidelines for safe handling of hazardous drugs." (DSOF ¶¶11, 12, 14, 15.)

According to the instructions, before the Injector and Protector are engaged with each other, the Injector is attached to a syringe to form a "syringe unit" (DSOF ¶¶11, 28, 37–38), and the Protector is attached to the vial cap of a container filled with drugs, forming a "vial assembly." (DSOF ¶¶14, 33, 38.) Before building the syringe unit, the user, following the instructions, may either fill the syringe with an amount of air equal to the amount of drug that the user wants to extract from a drug vial or load the syringe with diluent if the user wants to reconstitute a drug. (DSOF ¶¶7–8, 23, 28, 39; PSOAF ¶14.) An example of a syringe unit is shown below:

(DSOF ¶23.) The Protector, meanwhile, is snapped on to a drug vial to form the vial assembly, which may contain either liquid or powdered drugs, and once the Protector and drug vial are engaged they become "fixedly attached," as shown below:

(DSOF ¶¶8, 23–24; PSOAF ¶¶16–18.)

Once the syringe unit and vial assembly are created, the procedure for engaging the Injector and Protector involves a "push-turn-push" process, while disengagement involves a "pull-turn-pull" process, as illustrated below:



(DSOF ¶12.) This process first involves "pushing," or sliding, the Injector's bayonet connector "wings" into "indents" on the Protector's bayonet receptacle. (DSOF ¶¶7–8, 12, 15, 23–24, 30–31.) The user then turns the white grip of the Injector 90 degrees, locking the wings into the mating component's bayonet receptacle and at the same time unlocking the safety mechanism of the Injector that prevents it from compressing. (*See id*.) Once rotated and locked, the Injector can be compressed by pushing it down to the "activated position," enabling fluid or air transfer between the vial and syringe. (*See id.*) Once the drug has been transferred to the syringe, the syringe unit is disengaged from the vial assembly using the reverse pull-turn-pull method and may then be attached to a different mating component to deliver the drug to a patient. (*See id*.)

BD offers a general warranty policy for all of its products. (*See* PSOAF ¶5.) The applicable warranty for the PhaSeal System states:

> BD expressly warrants that all goods and services supplied under this agreement are merchantable and fit for the purposes intended and free of defects in workmanship and material. BD further warrants that it has full and marketable title to all goods and services furnished to customer under this agreement and that the furnishing of such goods and services to customer does not violate, in whole or in part, and provision of any law, common law, or regulation concerning copyrights, trade secrets, trademarks, trade names, services marks, patents or other provisions regulating or concerning intellectual/intangible property rights. BD further

> warrants the accuracy of all claims made in BD's descriptive literature. Customer reserves the right to reject the tendered goods and/or services and/or to hold BD responsible for any loss, direct or indirect, caused by breach of warranty, defective material or workmanship, or any other failure by BD to deliver conforming goods and service. Acceptance or use of articles ordered shall not constitute a waiver of any claim under this warranty.

(*See* Dkt. 463 at 7.)[3]

B. There is no evidence on which a reasonable jury could find that BD conditions the receipt of a benefit on performing the '192 Patent.

As recognized in the order denying BD's motion to dismiss, Baxter has proceeded on the theory that BD is liable for direct infringement under 35 U.S.C. § 271(a) based on its conditioning of the receipt of certain benefits on performing the patented method. It relies on the standard announced in *Akamai Technologies, Inc.* v. *Limelight Networks, Inc.*, 797 F.3d 1020 (Fed. Cir. 2015) (*Akamai V*). (*See* dkt. 71 at 3.)

