IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HORATIO WASHINGTON DEPOT TECHNOLOGIES LLC, Plaintiff, v. TOLMAR, INC., TOLMAR PHARMACEUTICALS, INC., and TOLMAR THERAPEUTICS, INC., Defendants.	)	Civil Action No. 17-1086-LPS

REPORT AND RECOMMENDATION

Presently before the Court is Defendants TOLMAR, Inc., TOLMAR Pharmaceuticals, Inc., and TOLMAR Therapeutics, Inc.'s (collectively "Defendants" or "TOLMAR") motion to dismiss for failure to state a claim (the "Motion"), filed pursuant to Federal Rule of Civil Procedure 12(b)(6). (D.I. 12) Defendants argue that Plaintiff Horatio Washington Depot Technologies LLC's ("Plaintiff" or "Horatio") Complaint, (D.I. 1), which alleges infringement of United States Patent Nos. 5,932,547 (the "'547 patent"), 6,124,261 (the "'261 patent"), and 6,235,712 (the "'712 patent") (together the "asserted patents" or "patents-in-suit"), should be dismissed for various reasons. For the reasons that follow, the Court recommends that Defendants' Motion be GRANTED-IN-PART and DENIED-IN-PART.

I. BACKGROUND

A. Factual Background

Plaintiff is the owner of the asserted patents by assignment and has the right to sue for past damages. (*Id.* at ¶¶ 17-19) The asserted patents are all titled "Non-Aqueous Polar Aprotic Peptide Formulations[,]" and were issued between 1999 and 2001. (*Id.*) The '547 and '261 patents (the "formulation patents") "are directed to stable, non-aqueous formulations of a peptide compound and solvent," while "the '712 patent is directed to methods of preparing those

formulations and treating prostate cancer using those formulations." (D.I. 13 at 4) At the time of the filing of this action in August 2017, the three asserted patents had already expired on June 13, 2017. (*Id.* at 3) Further information about the patents and products reading on the patents is set forth in Section III.

According to the Complaint, Defendant "TOLMAR Pharmaceuticals, Inc. holds approved New Drug Applications ('NDA')" for various doses of its branded drug Eligard® (the "accused product"). (D.I. 1 at ¶ 23) "Eligard is indicated for use in the palliative treatment of advanced prostate cancer" and "contains leuprolide acetate, a luteinizing hormone-release hormone (LH-RH) related compound as its active pharmaceutical ingredient." (*Id.*) Plaintiff alleges that Defendants directly, indirectly and willfully infringed the patents-in-suit relating to the making, using, selling or offering for sale of Eligard. (*Id.* at ¶¶ 29-109)

B. Procedural Background

On August 3, 2017, Plaintiff filed this action against Defendants. (D.I. 1) On August 11, 2017, Chief Judge Leonard P. Stark referred the case to the Court to resolve any and all matters with regard to scheduling, as well as any motions to dismiss, stay, or transfer venue. (D.I. 8)

On September 27, 2017, Defendants filed the instant Motion, (D.I. 12), and briefing was completed on November 15, 2017, (D.I. 21). The Court heard oral argument on the Motion at the request of all parties on May 9, 2018. (D.I. 59 ("Tr.")) Thereafter, Defendants filed two notices of subsequent authority, (D.I. 49; D.I. 57), and Plaintiff filed a statement in response to the second notice, (D.I. 58).

II. STANDARD OF REVIEW

Pursuant to Rule 12(b)(6), a party may move to dismiss the plaintiff's complaint based on the failure to state a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6). The sufficiency of pleadings for non-fraud cases is governed by Federal Rule of Civil Procedure 8, which requires "a short and plain statement of the claim showing that the pleader is entitled to

relief[.]" Fed. R. Civ. P. 8(a)(2). In order to survive a motion to dismiss pursuant to Rule 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (internal quotation marks and citation omitted). In assessing the plausibility of a claim, first the court separates the factual and legal elements of a claim, accepting "all of the complaint's well-pleaded facts as true, but [disregarding] any legal conclusions." *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210-11 (3d Cir. 2009). Second, the court determines "whether the facts alleged in the complaint are sufficient to show that the plaintiff has a 'plausible claim for relief.'" *Id.* at 211 (quoting *Iqbal*, 556 U.S. at 679).

A plausible claim does more than merely allege entitlement to relief; it must also demonstrate the basis for that "entitlement with its facts." *Id.* Thus, a claimant's "obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do[.]" *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (citations omitted). In assessing the plausibility of a claim, the court must "'construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief.'" *Fowler*, 578 F.3d at 210 (quoting *Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008)).

III. DISCUSSION

Defendants assert various grounds for dismissing some or all of the Counts in the Complaint. One of those grounds is the argument that all claims of infringement of the two formulation patents should be dismissed because Plaintiff failed to plead compliance with the marking statute, 35 U.S.C. § 287(a) ("Section 287(a)" or "the marking statute"). (D.I. 13 at 3, 17-20) At oral argument, the parties spent most of their time addressing that issue. (*See* Tr. at 23-25, 31 (the Court explaining that the marking issue was at the top of its decision tree, and

both sides agreeing that it should be)) Therefore, the Court will address the marking issue first, and will address the other alleged pleading deficiencies thereafter.

A. Failure to Plead Compliance with the Marking Statute

Under Section 287(a):

> Patentees, and persons making, offering for sale, or selling within the United States any patented article for or under them . . . may give notice to the public that the same is patented, either by fixing thereon the word "patent" or the abbreviation "pat.", together with the number of the patent, or by fixing thereon the word "patent" or the abbreviation "pat." together with an address of a posting on the Internet, accessible to the public without charge for accessing the address, that associates the patented article with the number of the patent, or when, from the character of the article, this can not be done, by fixing to it, or to the package wherein one or more of them is contained, a label containing a like notice. In the event of a failure so to mark, no damages shall be recovered by the patentee in any action for infringement, except on proof that the infringer was notified of the infringement and continued to infringe thereafter, in which event damages may be recovered only for infringement occurring after such notice. Filing of an action for infringement shall constitute such notice.

35 U.S.C. § 287(a). Thus, when required by the statute, notice that sales of a product may constitute patent infringement may be given to the alleged infringer in one of two ways: (1) via constructive notice, by properly marking the patentee's own product (or its packaging); or (2) via actual notice (such as by filing an infringement action against the infringer). *See Lambda Optical Sols., LLC v. Alcatel-Lucent USA Inc.*, Civil Action No. 10-487-RGA-CJB, 2015 WL 5470175, at *3 (D. Del. July 29, 2015) *report and recommendation adopted sub nom. LAMBDA Optical Sols. LLC v. Alcatel Lucent USA Inc.*, No. CV 10-487-RGA, 2015 WL 5458269 (D. Del. Sept. 17, 2015).