Under *Akamai V*, direct infringement "occurs where all steps of a claimed method are performed by or attributable to a single entity," but where, as alleged in this case, "more than one actor is involved in practicing the steps, a court must determine whether the acts of one are attributable to the other such that a single entity is responsible for the infringement." 797 F.3d at 1022. Liability lies where the "alleged infringer conditions participation in an activity or receipt of a benefit upon performance of a step or steps of a patented method and establishes the manner or timing of that performance." *Id.* at 1023. Whether a single actor directed or controlled the acts

[3] This warranty was not presented as the applicable warranty for the PhaSeal System in any party's Rule 56.1 statements. This warranty policy was included as one of five documents that supported Baxter's asserted additional material fact no. 5. In that asserted additional fact, Baxter quoted language from multiple sources and did not include precise attribution to each quotation, resulting in a mishmash of warranty language in a single asserted fact. After reviewing the source material, the court accepts that the warranty in this decision is the applicable PhaSeal System warranty because BD identified it in its reply brief as the applicable policy.

of a third party depends on the circumstances of each case. *Id*. Mere guidance or instruction, however, is insufficient. *See Travel Sentry, Inc.* v. *Tropp*, 877 F.3d 1370, 1380 (Fed. Cir. 2017).

Baxter alleges that BD directs or controls users to follow its printed instructions (assuming those instruct the users to follow the method) by conditioning the receipt of two benefits on doing so. The first claimed benefit is safety, namely, the "ability to properly and safely mix, reconstitute and/or dilute a drug prior to administering it to a patient." And the second benefit is a warranty.

Now, having moved past the pleading stage, BD argues and has persuasively shown that there is no evidence supporting either alleged benefit. In support of its claim, Baxter identifies several facts in a bullet point list that it believes show that "it clearly is the case that a reasonable jury could find for [it] on direct infringement." But Baxter neglects to include any accompanying explanation, leaving it up to the court to accept that these facts support one or the other alleged benefit. The failure to fully develop this argument borders on forfeiture. *See United States* v. *Alden*, 527 F.3d 653, 664 (7th Cir. 2008).

Forfeiture aside, Baxter's cited evidence does not carry the day. Beginning with the warranty, no language in the applicable warranty[4] could reasonably be construed as containing a requirement that users perform the printed instructions or risk voiding the warranty. Indeed, the instructions contemplate users following local guidelines, regulations, and facility policies. And Baxter has no other evidence supporting the inference that BD conditions the validity of its warranty on users performing BD's instructions. (*See, e.g.*, dkt. 442 at 29 (BD witness explaining warranty).)

[4] The extent of Baxter's effort at identifying the applicable warranty is a reference to its asserted additional material fact 5. (Dkt. 450 at 10.) BD disputed that fact and for reasons explained in footnote 3 of this decision, *supra* p. 8, Baxter's cited evidence does not support the asserted fact.

Regarding the safety benefit, Baxter first cites the fact that the PhaSeal System is under BD's "Hazardous Drug Safety business unit" and its purpose is to reduce the risk of exposure to hazardous drugs. But the use of the PhaSeal System itself and mere existence of instructions are insufficient to show the conditioning of a benefit. *See, e.g.*, *NeuroGrafix* v. *Brainlab, Inc.*, No. 12 C 6075, 2020 WL 5642946, at *8 (N.D. Ill. Sept. 21, 2020) (defendant's sale of accused infringing software in itself did not support theory of direct infringement even though third parties perform steps of claimed method); *F'real Foods, LLC* v. *Hamilton Beach Brands*, 457 F. Supp. 3d 434, 445 (D. Del. 2020) ("providing instructions to a retailer in no way establishes the timing of the retailer's use of the [allegedly infringing device]"). This evidence is insufficient to show that BD crossed the line from mere guidance to conditioning.

Baxter also cites BD's stated goal of training all PhaSeal System users on its purpose and how it works (*see* PSOAF ¶3), and it claims that a BD witness admitted that if a user failed to follow the printed instructions BD would "go in and view the customer's practices and procedures and work with them to … get it to work to their satisfaction" (PSOAF ¶4).

These pieces of evidence also fall short. That BD aspires to train every user on the PhaSeal System is a vague claim, failing to describe how or whether BD exceeded mere guidance or instruction in pursuit of that goal. In fact, the BD witness who made that statement also explained that BD does not simply instruct users on its printed instructions and, based on all of his answers about BD's customer service, BD apparently does not adhere to one particular way of instructing or training users. (*See* dkt. 442 at 19–20.) Baxter's related assertion that BD trains users on its instructions if they do not follow them is not supported by the cited witness testimony. The purported supporting testimony of that assertion comes from a response to a question about BD's warranty, described above. The witness explained that BD would assist

users with their specific, unique problems and practices, whatever they might be, but nothing in his testimony suggests that the answer to any of those problems was to "show[ ] them how to use [the PhaSeal System] in an infringing manner," *NeuroGrafix*, 2020 WL at 5642946, at *18, if the user wanted to obtain the safety benefit. Asking a jury to find that BD instructed users on the method patent based on this evidence requires speculation. *See Nat'l Inspection & Repairs, Inc.* v. *George S. May Int'l Co.*, 600 F.3d 878, 886 (7th Cir. 2010).

Last, Baxter points to opinion testimony from its expert, Karl Leinsing, that was elicited on cross-examination. Leinsing, an engineer, opined that the U.S. Food and Drug Administration (which approves the device), BD, and facilities and clinicians all would expect that users will follow a manufacturer's instructions. The introduction of these opinions through cross-examination after the deadline for submitting infringement reports is procedurally improper and thus disregarded. *See* LPR 5.3. Moreover, Leinsing's admission that those opinions were not within his area of expertise, that is, he was unqualified to opine on such matters, renders them unreliable and thus incapable of passing muster under *Daubert* v. *Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993), and Federal Rule of Evidence 702. And he offered no specific factual basis from which a reasonable jury could otherwise conclude that the existence of BD's instructions amounted to a set of requirements that users follow to receive the safety benefit.

In summary, Baxter has not met its burden to avoid summary judgment by identifying sufficient evidence for a reasonable jury to conclude that BD conditions the receipt of the "ability to properly and safely mix, reconstitute and/or dilute a drug prior to administering it to a patient" or the validity of a warranty on performing the method patent.

C. The undisputed evidence shows that the PhaSeal System has a substantial noninfringing use, thus defeating the contributory infringement claim.

To show contributory infringement, Baxter must prove that BD sells the accused device for use in practicing the method patent and that the accused device is "not a staple article or commodity of commerce suitable for substantial noninfringing use[.]" 35 U.S.C. § 271(c). Thus, if the accused device is good for something else other than performing the method patent, the manufacturer is not liable as a contributory infringer. *See Ricoh Co.* v. *Quanta Computer Inc.*, 550 F.3d 1325, 1337 (Fed. Cir. 2008) ("a component, specially adapted for use in the patented process and with no substantial noninfringing use, would plainly be 'good for nothing else' but infringement of the patented process") (quoting *Metro-Goldwyn-Mayer Studios, Inc.* v. *Grokster, Ltd.*, 545 U.S. 913, 932 (2005)).

BD explains that the PhaSeal System assembled with a syringe that is pre-loaded with air is a substantial non-infringing use because in that configuration it can only facilitate fluid transfer but cannot reconstitute drugs. Baxter responds that this argument should be rejected because it runs afoul of the court's claim construction of "reconstitution device" as a device that "does not require that the method of the '192 Patent's first claim be used exclusively in reconstitution."

That the construction of "reconstitution device" does not require that the accused device be exclusively used for reconstitution is a separate issue that is not dispositive of whether the accused device is capable of a substantial noninfringing use. Baxter does not dispute that the device that results from assembling the Injector and Protector with a syringe preloaded with air is a substantial noninfringing use. In that configuration, the accused device is good for something else other than reconstitution. (*See* DSOF ¶28 (Leinsing: "there are other uses of the system").) The accused device may still qualify as a "reconstitution device" even though it has non-

reconstitution uses, but one of those uses is a substantial noninfringing use and that precludes contributory infringement. Thus, BD is entitled to summary judgment on the contributory infringement claim.

D. The undisputed evidence shows that PhaSeal System users do not perform the second "inserting" step of claim 1.

BD argues that PhaSeal System users who follow its printed instructions do not perform the second step of claim 1 of the method patent. As explained, there are two steps: (a) the "providing" step and (b) the "inserting" step:

> [a] providing a reconstitution device having first and second ends, the second end having a receiving chamber dimensioned to receive the top of the container for fixedly attaching the device to the container, the device having a central channel housing a piercing member, the device further having first and second sleeve members capable of sliding axially with respect to one another from an inactivated position where the piercing member is outside the receiving chamber to an activated position where a portion of the piercing member is positioned inside the receiving chamber; and
>
> [b] inserting the top of the container into the receiving chamber of the device and fixedly attaching the container therein when the device is in the inactivated position.