The statute's language and related requirements set up a few different possible scenarios. For example, if a patentee (or other person mentioned in the statute) never produces or sells a patented product, then the patentee/person's ability to recover damages is not limited by the

statute. *Id.* (citing *Texas Dig. Sys., Inc. v. Telegenix, Inc.*, 308 F.3d 1193, 1219-20 (Fed. Cir. 2002)). On the other hand, if a patentee produces or sells a patented product, but does not mark the patented product in a manner described in Section 287(a), it forfeits the right to recover damages for the period in which it was producing or selling the unmarked product (unless and until it provides the actual notice to the potential infringer). *Id.* Relatedly, the Court has also concluded that if a patentee produces or sells an unmarked patented product—but then later ceases such production/sales—it may still not collect damages thereafter for infringement until it takes active steps to address the failure to mark, such as by affirmatively providing notice to a potential infringer. *Id.* at *5; *see also Arctic Cat Inc. v. Bombardier Recreational Prods., Inc.*, Case No. 14-cv-62369-BLOOM/Valle, 2018 WL 3820610, at *7 (S.D. Fla. Aug. 10, 2018) (explaining that where the plaintiff/patentee's product was not marked for a period of time, the fact that the patentee thereafter ceased selling the unmarked product for over a year did not entitle it to damages as of the date that the product came off of the market; instead, in order to be able to recover damages thereafter, the patentee "needed to begin marking the products or provide actual affirmative notice to an alleged infringer[]" in order to cure non-compliance with the marking statute).

Patents that contain only method claims, such as the '712 patent, are not subject to the notice provisions of Section 287(a), *ActiveVideo Networks, Inc. v. Verizon Commc'ns, Inc.*, 694 F.3d 1312, 1334 (Fed. Cir. 2012), whereas the formulation patents, which contain only product claims, are subject to those provisions. It is plaintiff's burden to both plead and prove compliance with the marking statute. *Arctic Cat Inc. v. Bombardier Recreational Prods. Inc.*, 876 F.3d 1350, 1366 (Fed. Cir. 2017); *Sentry Prot. Prods., Inc. v. Eagle Mfg. Co.*, 400 F.3d 910, 918 (Fed. Cir. 2005).

Defendants argue that: (1) Plaintiff was obligated to and has failed to plead compliance with Section 287(a) in the Complaint; and (2) this dooms its claims of infringement of the formulation patents. Its argument takes some time to set out, and goes as follows:

(1) The Complaint contains allegations that Defendants had knowledge of the asserted patents since at least May 20, 2010. On that date, during the prosecution of TOLMAR's United States Patent No. 8,486,455 (the "'455 patent"), TOLMAR submitted an Information Disclosure Statement ("IDS") (attached as an exhibit to the Complaint), in which TOLMAR cited to the December 2009 edition of the United States Food and Drug Administration's ("FDA") Approved Drug Products With Therapeutic Equivalence Evaluations (the "Orange Book")—and more particularly, to the Orange Book's reference to "[Leuprolide] Acetate (12/2009)." (D.I. 1 at ¶ 26 & ex. F) Plaintiff also attaches to the Complaint what is purported to be a portion of the same December 2009 edition of the Orange Book. (*Id.*, ex. D) In that portion of the Orange Book, ten patents—including the three asserted patents here—are listed under the heading "Leuprolide Acetate – Viadur[,]" meaning that the patents were therein associated with the drug product Viadur®. (*Id.*, ex. D at 13)

(2) Defendants argue that because the two formulation patents were listed in connection with Viadur in this edition of the Orange Book, this means that the patents "either cover Viadur or a method of using Viadur." (D.I. 13 at 19 (citing 21 C.F.R. 314.53))

(3) Defendants then note that it is undisputed that from at least 2000 to 2008, Viadur was "commercially marketed in the U.S." by ALZA Pharmaceuticals ("ALZA"), Plaintiff's predecessor as owner of the asserted patents. (D.I. 13 at 20; *see also id.* at 4; D.I. 1, ex. D at 13; D.I. 19 at 11 (Plaintiff noting that Viadur was marketed by ALZA until 2008); Tr. at 4 (Defendants' counsel noting that Viadur was sold in the United States from 2000 to 2008))

(4) Defendants further allege that "at some point prior to 2011[,] Viadur was discontinued, and . . . there was no product covered by the Asserted Patents commercially marketed in the United States from 2011-2017." (D.I. 13 at 20; *see also* D.I. 1 at ¶ 21 (Plaintiff pleading that "[f]rom 2011 to 2017, there was no product for the patentees to mark with the patent numbers in the United States[]"))

(5) Defendants note that ALZA later assigned the asserted patents to a third party; the "third party [] owned the patents until they expired in June of 2017." (Tr. at 5) Plaintiff then acquired the asserted patents by assignment on July 26, 2017, one week prior to filing the instant suit. (*Id.*; *see also* D.I. 13 at 4 n.2; D.I. 19 at 18)

(6) Because Viadur read on the asserted patents, Defendants argue that ALZA was required to mark the Viadur product/packaging. The Complaint, however, contains no allegations that ALZA did so. (D.I. 13 at 20; *see also*

D.I. 1) In light of the fact that it is not pleaded that ALZA provided the required constructive notice of infringement to entities like Defendants (and in light of the fact that Defendants were not given actual notice of their own patent infringement during the damages period), Defendants argue that ALZA's failure to mark means that Plaintiff, as a later-acquiring holder of title to the formulation patents, cannot recover damages as to those patents from Defendants. (D.I. 13 at 6, 20) In other words, ALZA's failure to mark prohibited not only *it* from collecting patent damages until actual notice of infringement was given, but it also serves to prohibit *Plaintiff* from collecting such damages as well.

(7) And since the formulation patents expired before suit here was brought against Defendants, the filing of the Complaint cannot provide actual notice of infringement to Defendants. Therefore, Defendants assert that the infringement claims as to the formulation patents should be dismissed. (D.I. 13 at 19-20)

For its part, Plaintiff does not dispute that the formulation patents covered Viadur. (D.I. 19 at 11 ("There is no current dispute that the [formulation] patents covered . . . Viadur[]"); Tr. at 36 (Plaintiff's counsel acknowledging that one can reasonably infer from the Complaint that Viadur read on the claims of the asserted patents at issue here); *id.* at 61-62) Rather, Plaintiff makes two main arguments in opposition: (1) the Orange Book listing of the formulation patents for Viadur satisfied the marking requirement of Section 287(a); and/or (2) even assuming ALZA failed to mark Viadur with the formulation patents,[1] this should not prevent Plaintiff from seeking damages here, since Plaintiff only acquired the patents in July 2017, and Plaintiff was

[1] Plaintiff does not concede that Viadur was not physically marked; rather, Plaintiff asserts that it is ignorant on the topic. (*See* D.I. 19 at 19 (explaining that "it would be inappropriate to require Horatio to plead unknown facts regarding a discontinued product [i.e., whether Viadur was marked]" and that "whether a product covered by the [a]sserted [p]atents was marked[is] in the control of . . . third parties and discovery would be needed to determine the details[]"); *see also id.* at 14 (asking the Court, if it should decide that the Orange Book listing of the formulation patents did not satisfy the marking statute, to allow Plaintiff "through discovery, including third-party subpoenas, to establish that Viadur[] was marked[]")) Plaintiff's request for discovery is discussed further below.

then a "good faith third party purchaser[] of [the] patents who never manufactured any patented product and who [is] not under the control of the patentee or in privity with the prior assignee[.]" (D.I. 19 at 11-19) The Court will address each argument in turn, and thereafter will take up a related argument regarding discovery.

1. The Orange Book and Section 287(a)

Plaintiff's first argument is that the Orange Book's listing of the formulation patents alongside Viadur satisfied Section 287(a)'s requirements. (*Id.* at 11-12) Plaintiff asserts that the Orange Book listing of the formulation patents amounts to both actual notice and constructive notice under Section 287(a). (*Id.* at 12)

a. Actual Notice

The Court first addresses the marking statute's actual notice alternative. "Actual notice [under Section 287(a)] requires the affirmative communication of a specific charge of infringement by a specific accused product or device." *Amsted Indus. Inc. v. Buckeye Steel Castings Co.*, 24 F.3d 178, 187 (Fed. Cir. 1994). Rather than focusing on whether the defendant knew of the patent or of its infringement, "[t]he correct approach to determining notice under [Section 287(a)] must focus on the action of the patentee[.]" *Id.*

In *Amsted Indus. Inc.*, the United States Court of Appeals for the Federal Circuit found that a letter from the plaintiff, which was addressed to the "whole industry" and described the plaintiff's acquisition of certain patents relating to railway cars, was insufficient to provide actual notice under the marking statute. *Amsted Indus. Inc.*, 24 F.3d at 180, 187. The letter at issue was "broadcast to a number of [] companies [including the defendant]" and it: (1) advised that the plaintiff had acquired a number of patents, including the one at issue, from a third party; (2) indicated that the plaintiff would enforce its rights under those patents; and (3) asked the industry

to respect the plaintiff's patents, to become acquainted with the patent at issue and to "refrain from supplying or offering to supply component parts which would infringe or contribute to the infringement of the patent[.]" *Id.* at 186. The Federal Circuit found that the letter "was not notice within the meaning of [Section 287(a)]." *Id.* at 187. The *Amsted* Court explained that for purposes of Section 287(a), actual "notice must be of 'the infringement,' not merely notice of the patent's existence or ownership[,]" and that the plaintiff's letter did not give notice "of a specific charge of infringement by a specific accused product or device." *Id.* This was in contrast to a later letter sent by the plaintiff, which undisputedly provided sufficient actual notice under Section 287(a). That later letter was sent specifically to the defendant; it addressed the defendant's own center plate for a freight car (enclosing a photo of said center plate), asserted that the center plate infringed the patent at issue and demanded that the defendant cease and desist from further production and sales of the product. *Id.* at 186-87; *compare Gart v. Logitech, Inc.*, 254 F.3d 1334, 1346 (Fed. Cir. 2001) (noting that a letter containing references to the patent at issue and to the accused product being sold, as well as a suggestion that the defendant should have patent counsel review the patent "'to determine whether a non-exclusive license under the patent is needed[]'" provided sufficient actual notice of infringement), *with Philips Elecs. N. Am. Corp. v. Contec Corp.*, 312 F. Supp. 2d 649, 652 (D. Del. 2004) (finding that the plaintiff's letter to the defendant enclosing a copy of the patents-in-suit and requesting a meeting "'to discuss these patents and our license terms'" did not provide actual notice of infringement, because it did not provide a specific charge of infringement by a specific accused product or device), *aff'd,* 177 F. App'x 981 (Fed. Cir. 2006).

Plaintiff explains that "[a]s part of the new drug approval process, the [drug] manufacturer *must* inform [the] FDA of all patents 'with respect to which a claim of patent

infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.'" (D.I. 19 at 12 (certain emphasis in original) (quoting 21 U.S.C. §§ 355(b)(1), (c)(2))) The FDA proceeds to list all such patents in the Orange Book. (*Id.*) The Orange Book thus gives "notice to potential infringers of the patents covering an FDA-approved product[and] any company seeking to make an equivalent or similar branded or generic version of an FDA-approved product is on specific notice of the patents associated with that product and thus is notified of infringement." (*Id.* at 13)

Having described the Orange Book's function, Plaintiff then argues that the listing of the formulation patents in the Orange Book can be said to have provided actual notice to Defendants of their infringement of the formulation patents. According to Plaintiff, this is because "drug product manufacturers are required by law to monitor the Orange Book, and in certain cases, are required to certify to the noninfringement of the listed patents[,]" and thus the "Orange Book listing should be viewed *sui generis* given its unique, highly-regulated nature." (*Id.* at 12) The Court disagrees with Plaintiff's argument, for at least two reasons.

First, Plaintiff's argument flies in the face of the Federal Circuit's reasoning in *Amsted.* Even if Defendants consulted the Orange Book and learned of the formulation patents at some point prior to the filing of the Complaint, that simply could not amount to Plaintiff having made a "specific charge of infringement [to Defendants.]" *Amsted Indus. Inc.*, 24 F.3d at 187. By listing the formulation patents in the Orange Book, Plaintiff's predecessor was not engaging in any *specific communication with TOLMAR* at all (let alone communicating to TOLMAR that it infringed those patents). And relatedly, even if Defendants had previously consulted the Orange Book and had seen the formulation patents listed there as being associated with Viadur, they would not have been provided notice of the "specific accused product or device" that is now

alleged to infringe the formulation patents. *Id.* This is because the only such "accused product" that the Orange Book could even possibly be calling out in such a scenario is a "generic version of Viadur" (which Defendants do not and did not make). (D.I. 21 at 5)

Second, the decision in *Merck & Co. v. Medplan Health Consulting, Inc.*, No. 05 Civ. 3650(DC), 2006 WL 1676229 (S.D.N.Y. June 14, 2006)—the only case cited by the parties that discusses whether a listing in the Orange Book satisfies Section 287(a)—also supports the Court's conclusion. (D.I. 19 at 13; D.I. 21 at 5-6) In *Merck & Co.*, the court found, as a matter of first impression, that an Orange Book listing does not constitute actual notice to an accused infringer for purposes of Section 287(a). *Merck & Co.*, 2006 WL 1676229, at *5. The patent at issue in that case was "listed five times for various dosages under the product name 'SIMVASTATIN; ZOCOR.'" *Id.* The plaintiffs argued, like Plaintiff does here, that the Orange Book was "not just a generalized warning" to the defendants (who were actually manufacturers of a generic version of the plaintiffs' drug), but rather that it gave "direct and specific notice to an audience that is required by statute to seek out and heed that notice." *Id.* at *6 (internal quotation marks and citation omitted). The court disagreed, explaining that the Orange Book listing at issue "does not reference defendants or their products, nor was it sent directly to defendants[,]" and that "[t]he Orange Book is merely a catalog that informs the public of the patent's existence[, which] is just the kind of generalized warning to the industry that the courts have routinely found do not provide sufficient notice." *Id.* at *5. The *Merck & Co.* Court concluded that the plaintiffs' argument—"that defendants were required to consult the Orange Book under the relevant statutory scheme and had they done so they would have received notice"—was an improper attempt to get the court "to focus on defendants' actions instead of [plaintiffs']." *Id.* at *6.

b. Constructive Notice

Plaintiff also argues that the listing of the formulation patents in the Orange Book provided constructive notice of the formulation patents. As noted above, "constructive notice by marking" is the other method by which a patentee can provide notice of a patent to an infringer under Section 287(a). *Minks v. Polaris Indus., Inc.*, 546 F.3d 1364, 1376 (Fed. Cir. 2008) (internal quotation marks and citation omitted). Plaintiff argues that "the Orange Book [can] provide[] constructive notice because it unambiguously associate[d] patents covering a pharmaceutic product with the patented product." (D.I. 19 at 13) The Court disagrees.