(DSOF ¶5.) "Fixedly attaching" was construed by the court to mean "attaching such that in order to remove the container from the reconstitution device one would have to exert a force considerably in excess of that normally used to operate the device, such that the force likely would break, detach, or noticeably deform the device in the process." (Dkt. 308 at 1.) As stated above, "[i]nactivated position" was construed as the "[p]osition in which the piercing member does not establish fluid communication with the drug container," in contravention to the "activated position," defined as the "[p]osition in which the piercing member establishes fluid communication with the drug container." (*Id.* at 3.)

BD argues that users following its instructions do not perform the "inserting" step for two reasons, both of which are primarily based on the fact that the accused device is made up of two

components. First, BD contends that the accused device is never fixedly attached to a drug vial. BD explains that the Injector is releasably, not fixedly, attached to the Protector, and thus the reconstitution device that is contemplated in the providing step of the '192 Patent, with all its described elements, is never fixedly attached to a drug vial. And the accused device is not subject to "break, detach, or noticeably deform" when removed from a drug vial, because, again, the Injector is releasably engaged with the Protector and thus the drug vial. Second, BD argues that the accused device is not in the "inactivated position" when attached to a drug vial because the "inactivated position" describes components within the Injector and BD instructs users to attach the Injector only after the vial assembly is created.

Baxter responds that nothing in the patent requires that any element of the accused device other than the "receiving chamber" of the Protector remain fixedly attached to the drug vial. And disengagement of the releasably attached Injector from the Protector does not disconnect the fixedly attached drug vial from the Protector. As for the requirement that the device be in the "inactivated position" when fixedly attached, Baxter maintains that its infringement theory is based on the understanding that the device was assembled and in the inactivated position (with a retracted cannula, *i.e.*, needle) before being fixedly attached.[5]

Although BD's two bases for noninfringement are closely related in that they rely on the fact that the device consists of two parts, the resolution of the first basis presents a close call but the second is clear cut: BD instructs users to first attach the Protector, by itself, to a drug vial. At this point, the accused device does not exist because BD has not instructed users to engage the Injector. The Injector, meanwhile, remains disengaged so that the syringe unit can be assembled.

[5] This decision does not consider new infringement theories presented for the first time on summary judgment. (*See* dkt. 463 at 12–13 (BD's reply brief citing Baxter's response at dkt. 450 at 14–15).)

The Injector is in the inactivated position, but it is not connected to the Protector, and so no device in the inactivated position is being attached to the drug vial. Thus, BD does not instruct users on the method patent. BD is entitled to summary judgment on this basis as well.

III. BD's motion for summary judgment on the '237 Patent claims

BD argues that it is entitled to judgment as a matter of law because the PhaSeal System, *i.e.*, the accused device of the Injector engaged with a Protector, does not perform two means-plus-function claim limitations of the '237 Patent.

Patent infringement is shown where the asserted claims cover the accused device literally or by equivalence. *See Advanced Cardiovascular Sys., Inc.* v. *Scimed Life Sys., Inc.*, 261 F.3d 1329, 1336 (Fed. Cir. 2001). After the claims have been construed to determine their scope and meaning, those construed claims are compared to the accused device. *Id*. "[T]o meet a means-plus-function limitation," as is the case here, "an accused device must (1) perform the identical function recited in the means limitation and (2) perform that function using the structure disclosed in the specification or an equivalent structure." *Carroll Touch, Inc.* v. *Electro Mech. Sys., Inc.*, 15 F.3d 1573, 1578 (Fed. Cir. 1993). "Literal infringement of a [means-plus-function] limitation requires that the relevant structure in the accused device perform the identical function recited in the claim and be identical or equivalent to the corresponding structure in the specification." *Odetics, Inc. v. Storage Tech. Corp.*, 185 F.3d 1259, 1267 (Fed. Cir. 1999). "[S]ummary judgment of noninfringement is proper when no reasonable factfinder could find that the accused product contains every claim limitation or its equivalent." *Medgraph, Inc.* v. *Medtronic, Inc.*, 843 F.3d 942, 949 (Fed. Cir. 2016).