The language of Section 287(a) matters here. The statute provides for two methods by which a patentee can provide constructive notice that an article it makes or sells is patented: "*either* by [1] fixing thereon the word 'patent' or the abbreviation 'pat.', together with the number of the patent, or by fixing thereon the word 'patent' or the abbreviation 'pat.' together with an address of a posting on the Internet . . . that associates the patented article with the number of the patent[,] *or* [2] when, from the character of the article, this can not be done, by fixing to it, or to the package wherein one or more of them is contained, a label containing a like notice." 35 U.S.C. § 287(a) (emphasis added). The statute's use of "either" and "or" indicates to the Court that, aside from providing actual notice of infringement, a patentee can *only* satisfy the requirements of Section 287(a) by physically marking the product in certain ways, or, when that is not possible, by physically marking a label attached to the article or to its packaging. To be sure, there are other legal contexts in which a party can provide "constructive notice" of a fact in broader, more varied ways. *See, e.g., Saldana v. Kmart Corp.*, 260 F.3d 228, 232 (3d Cir. 2001) (discussing whether a store had "constructive notice" of a risk of harm in a tort lawsuit). But in the Section 287(a) context, "[c]onstructive notice requires the record to show that 'the patentee

consistently marks substantially all of its patented products[,]'" *SEB S.A. v. Montgomery Ward & Co.*, 594 F.3d 1360, 1378 (Fed. Cir. 2010) (citation omitted), and that requirement is strictly interpreted.[2] There is not a third, more lenient "Orange Book" form of constructive notice listed in the statute, and the Court cannot re-write the statute to include one for Plaintiff's benefit.

The Court's decision here is also in line with the underlying purposes of the marking statute. Such purposes are: "1) helping to avoid innocent infringement; 2) encouraging patentees to give notice to the public that the article is patented; and 3) aiding the public to identify whether an article is patented." *Rembrandt Wireless Techs., LP v. Samsung Elecs. Co., Ltd.*, 853 F.3d 1370, 1383 (Fed. Cir. 2017) (internal quotation marks and citation omitted). These three related purposes all seek to "protect[] the public's ability to exploit an unmarked product's features without liability for damages until a patentee provides" notice. *Id.* "While the

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[2] *See e.g., Acantha LLC v. DePuy Orthopaedics Inc.*, Case No. 15-C-1257, 2018 WL 1951231, at *4 (E.D. Wis. Apr. 25, 2018) ("Because [patentee-plaintiff] has not established that the surgical technique guides [in which the patent number was listed] were distributed or shipped with the licensed products, it cannot rely on the fact that these guides contain its patent number to show that it complied with the requirements of [Section] 287(a)"); *A to Z Machining Serv., LLC v. Nat'l Storm Shelter, LLC*, No. CIV-10-422-C, 2011 WL 6888543, at *3 (W.D. Okla. Dec. 29, 2011) (concluding that a patentee's act of affixing its website to its patented product did not satisfy Section 287(a) because the patentee did not include the word patent or an abbreviation thereof); *Stryker Corp. v. Intermedics Orthopedics, Inc.*, 891 F. Supp. 751, 829-30 (E.D.N.Y. 1995) (finding that where "the patent mark was put in" nationally distributed literature regarding a device, but where that literature was distributed "separately from the [patented] devices[,]" this did not satisfy the constructive notice requirements of Section 287(a), as the marking was not on "a label . . . fixed to the [device's] package" nor was it "in the packaging" of the patented device) (emphasis omitted), *aff'd on other grounds*, 96 F.3d 1409 (Fed. Cir. 1996); *Calmar, Inc. v. Emson Research, Inc.*, 850 F. Supp. 861, 868 (C.D. Cal. 1994) (explaining that product fact sheets marked with the patent that were "left with actual or prospective customers upon delivery of [patented] product samples" or "included with shipments of [patented article] samples to such customers" were insufficient to meet the constructive notice requirement, as "merely marking some literature associated with a patented article is insufficient to satisfy the marking requirements of the statute").

Orange Book is [certainly] available to the public," *Merck & Co.*, 2006 WL 1676229, at *5, listing a patent there along with the name of a branded drug product would not provide the same type of notice that an "article is patented" as does the statutorily-listed forms of constructive notice. Those statutorily-approved forms of notice physically link the identification of the patent number with the *actual product itself (or its packaging)*—such that the public can associate the patent with the patented item in a very immediate, tangible way. Requiring the public to consult the Orange Book to learn of patent protection for a drug seems at least one step removed from that type of clear linkage.[3]

c. Conclusion

Therefore, the Court finds that the inclusion of the formulation patents in the Orange Book was insufficient to satisfy either the actual notice or constructive notice provisions of Section 287(a).

2. Plaintiff and Its Good Faith Purchase of the Formulation Patents

Plaintiff's next argument is that even if its predecessor ALZA did fail to mark a patented product for some period of time, and even if actual or constructive notice of infringement was not provided to Defendants, Section 287(a) still should not apply to it. Plaintiff notes that it was neither the original patent holder who may have sold unmarked products (that was ALZA), nor a licensee or a successor-in-interest to ALZA. In light of this, Plaintiff argues that even if ALZA's failure to mark could be held against *ALZA* (or ALZA's licensee or its successor-in-interest), Section 287(a) should not be "read . . . so broadly as to sweep within its scope good faith third

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[3] Further, while the existence of the Orange Book may be common knowledge to some or many in patent- and pharmaceutical-related professions, it seems unlikely that all of the interested public-at-large knows of the Orange Book's existence.

party purchasers of patents [like Plaintiff] who *never manufactured any patented product* and who are *not under the control of the patentee or in privity with the prior assignee*." (D.I. 19 at 17 (emphasis added))[4] Put differently, Plaintiff argues that Defendants "ignore[] the distinction between patentees and persons making or selling patented products on their behalf versus an unrelated third-party purchasing title to the patent in good faith." (*Id.* at 16-17) From there, Plaintiff makes various policy-based or equity-based arguments about why a patentee in Plaintiff's shoes (i.e., "an unrelated third party purchasing title to the patent in good faith") should not be precluded from obtaining damages pursuant to Section 287(a). (*Id.* at 17-18)

The problem for Plaintiff is that, in the end, the answer here depends not on the Court's view of policy or equity but instead on a question of statutory construction—i.e., on who counts as a "[p]atentee[]" for purposes of Section 287(a). (D.I. 21 at 6 n.3 (Defendants noting that "marking is an issue of statutory construction, not equity")) After all, Section 287(a) sets out certain marking and notice requirements for "[p]atentee[s]" (and those persons who make, offer

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[4] At oral argument, regarding this "good faith purchaser" theory, Plaintiff's counsel made a new argument that was not fairly presented in its briefing. Plaintiff's counsel asserted that another reason why Section 287(a) should not limit its pre-suit damages was that there was no *product continuity* between the ALZA product that was allegedly unmarked and any product that Plaintiff has made or sold. (Tr. at 32-33) Put another way, Plaintiff's counsel asserted that the requirements of Section 287(a) do not attach to a later assignee of a patent "where there is no nexus between the activities that [the prior patentee and current patentee] engaged in." (*Id.* at 38-39; *see also id.* at 45 (Plaintiff's counsel explaining that "[t]he way I [] look at it, there are two components" regarding whether the current owner of the patent is bound by a previous patent owner's failure to mark: (1) "is there a product going through that consistent chain" and (2) "how are the parties related"); *id.* at 40, 50 (Plaintiff's counsel suggesting that a prior patentee's failure to mark one patented product should not curb a plaintiff's ability to recover damages from an infringer who copies a second, unrelated patented product of the plaintiff)). As this argument was not made in Plaintiff's briefing, it is waived. *See Johnson-Braswell v. Cape Henlopen Sch. Dist.*, Civil Action No. 14-1089-RGA, 2015 WL 5724365, at *12 n.9 (D. Del. Sept. 29, 2015); *L-3 Commc'ns Corp. v. Sony Corp.*, Civil Action No. 10-734-RGA, 2014 WL 4674815, at *3 (D. Del. Sept. 12, 2014) (noting that an argument raised for the first time during oral argument is waived).

for sale or sell a patented article "for or under" a patentee), and related limitations on how a "patentee" can recover damages. 35 U.S.C. § 287(a). If Plaintiff counts as a "[p]atentee[]" then the inquiry is over—the statute's requirements would then apply to it too.

In order to determine the correct meaning of the word "[p]atentee[]" in Section 287(a), the Court turns to the text of 35 U.S.C. § 100(d) ("Section 100(d)").[5] According to Section 100(d), "[w]hen used in this title unless the context otherwise indicates . . . (d) The word 'patentee' includes *not only the patentee to whom the patent was issued but also the successors in title* to the patentee." 35 U.S.C. § 100(d) (emphasis added). Section 100(d), then, purports to define the term "patentee" for use in the remainder of the "title[,]" including Section 287(a). And it makes clear that when a statute like Section 287(a) is referring to (or proscribing) the acts of a "[p]atentee[,]" its strictures relate both to an original patentee and to a later-acquiring patent holder. *See Morrow v. Microsoft Corp.*, 499 F.3d 1332, 1339 (Fed. Cir. 2007) (explaining that

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[5] Other courts have looked to Section 100(d) to understand the meaning of terms in Section 287(a). For example, in *In re Elonex Phase II Pwr. Mgmt. Litig.*, No. 01-082 GMS, 2002 WL 242363 (D. Del. Feb. 20, 2002), this Court sought to determine whether a party's status as the exclusive licensee of patents-in-suit for a period of time was sufficient to render it the "patentee" for Section 287(a) notice purposes. *Elonex*, 2002 WL 242363, at *4. In assessing this question, the *Elonex* Court (citing to Federal Circuit caselaw in support) looked to how the terms "patentee" or "successor in title to the patentee" had been interpreted for purposes of Section 100(d). *Id.* (citing *Enzo APA & Son, Inc. v. Geapag A.G.*, 134 F.3d 1090, 1093 (Fed. Cir. 1998) (internal quotation marks omitted)). It noted that because these terms had been found (in the Section 100(d) context) to apply to a party who holds an exclusive license to a patent, Section 287(a)'s requirements should also apply to an exclusive licensee. *Id.*; *see also Mass. Inst. of Tech. v. Abacus Software, Inc.*, No. 5:01cv344, 2004 WL 5268123, at *19 (E.D. Tex. Aug. 4, 2004) (assessing Section 100(d)'s definition of "'patentee'" in analyzing Section 287(a)'s meaning); (Tr. at 38 (Plaintiff's counsel agreeing that Section 100(d)'s definition applies to words used in the remainder of the Patent Act)).

for purposes of Section 100(d), a "successor[] in title is the party holding *legal title* to the patent") (internal quotation marks and citation omitted) (emphasis and alteration in original).[6]

With the meaning of the statutory language now understood, the Court's remaining analysis is straightforward. Plaintiff is a successor in title to the original patentee. It is the assignee of the asserted patents and, as such, has brought a civil action for infringement of those patents in its own name. *See Enzo APA & Son, Inc. v. Geapag A.G.*, 134 F.3d 1090, 1093 (Fed. Cir. 1998) ("[A]n assignee is the patentee and has standing to bring suit for infringement in its own name." (citing Section 100(d)); *see also* (D.I. 1 at ¶¶ 17-19 (explaining that Plaintiff "is the owner of the [asserted patents] by assignment and has the right to sue for past damages")). Thus, if there was a failure to mark by any prior or current patentee (as there was here, by prior patentee ALZA), then "no damages shall be recovered *by the patentee* [including current patentee Plaintiff] in any action for infringement, except on proof that the infringer was notified of the infringement and continued to infringe thereafter[.]" 35 U.S.C. § 287(a); *cf. Grain Processing Corp. v. Am. Maize-Prods. Co.*, 185 F.3d 1341, 1347 n.3 (Fed. Cir. 1999) (explaining that damages were unavailable to the patent holder/plaintiff prior to the filing of the instant suit, as "neither [plaintiff] nor its *predecessor in interest* had marked the [patented] products with the patent numbers pursuant to [Section 287(a)]") (emphasis added).

As for Plaintiff's assertion that this result is "inequitable[,]" (D.I. 19 at 17), or that it "would impose upon a purchaser [like Plaintiff] . . . the insurmountable burden of determining" whether a prior patented product sold by a previous patentee had been marked, (*id.* at 18), such

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[6] Although Section 100(d) says that its definition of "patentee" need not apply when "context otherwise indicates[,]" 35 U.S.C. § 100(d), Plaintiff has not sufficiently explained why the "context" of Section 287(a) indicates that the definition set out in Section 100(d) should not apply here.

arguments are not for the Court. With that said, it is not clear to the Court that this result *is* inequitable,[7] or that the burden Plaintiff speaks of really *is* all that "insurmountable."[8] But whether it is, or it is not, the Court is in no position to re-write a statute's text.[9]

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[7] As to the point about equity, the Court finds Defendants' "bundle of rights" rejoinder to be persuasive. At oral argument, Defendants' counsel argued that ALZA would have been unable to convey any greater patent rights than it held to the entity that eventually assigned the rights to Plaintiff (the "intermediate assignee"), and that this intermediate assignee could not in turn have conveyed any greater patent rights than it held to Plaintiff. (Tr. at 30) And because ALZA did not have the right to recover pre-actual notice damages on the formulation patents based on a failure to mark Viadur, it stands to reason that: (1) it could not convey the right to recover such damages to the intermediate assignee, who (2) in turn, could not convey such rights to Plaintiff. (*Id.*) Indeed, Plaintiff's counsel agreed that a patentee cannot sell more patent rights than it owns. (*Id.* at 47) If this is so, then the Court is hard-pressed to see how it would be "equitable" for Plaintiff to obtain greater rights to sue for damages on the asserted patents than those maintained by ALZA or by the intervening assignee. Moreover, it would seem somewhat inequitable— and certainly contrary to the purposes of the marking statute—to allow a patentee to have its failure to mark excused by simply assigning the patent (for a fee) to some other unrelated entity. (*Id.* at 21)

[8] With regard to the point about insurmountability, determining whether a prior owner of a patent ever released a product covered by that patent does not seem all that "insurmountable" (at least under the circumstances at issue here). Instead, it seems like the type of due diligence that Plaintiff could have done before buying the patent rights (i.e., by asking a prior purchaser, or exploring the public record). (*See* Tr. at 64 (Defendants' counsel arguing that "what ALZA did from 2000 to 2008 was certainly something that the Plaintiff in this case could have done due diligence on"))

[9] Plaintiff also makes another argument in its briefing relating to 35 U.S.C. § 286 ("Section 286"), which is the part of the Patent Act that explains that a plaintiff may not recover damages "for any infringement committed more than six years prior to the filing of the complaint[.]" (D.I. 19 at 14-19) Here, the six-year pre-suit damages period runs from 2011 to 2017, and Plaintiff alleges that no products covered by the formulation patents were made or sold by ALZA during that time period. (*Id.* at 14; *see* D.I. 1 at ¶ 21) Plaintiff's point seems to be that even if there was a marking failure by ALZA in the past, so long as no such unmarked products were marketed or sold *in the six-year pre-suit damages window*, Section 287(a)'s proscription on damage recovery should not apply.