As explained below, the evidence is such that no reasonable jury could conclude that the device of an Injector engaged with a Protector infringes on one of the claim limitations. (Thus, it is not necessary to address the second.)

A. The undisputed facts regarding the ’237 Patent[6]

1. The ’237 Patent

The ’237 Patent describes a “Sliding Reconstitution Device with Seal.” (DSOF ¶4.) Claim 1, the sole independent claim of the patent, states the following, with the limitations that BD argues are not infringed by the accused device emphasized in bold:

> A Connector device for establishing fluid communication between a first container and a second container comprising:
>
> [1a] a first sleeve member having a first end and a second end and a sidewall defining a chamber, the first sleeve member having at the first end a first attaching member adapted to attach to the first container;
>
> [1b] a second sleeve member having a first end and a second end, the second sleeve member being associated with the first sleeve member and is movable axially with respect thereto from an inactivated position to an activated position;
>
> [1c] **a second attaching member on the second end of the second sleeve and adapted to attach the second sleeve member to the second container**;
>
> [1d] a piercing member positioned in the chamber and projecting from one of the first and second sleeve members for providing a fluid flow path from the first container to the second container; and
>
> [1e] **means positioned on the first sleeve member for preventing the first sleeve member from becoming disassociated from the second sleeve member**.

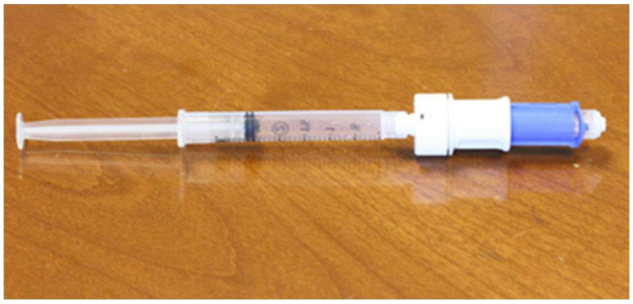
(DSOF ¶5.) Claim 15 of the ’237 Patent states, “The device of claim 1 wherein the means for preventing the first sleeve member from becoming disassociated from the second sleeve member comprises a stop at the first end of the first sleeve member.” (DSOF ¶6.)

2. The accused connector device

As explained in regard to the motion for summary judgment on the ’192 Patent, the PhaSeal System is a set of products that mate with each other using a sealed bayonet connection.

[6] References to the parties LR 56.1 factual assertions regarding the motion for summary judgment on the ’237 Patent claims are identical to those for the motion for summary judgment on the ’192 Patent claims.

(DSOF ¶¶8–10.) Again, relevant here, are the Injector and Protector, and together they form the accused "connector device" of the '237 Patent. (DSOF ¶¶24, 32.) Below on the left is an image of a syringe unit, which is the Injector attached to a syringe, and on the right is a vial assembly, which is the Protector attached to a drug vial:

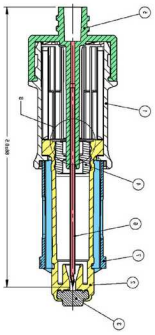


(DSOF ¶¶35–36.)

The Injector contains the male portion of the bayonet connection, and the Protector the female. (DSOF ¶¶8, 12.) The two components are engaged with the push-turn-push method and disengaged with the pull-turn-pull method. (DSOF ¶12.)

The Injector is shown in more detail below:

ITEM NO.	DESCRIPTION
1	CYLINDER
2	PISTON
3	MEMBRANE
4	SEALING
5	NEEDLE HOUSING
6	CANNULA
7	SAFETY SLEEVE



(DSOF ¶18; PSOAF ¶1.)