Plaintiff's argument is unpersuasive. Plaintiff provides no legal support for the proposition that "Section 287's marking limitation should be commensurate with Section 286's time limitation on damages." (D.I. 19 at 19; *accord* D.I. 21 at 7 ("Plaintiff cites no case law to support th[e] novel proposition[]" that "the marking requirement [should be tied] to the six-year

3. Plaintiff's Request for Discovery on Marking

Lastly, Plaintiff states that even if the Court accepts Defendants' arguments regarding marking, dismissal of the formulation patents is premature. It asks for the ability to take discovery on the marking issues and to amend the operative complaint thereafter. (*Id.* at 20)

The Court recommends, to the contrary, that the claims of infringement of the expired '547 and '261 patents should be dismissed with prejudice. *See Lans v. Digital Equip. Corp.*, 252 F.3d 1320, 1324 (Fed. Cir. 2001) (affirming dismissal of claims of patent infringement where the patent had already expired, and where Section 287(a) prevented the patentee from recovering any damages for infringement during the term of the patent); *Jackson v. Intel Corp.*, No. 09 C 2178, 2009 WL 2851742, at *2 (N.D. Ill. Aug. 31, 2009) (noting that if a patentee cannot state a claim for damages, due to failure to plead compliance with the marking statute, then "he has failed to state a claim for patent infringement"). Plaintiff chose to purchase the formulation patents, and it knows that a former patentee (ALZA) previously made and sold a product (Viadur) that read on these patents. (D.I. 1, ex. D at 13) It, however, apparently filed suit without having gathered sufficient information about the extent to which ALZA marked its product; thus, it could not plead facts in the Complaint asserting that ALZA did so. Thus, it acknowledges that as of today, it is not aware of (and cannot plead) facts needed to state a viable claim for damages as to the formulation patents. (D.I. 19 at 14 (Plaintiff asserting that it "should be allowed the opportunity through discovery" to "establish that Viadur[] was marked")) In such a scenario, there is not a

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limitation on damages[.]")) Second, Plaintiff fails to provide any other reasons why the Court should adopt this novel position. The Court finds it notable that neither Section 286 nor Section 287 directly references the other. Additionally, the plain language of Section 287(a) recites that "[i]n the event of failure so to mark, no damages shall be recovered by the patentee in *any action* for infringement[.]" 35 U.S.C. § 287(a) (emphasis added). No time limitation is presented or referenced.

basis to permit Plaintiff to take discovery in order to try to develop facts that should already be in its possession. *Cf. Cognex Corp. v. Microscan Sys., Inc.*, 990 F. Supp. 2d 408, 417 (S.D.N.Y. 2013).

B. Plausible Allegations of Infringement

Defendants also argue that the claims of direct, indirect, and willful infringement of the asserted patents should be dismissed for failure to plead sufficient facts as to some of the elements of such claims.[10] The Court will address each ground for dismissal below.

1. Direct Infringement

Defendants argue that Plaintiff's allegations of direct infringement of the asserted patents are insufficient because: (1) Plaintiff failed to allege that Defendants' accused product meets the claim limitations of at least some of the asserted patent claims; (2) Plaintiff failed to allege that Defendants actually make, use, sell, or offer to sell the formulation claimed in the '547 and '261 patents or use the methods claimed in the '712 patent; and (3) any allegations of direct infringement based on Defendants' conduct in developing and testing the accused product are protected under the safe harbor provision of 35 U.S.C. § 271(e)(1) ("Section 271(e)(1)"). (D.I. 13 at 13-17) The Court will take up each of these arguments.

a. Matching Claim Limitations to the Accused Product

In order to adequately plead direct (and indirect and willful) infringement, a plaintiff needs to have pleaded facts that plausibly indicate that the accused products contain each of the

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[10] Given the findings regarding marking above, technically the only remaining claims would be those asserting infringement of the '712 patent. However, because this is a Report and Recommendation, and because the parties made plausibility-type arguments regarding all asserted patents, the Court will address all of the asserted patents below in this subsection.

limitations found in the claim. *Microchip Tech., Inc. v. Delphi Auto. Sys., LLC*, Civil Action No. 17-1194-LPS-CJB, 2018 WL 605893, at *2 (D. Del. Jan. 29, 2018); *see also e.Digital Corp. v. iBaby Labs, Inc.*, Case No. 15-cv-05790-JST, 2016 WL 4427209, at *3-4 (N.D. Cal. Aug. 22, 2016); *Raindance Techs., Inc. v. 10x Genomics, Inc.*, Civil Action No. 15-152-RGA, 2016 WL 927143, at *2-3 (D. Del. Mar. 4, 2016).

Plaintiff asserts that Defendants infringe "at least claims 1, 2, 4, and 6 of the '547 patent[,]" "at least claims 3, 4, 23, 26, 32, 33, and 36 of the '261 patent[,]" and "at least claims 1, 2, 4, 8, 9, 10, and 12-16 of the '712 patent[.]" (D.I. 1 at ¶¶ 30, 57, 84) All of those claims recite, at a minimum, "[a] stable non-aqueous formulation of a peptide compound" that is comprised of "at least one [] peptide compound" and "at least one polar aprotic solvent[.]" (*See, e.g.*, '547 patent, col. 13:32-35 (independent claim 1, on which claims 2, 4 and 6 are dependent); '261 patent, cols. 13:66-14:3 (independent claim 3, on which claims 23, 26 and 32 are dependent); *id.*, col. 14:4-7 (independent claim 4, on which claims 33 and 36 are dependent); '712 patent, col. 14:4-9 (independent claim 1, which is a method of preparing the peptide compound/polar aprotic solvent formulation, and on which claims 2, 4 and 16 are dependent); *id.*, col. 14:41-45 & Certificate of Correction (independent claim 8, on which dependent claims 9, 10 and 12-15 are dependent)) Exemplary is claim 1 of the '547 patent, which recites:

> **1.** A stable non-aqueous formulation of a peptide compound comprising:
>
> a) at least one peptide compound; and
>
> b) at least one polar aprotic solvent,
>
> wherein said peptide compound is an LHRH-related compound.

('547 patent, col. 13:32-37)

In its Complaint, Plaintiff alleges that the accused product, Eligard, "contains leuprolide acetate, a luteinizing hormone-release hormone (LH-RH) related compound as its active pharmaceutical treatment." (D.I. 1 at ¶ 23) Plaintiff further alleges that Defendants "prepared stable non-aqueous formulations of leuprolide acetate in polar aprotic solvents by dissolving leuprolide acetate in the solvent *N*-methyl-2-pyrrolidone at least while developing and testing the formulation." (*Id.* at ¶ 24) And Plaintiff also explains that the "prescribing information for Eligard states that it is an injectable suspension of leuprolide acetate containing a polymer and a polar aprotic solvent for subcutaneous administration where the formulation forms a solid drug delivery depot that provides continuous release of leuprolide acetate for up to six months." (*Id.* at ¶ 25)

These allegations plead facts that make it plausible that the accused product is made up of the formulation described in the claims; Defendants do not argue otherwise. However, Defendants assert that Plaintiff has failed to allege that *other* limitations of particular asserted claims are met, and thus, that Plaintiff has failed to sufficiently plead direct infringement of those claims. (D.I. 13 at 13-14) These further limitations include, *inter alia*, that the formulation: (1) does "not contain components containing added water[,]" ('261 patent, col. 14:2-3 (independent claim 3)); (2) "exhibits bacteriostatic, bactericidal[,] or sporicidal activity[,]" (*id.*, col. 14:7-8 (independent claim 4)); (3) "comprises at least about 10% (w/w) peptide compound[,]" ('547 patent, col. 13:38-39 (dependent claim 2); '261 patent, cols. 14:49-50, 15:3-4 (dependent claims 23 and 33); '712 patent, col. 14:11-12 (dependent claim 2)); or (4) "is stable at 37° C[] for at least 3 months[,]" ('547 patent, col. 13:47-48 (dependent claim 6); '261 patent, cols. 14:55-56, 15:9-10 (dependent claims 26 and 36)).