The Injector contains a translucent Piston (yellow in the image above) that is surrounded by a blue Safety Sleeve. (DSOF ¶26.) The Safety Sleeve has two tabs at the end where the bayonet connection is made, and if not engaged with a Protector (or similar PhaSeal System component) they are locked into recesses on the Piston that prevent it from rotating. (DSOF ¶27)

In the push-turn-push process of engaging the Injector to a bayonet receptacle on a Protector, at the initial push step, two wings on the Injector slide into indents on the Protector. (DSOF ¶¶8–9, 12, 16, 24.) And continuing to push allows the end that contains the two tabs to flex, thereby unlocking and disengaging the tabs from the recesses on the Piston. (DSOF ¶¶29, 30.) Once disengaged, the Piston is able to rotate, allowing the turn step to occur. (*Id.*) The user then turns, while holding the white grip on the Cylinder, 90 degrees until the wings at the end of the Piston lock into place. (DSOF ¶¶16, 27, 30.) Once the turn is completed, only then can the Injector compress, allowing the final push stage, and thereby causing the cannula (needle) to puncture the membranes on the Injector and Protector to create a sealed connection between the syringe and drug vial. (DSOF ¶¶29, 30.)

Accomplishing this engagement process keeps the drug transferring system closed and safe. (DSOF ¶10.) Not only does the system prevent exposure to hazardous drugs, but it also prevents exposure to the needle inside the Injector, as the name Safety Sleeve implies. (DSOF ¶30.) BD's instructions warn users to "Always grip white components when using the BD

PhaSeal System, "Do not grip blue part of the Injector," and "NOTE: Avoid touching blue portion of Injector." (DSOF ¶¶8, 12, 15.)

Karl Leinsing, Baxter's expert, however, was able to cause the Injector to compress when not engaged with a Protector, thereby showing that the Needle Housing prevents the white Cylinder from becoming disassociated with the Piston and blue Safety Sleeve, *i.e.*, the means for preventing disassociation claim limitation of the '237 Patent. (DSOF ¶28; PSOAF ¶¶1–9.) Leinsing was able to disengage the tabs himself by overcoming them, in that he manually lifted or forced them out of the Piston recesses with his hand. (*See* DSOF ¶¶27–29.)

B. BD is entitled to summary judgment because the accused connector device of either an Injector engaged with a Protector or Injector standing alone does not perform the disassociation claim limitation.

Although there are two means-plus-function claim limitations at issue, only the "disassociation" claim limitation is decided here, and its outcome is dispositive of whether there is infringement. The disassociation claim limitation is the "means positioned on the first sleeve member for preventing the first sleeve member from becoming disassociated from the second sleeve member." Baxter's infringement theory for this claim limitation is based on its contention that the Needle Housing performs the connector device's claimed limitation of "preventing the first sleeve member" (the white Cylinder) "from becoming disassociated from the second sleeve member" (the Piston and blue Safety Sleeve). (*See* PSOAF ¶¶1, 2.) Baxter's evidence of infringement is based on Leinsing's report that "the piston (2) became detached from the blue safety sleeve (7) and contacted and moved the cap of the needle housing (5) [off and to the right] since the cap was not affixed to the ring of the white cylinder (1) for the purposes of the test." (PSOAF ¶6.) As a result, the Cylinder and Piston were able to become disassociated, demonstrating that the Needle Housing is the means for preventing such disassociation. (PSOAF ¶¶7, 8, 9.)

BD offers two independent bases on which to conclude that there is no infringement. First, BD argues that there is no evidence that the accused connector device (the combined Injector and Protector) performs the claim limitation because Baxter's evidence of infringement was based on the Injector standing alone. According to Leinsing, before the Injector is engaged with the Protector to form the "connector device," movement of the Piston (and therefore any risk of disassociation) is prevented by the engagement of the Injector's Safety Sleeve tabs that fit into recesses on the Piston. But when BD asked Leinsing to repeat the demonstration showing that the Needle Housing prevented the Injector sleeves from "disassociating," he admitted that "it only comes out when it's detached from the Protector." (DSOF ¶31.) Leinsing therefore did not evaluate whether the Needle Housing performs the claim limitation when the Injector and Protector are engaged.

Baxter does not dispute that the engagement of the Injector and Protector, *i.e.* the fully assembled accused connector device, prevents the sleeves from disassociating. Rather, Baxter argues that it is sufficient to show infringement based on the means for preventing disassociation being effective before attachment of the components, and it makes a cursory claim that the accused connector device may still infringe if the Needle Housing acts as an additional means for preventing disassociation. Although BD offers persuasive reasons why these two arguments are not meritorious, these infringement theories need not be considered at this late stage because they are presented here on summary judgment for the first time. (*Cf.* Dkt. 470 at 6–7 (faulting BD for improperly relying on information not disclosed in final invalidity contentions)). Because Baxter has not presented evidence that in the accused connector device the Needle Housing performs the disassociation claim limitation, there is no evidence of infringement and thus BD is entitled to summary judgment on this basis.

BD's second basis for noninfringement is that even if the Injector alone were the accused connector device, Baxter's evidence of infringement is impermissibly based on the abuse or modification of the Injector. Evidence that an accused device is reasonably capable of infringing use can support infringement, but evidence of infringement based on abuse, modification, or some type of alteration that is contrary to the intended design of the accused device cannot support infringement. *See, e.g.*, *High Tech Med. Instrumentation, Inc.* v. *New Image Indus., Inc.*, 49 F.3d 1551, 1556 (Fed. Cir. 1995).

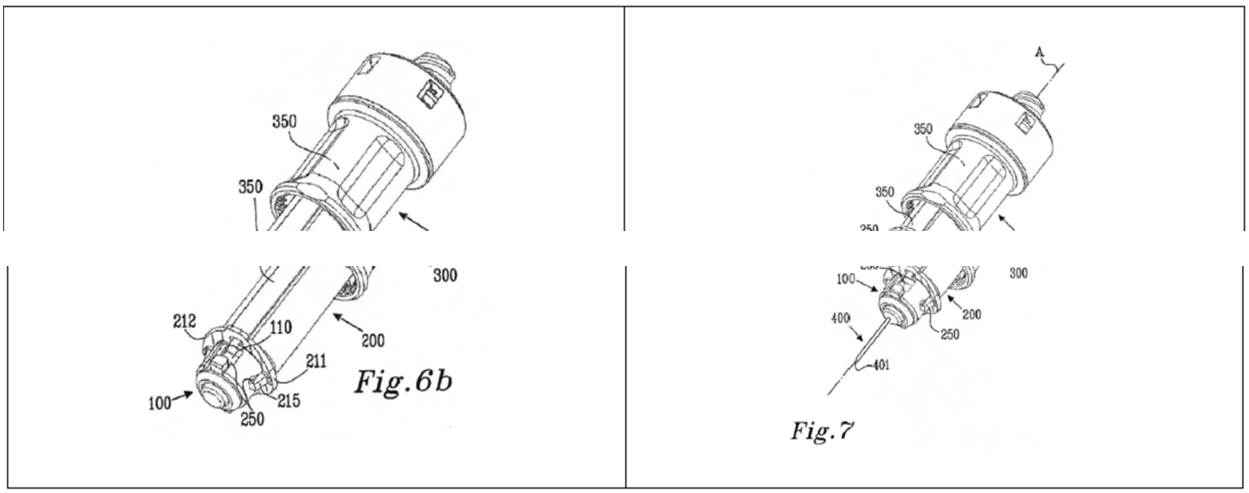
Here, Leinsing demonstrated the disassociation claim limitation in the Injector by manually overcoming the Safety Sleeve's locking tabs, a safety feature that is designed to prevent a user from compressing the Injector when not engaged with a Protector or similar PhaSeal System component, thereby allowing the Needle Housing to act as a stop for the movement of the Piston. Normally, two tabs on the end of the Safety Sleeve lock into recesses on the Piston, preventing it from turning and compressing. When the Safety Sleeve is pushed against the bayonet receptable of the Protector, it causes two portions of the Safety Sleeve that hold the tabs to flex and disengage the tabs from the recesses. When disengaged, the user can then perform the turn step, rotating the Cylinder 90 degrees to lock the wings at the end of the Piston into the bayonet receptable. After locking the wings in place, the user can then complete the final push step, causing the Injector to compress and the needle to pierce through the membranes of the combined PhaSeal System components and into a drug vial. Although the instructions are not controlling on the question of whether an accused device is capable of infringing, *see I-Flow LLC* v. *Progressive Med., Inc.*, No. SACV 12 C 1064, 2014 WL 12577152, at *5 (C.D. Cal. Jan. 7, 2014), it is worth noting that they contain several warnings

that the user should hold only white components and not the blue parts (*see* DSOF ¶¶ 8, 12, 15). The Safety Sleeve that Leinsing manipulated is blue.

Leinsing's manual overcoming of the safety mechanism by flexing the tabs on the Safety Sleeve is inherently an act of altering the device because it is contrary to its intended design and normal function of the Injector by itself and Injector and Protector combined. As such, it is not evidence that the Needle Housing is reasonably capable of acting as a stop for the Piston to prevent disassociation.

Baxter nevertheless argues that there is at least a question of fact as to whether the accused device is reasonably capable of operating in an infringing way. But its arguments lack grist. Baxter first contends that there is no evidence of abuse or modification of the Injector because, it claims, Leinsing did nothing more than simulate what the Injector was designed to do. Not exactly. Baxter ignores that the Safety Sleeve was designed to disengage the tabs only when engaged with certain PhaSeal System products. Leinsing's ability to accomplish the first push step and second turn step on the Injector when not engaged with a Protector required that he, by hand, manually simulate what the Injector and Protector accomplish together when engaged. The evidence of altering is therefore apparent in the manual disengagement of the tabs by hand. That alteration is so contrary to the Injector's normal operation that it in no way could be considered a reasonably capable use.

Baxter also points to two figures in BD's patent on the Injector showing the Injector with the Safety Sleeve disengaged and needle exposed, just as Leinsing had demonstrated in his report, as evidence that the Injector is reasonably capable of performing the claim limitation.



(PSOAF ¶16.). But those illustrations do not display the normal function of the Injector. The accompanying text to figure 7 states that it is an illustration of the configuration of the Injector (a "piercing member protection device") "after connection" with a PhaSeal System component with a bayonet receptacle, such as the Protector, and when connected "a user never runs the risk of being exposed to the" needle. (*See* dkt. 434-3 at 17 (Baxter Ex. BX3); RPSOAF ¶16.) Thus, BD's patent is not evidence that the Injector alone is designed to operate or is reasonably capable of operating as Leinsing claimed.

Last, Baxter argues that its evidence of infringement establishes that the accused product is at least reasonably capable of infringement. But, again, the evidence does not show a reasonable capability of infringement because it is based on altering the device to make it do something that it was not intended to do or otherwise did do. Like the "loosening" of "easily removeable set screws" that allowed an accused device to rotate and thus perform a claim limitation in *High Tech Medical Instrumentation*, Leinsing flexed two tabs out of their locked position in order to perform the claim limitation, in contravention of its design and normal configuration. *See* 49 F.3d at 1556. Put differently, the Safety Sleeve with its two tabs is "the difference between infringement and non-infringement because [overcoming it] fundamentally

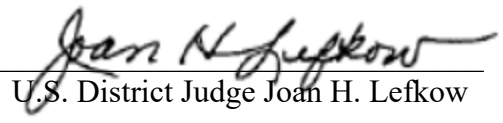
changed the operation of the accused device." *Krippelz* v. *Ford Motor Co.*, No. 98 C 2361, 2003 WL 466109, at *4 (N.D. Ill. Feb. 24, 2003) (explaining *High Tech Med. Instrumentation*). There is no other evidence suggesting that overcoming this safety mechanism serves any functional purpose or that the Injector is commonly or reasonably used in the altered way.

Thus, if one assumes that the Injector alone can support its infringement theory, there is no genuine dispute of fact that the Needle Housing does not act as a stop for the Piston to prevent disassociation without being altered, and so the Injector does not perform the disassociation claim limitation. Summary judgment for BD is therefore proper.

CONCLUSION AND ORDER

Defendant Becton, Dickinson and Company's motions for summary judgment on the '192 Patent and '237 Patent claims (dkts. 353, 396) are granted. This order and the order on the '103 Patent claim (dkt. 275) resolve all claims in defendant's favor. The Clerk is directed to enter judgment accordingly. Defendant's motion for summary judgment on willfulness and damages (dkt. 375) and motions to strike certain portions of expert testimony (dkts. 367, 402) are denied as moot. Plaintiff Baxter International, Inc.'s motion for partial summary judgment (dkt. 358) is denied as moot. Case terminated.

Date: August 22, 2022



U.S. District Judge Joan H. Lefkow