Defendants are correct that Plaintiff has not pleaded facts relating to these claim limitations, sufficient to explain why it is plausible that Defendants' product/acts satisfy those elements of the claims. Nor is this a case where the Court can otherwise figure out on its own why it is that the accused product, or methods of using it, necessarily implicates those limitations. *Cf. Disc Disease Sols. Inc. v. VGH Sols., Inc.*, 888 F.3d 1256, 1260 (Fed. Cir. 2018) (finding that the plaintiff had provided fair notice of infringement to the defendant, where (1) the case involved "a simple technology"; (2) the asserted patents were attached to the complaint; (3) the complaint specifically identified the accused products, and attached photos of the products as exhibits; and (4) the complaint alleged that the accused products "meet each and every element of at least one claim of [the plaintiff's patents]"). Plaintiff must have had its reasons for thinking that Defendants practiced these limitations of claims 3, 4, 22, 26, 33 and 36 of the '261 patent, claims 2 and 6 of the '547 patent, and claim 2 of the '712 patent. It should have just pleaded whatever facts it had relating to those reasons.

Thus, the Court recommends that Defendants' Motion be granted as to the direct infringement allegations regarding these claims, and that Plaintiff be given the opportunity to amend its Complaint to plead the above-referenced facts (to the extent Plaintiff's claims of infringement are not otherwise dismissed due to the marking issue).

b. Making, Using, or Selling the Claimed Formulation (or Using the Claimed Method) and the Safe Harbor

Defendants additionally argue that all of Plaintiff's direct infringement claims should be dismissed because Plaintiff failed to allege any facts that show that *Defendants themselves* make, use, sell or offer to sell the formulation claimed in the '547 and '261 patents, or use the methods claimed in the '712 patent. (D.I. 13 at 14) In this regard, they argue that the accused product, "as

sold, contains two separate syringes—one syringe filled with the Atrigel delivery system that includes a polymer dissolved in a biocompatible solvent, and another syringe that includes only leuprolide acetate"—and that only when the two syringes are later mixed by a medical professional is the accused formulation created. (*Id.* at 14-15; *see* D.I. 1, ex. E (Eligard prescribing information depicting two syringes that need to be mixed prior to administering)) Similarly, for the methods claimed in the '712 patent, Defendants assert that there are no allegations that *they* "perform[ed] a method which includes dissolving the peptide compound in a polar aprotic solvent" (claim 1) or that *Defendants* administered the allegedly infringing formulation (claim 8). (D.I. 13 at 15-16)

Plaintiff does not dispute that the accused product "as sold" does not directly infringe. Rather, it asserts in the Complaint that Defendants directly infringed the asserted claims "at least while developing and testing the [accused product]." (D.I. 1 at ¶ 24)

To this, Defendants counter that any direct infringement that occurred during "developing and testing" the accused product is protected by the safe harbor provision of Section 271(e)(1). (D.I. 13 at 13, 16-17) Section 271(e)(1) provides that:

> It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

35 U.S.C. § 271(e)(1). Section 271(e)(1)'s language is "'sufficiently broad' to 'leave[] adequate space for experimentation and failure on the road to regulatory approval.'" *Momenta Pharms., Inc. v. Teva Pharms. USA Inc.*, 809 F.3d 610, 619 (Fed. Cir. 2015) (citation omitted). Yet "some activities are outside [of] its protection[, such as] . . . information that may be routinely reported

to the FDA, long after marketing approval has been obtained." *Id.* (internal quotation marks and citation omitted). The Federal Circuit has also explained that "[t]he routine quality control testing of each batch [of an accused product] as part of the post-approval, commercial production process is [] not reasonably related to the development and submission of information to the FDA[.]" *Id.* at 620 (internal quotation marks omitted).

Plaintiff's argument here is that the Complaint's reference to Defendants' "developing and testing" the accused products is "not limited to uses reasonably related to seeking FDA approval." (D.I. 19 at 10 (internal quotation marks omitted)) "Rather, the allegations in the Complaint include *all* testing that [Defendants] performed, including testing that was not related to FDA approval but rather was related to 'commercial manufacture' or quality control tests not required for seeking FDA approval." (*Id.* (citing D.I. 1 at ¶ 24) (emphasis in original))

The Court is persuaded by Plaintiff's argument. At this Rule 12(b)(6) stage, the Court must credit all well-pleaded factual allegations in Plaintiff's favor. As such, the Court cannot rely on statements in Defendants' briefs that seek to contradict Plaintiff's allegations—like Defendants' statement that all of their "alleged activities during the research, development, and testing of its FDA-approved drug, Eligard . . . was for the purpose of obtaining data for submission of th[e] NDAs to the FDA." (D.I. 13 at 17) And it does seem plausible, for example, that the "testing" called out in the Complaint could have and did include post-approval quality control tests that were unrelated to an FDA submission. As such, the Court finds that Plaintiff has sufficiently alleged that Defendants directly infringed the asserted patents via their development and testing of the accused product.

2. Indirect and Willful Infringement

Defendants next assert that Plaintiff has failed to adequately plead indirect and willful infringement of the asserted patents because Plaintiff did not plausibly allege that Defendants had knowledge of the patents prior to the alleged period of infringement. (D.I. 13 at 8-12; D.I. 21 at 9-10)[11] Indirect infringement (that is, induced infringement and contributory infringement) both "require, *inter alia*, 'knowledge of the existence of the patent that is [allegedly] infringed' as well as 'knowledge that the acts [at issue] constitute patent infringement.'" *Princeton Dig. Image Corp. v. Ubisoft Entm't SA*, Civil Action No. 13-335-LPS-CJB, 2016 WL 6594076, at *4 (D. Del. Nov. 4, 2016) (alteration in original) (quoting *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 765-66 (2011)).[12] Likewise, a plausibly pleaded claim for willful infringement requires, *inter alia*, knowledge of the patent or patents at issue. *See Valinge Innovation AB v.*

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[11] Defendants also argue that Plaintiff's indirect infringement/willful infringement claims should fail because the accused product is not matched to the limitations of certain asserted claims. (D.I. 13 at 13) For the reasons discussed above with regard to this argument and direct infringement, the Court finds that the Motion should be granted as to the indirect infringement/willful infringement allegations regarding claims 3, 4, 22, 26, 33 and 36 of the '261 patent, claims 2 and 6 of the '547 patent, and claim 2 of the '712 patent. It also recommends that Plaintiff be given the same opportunity to amend these claims as was discussed above regarding the direct infringement allegations.

[12] Defendants further argue that the Complaint "does not contain any specific allegations related to a claim of contributory infringement[.]" (D.I. 13 at 8-9 n.5 (citation omitted)) However, this entire argument was contained in a few short lines found exclusively in a footnote and was not further taken up by Defendants. Therefore, the Court declines to consider it. *See GlaxoSmithKline LLC v. Glenmark Pharms. Inc., USA*, Civil Action No. 14-877-LPS-CJB, Civil Action No. 14-878-LPS-CJB, 2017 WL 8948972, at *8 n.5 (D. Del. May 24, 2017); *see also SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1320 (Fed. Cir. 2006) ("Further, arguments raised in footnotes are not preserved."); *UCB, Inc. v. Accord Healthcare, Inc.*, 201 F. Supp. 3d 491, 542 n.33 (D. Del. 2016) ("Arguments that are presented in limited form in footnotes are entitled to little weight."), *aff'd,* 890 F.3d 1313 (Fed. Cir. 2018).

Halstead New England Corp., Civil Action No. 16-1082-LPS-CJB, 2018 WL 2411218, at *13 (D. Del. May 29, 2018).

In the Complaint, Plaintiff alleges that Defendants knew of or were willfully blind to the asserted patents because: (1) on May 20, 2010, Defendants submitted the previously-referenced IDS as part of the application that led to their '455 patent, in which Defendants made reference to the December 2009 Orange Book listing for "Leuproli[d]e Acetate" and for "Lupron Depot Exclusivity"; (2) the asserted patents "were discernibly listed in the [December 2009 version of the] Orange Book in association with leuprolide acetate" under the drug product Viadur; such that (3) Defendants must have known about the asserted patents as of May 2010. (D.I. 19 at 2-3 (citing D.I. 1 at ¶ 26 & ex. D)) Plaintiff includes, as an exhibit, certain sections of the December 2009 Orange Book that concern the active ingredient leuprolide acetate. (D.I. 1, ex. D)[13] One of the sections in that exhibit is titled "PRESCRIPTION AND OTC DRUG PRODUCT PATENT AND EXCLUSIVITY LIST[.]" (*Id.*, ex. D at 11-13) In that section, there are three branded drug names that include the active ingredient leuprolide acetate: Eligard (the accused product here), Lupron Depot (various formulations), and Viadur. (*Id.*) The three asserted patents are listed alongside Viadur (and not with the other drug products) in this portion of the Orange Book. (*Id.* at 13)

Defendants argue that in submitting the IDS and in referencing the leuprolide acetate listing therein, they were actually calling out information relating to Lupron Depot-PED®, "an

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[13] In paragraph 26 of the Complaint, where Plaintiff makes the relevant allegations here, it cites to the "December 2009" edition of the Orange Book. (D.I. 1 at ¶ 26) However, the exhibit that Plaintiff attached to its Complaint purporting to represent the relevant portion of the December 2009 Orange Book is actually from the 2010 version of the Orange Book. (*Id.*, ex. D) It seems plausible, however, that this same listing of patents and products found in the 2010 version of the Orange Book was also found in the Orange Book in December 2009. (Tr. at 77)

entirely different leuprolide acetate product which has no connection to Viadur or the [a]sserted [p]atents." (D.I. 13 at 9)[14] Defendants argue that Plaintiff's theory—i.e., "that because [Defendants] knew of the Orange Book listing for Abbot Labs' leuprolide acetate product (Lupron Depot-PED), [Defendants] must have known of an entirely different product—Viadur—and also must have been aware that the Orange Book listing for Viadur [also] referenced the [a]sserted [p]atents"—is faulty. (*Id.*; *see also* D.I. 21 at 9-10)

The Court disagrees and finds that Plaintiff has sufficiently pleaded Defendants' knowledge of the asserted patents, as of the May 20, 2010 date on which Defendants allegedly submitted the IDS form. After all, there were only three drugs listed in the December 2009 Orange Book that contained the ingredient leuprolide acetate. Of those, we know that Defendants knew of the drug Eligard (and the patents associated with that drug found in the December 2009 version of the Orange Book), since Eligard was their drug. And we know that Defendants knew of another drug, Lupron Depot (and the patents associated with that drug in the same version of the Orange Book), since Defendants made reference in the IDS to Lupron

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[14] Defendants submitted a declaration along with their opening brief that purports to attach the actual Orange Book documents that were being referenced in the IDS; those documents are different than the Orange Book excerpt that Plaintiff attached to its Complaint, and they do not specifically reference Viadur. (D.I. 13 at 9; D.I. 14, ex. 1; D.I. 21 at 1; Tr. at 69-70, 72-73) There is a dispute between the parties as to whether the Court should consider the documents attached to Defendants' declaration. (D.I. 13 at 5 n.4; D.I. 19 at 4-5; D.I. 21 at 9-10) Yet even if the Court were to take these documents into account, the outcome would not change here. As is further set out below, Plaintiff's allegations and exhibits show that there were only three relevant, marketed drugs that contained leuprolide acetate as of 2010, and no one disputes that in the Orange Book at that time, the asserted patents were listed and associated with one of those three drug products (Viadur). For the reasons set out below, it is plausible that, regardless of the actual portion of the December 2009 Orange Book that Defendants were pointing to in the IDS, Defendants then knew about the patents that were associated with Viadur in that same edition of the Orange Book.

Depot-PED. (Tr. at 78) It seems thus plausible that Defendants would additionally have had knowledge of the third and final drug, Viadur, listed in that Orange Book (and, relatedly, the patents listed alongside Viadur, including the asserted patents). (*See* D.I. 19 at 2-3; Tr. at 79-80; *see also* D.I. 19 at 4 ("It strains credulity that [Defendants] could know about all leuprolide acetate patents in the December 2009 Orange Book except the [a]sserted [p]atents, particularly where they all relate to the same drug, and the [a]sserted [p]atents are listed on the very page that follows the patent lists for Lupron Depot[].")

Now, it could be that Defendants will later be able to prove that they were not then aware of Viadur and the asserted patents. (Tr. at 78-79 (Defendants' counsel suggesting that Defendants did not know of the Viadur product or the patents associated therewith in 2010, because Viadur was a "totally different" product than Eligard and Lupron Depot)) But plausibility is all that is required at the pleading stage, and that has been demonstrated here. For these reasons, the Court finds that Plaintiff sufficiently alleged knowledge of the asserted patents.[15]

IV. CONCLUSION

The Court recommends that Defendants' Motion be GRANTED with prejudice to the

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[15] Defendants also separately argue that claims for indirect infringement against Defendant TOLMAR Pharmaceuticals, Inc. should be dismissed. (D.I. 13 at 10 n.7) Defendants note that the allegation in the Complaint is that each of the three Defendants knew or were willfully blind to the asserted patents "since at least May 2010[,]" (D.I. 1 at ¶ 26); they argue that this cannot be reconciled with the fact that TOLMAR Pharmaceuticals, Inc. was incorporated on January 27, 2014. (*Id.* (citing D.I. 1 at ¶ 12)) This argument too was made only in a footnote and not addressed thereafter, and so the Court will not consider it further here. *See supra* n. 12. If it is true that TOLMAR Pharmaceuticals, Inc. was not in existence until January 27, 2014, then (absent some further argument) Plaintiff will not be able to prove this Defendant's liability for indirect/willful infringement damages until on or after that date.

extent that it seeks to dismiss Counts I-VI (infringement of the asserted claims of the '547 and '261 patents) for failure to comply with the marking statute. It recommends that the Motion also be GRANTED without prejudice (to the extent necessary, depending on the District Court's decision on the marking issue) as it relates to infringement allegations regarding claim 3, 4, 22, 26, 33 and 36 of the '261 patent, claims 2 and 6 of the '547 patent, and claim 2 of the '712 patent. It recommends that the Motion be DENIED on all other grounds.

Dated: November 1, 2018

Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE