IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GALDERMA LABORATORIES, L.P. and GALDERMA S.A.,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 18-1892-CFC-CJB
MEDINTER US, LLC, MEDINTER LTD., ANTECO PHARMA, LLC, ATTWIL VASCULAR TECHNOLOGIES LP, ATTWILL MEDICAL SOLUTIONS, INC., DERMAVANCE PHARMACEUTICALS, INC. and MEDGRAFT MICROTECH, INC.,	)	
Defendants.	)	

Jack B. Blumenfeld and Michael J. Flynn, MORRIS, NICHOLS, ARSHT & TUNNELL LLP, Wilmington, DE; Joseph A. Mahoney, MAYER BROWN LLP, Charlotte, NC; and B. Clayton McCraw and Ying-Zi Yang, MAYER BROWN LLP, New York, NY, Attorneys for Plaintiffs.

Melanie K. Sharp, James L. Higgins and Michelle M. Ovanesian, YOUNG CONAWAY STARGATT & TAYLOR, LLP, Wilmington, DE; Steven Lieberman, Rachel M. Echols, Daniel R. McCallum and Nicole M. DeAbrantes, ROTHWELL, FIGG, ERNST & MANBECK, P.C., Washington, DC, Attorneys for Defendant DermAvance Pharmaceuticals, Inc.

MEMORANDUM OPINION

February 14, 2020
Wilmington, Delaware

Christopher J. Burke

BURKE, United States Magistrate Judge

In this patent infringement action filed by Plaintiffs Galderma Laboratories, L.P. and Galderma, S.A. (collectively "Galderma" or "Plaintiffs") against Defendants Medinter US LLC and Medinter Ltd. (collectively "Medinter"), Anteco Pharma LLC, Attwill Medical Solutions, Inc., Attwill Vascular Technologies LP, DermAvance Pharmaceuticals, Inc. ("DermAvance") and Medgraft Microtech, Inc., presently before the Court is Defendant DermAvance's motion to dismiss for lack of subject matter jurisdiction and failure to state a claim, filed pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6) ("Motion"). (D.I. 40) For the reasons that follow, the Court orders that this Motion be GRANTED-IN-PART and DENIED-IN-PART.

I. BACKGROUND

A. Procedural Background

Plaintiffs filed their initial Complaint on November 29, 2018 against six of the seven current Defendants, including DermAvance; the Complaint alleged infringement of the two patents-in-suit: United States Patent Nos. 6,716,251 and 7,731,758 (collectively, the "patents-in-suit"). (D.I. 1) On February 19, 2019, DermAvance filed a motion to dismiss the claims against it pursuant to Rules 12(b)(1) and Rule 12(b)(6). (D.I. 20) Thereafter, on March 5, 2019, Plaintiffs filed the operative First Amended Complaint ("FAC") against all seven current Defendants, again alleging infringement of the two patents-in-suit. (D.I. 33) DermAvance then filed the instant Motion on March 19, 2019. (D.I. 40) Briefing on the Motion was completed on April 30, 2019. (D.I. 68)

On July 30, 2019, United States District Judge Colm F. Connolly referred this case to the Court to hear and resolve all pretrial matters, up to and including expert discovery matters. (D.I.

78) Then on September 13, 2019, all parties in the case consented to the Court's jurisdiction to resolve the instant Motion, as well as two other motions that were then pending. (D.I. 85)

B. Factual Background

The patents-in-suit are directed to bioresorbable injectable implants for human administration and reconstitutable products (which, upon the addition of water, become such implant products). (D.I. 33 at ¶¶ 24-25, 30-31 & exs. A-B; D.I. 41 at 5) In the FAC, Plaintiffs allege that the various Defendants (including DermAvance) infringe the patents-in-suit, in that Plaintiffs generally allege that Defendants manufacture, use, offer for sale and sell in the United States DERMA VEIL CUTANEOUS BIO-STIMULANT ("DERMA VEIL"), and that Defendants export from the United States that product. (*See generally* D.I. 33)

Medinter manufactures DERMA VEIL in the United States and then distributes the product internationally, (*id.* at ¶ 45); DERMA VEIL has been sold internationally since 2014, (*id.* at ¶ 63). The product has not yet been sold in the United States, but Plaintiffs allege that DermAvance "is actively seeking U.S. FDA [United States Food and Drug Administration, or "FDA"] approval for DERMA VEIL by having initiated a clinical trial on December 8, 2014." (*Id.* at ¶ 67) DermAvance and Medinter have entered into an agreement by which, if FDA approval is obtained, DermAvance will sell the DERMA VEIL product in the United States. (*Id.* at ¶¶ 49-50)

To the extent that other factual allegations are relevant to the resolution of this Motion, the Court will address them below in Section III.

II. STANDARD OF REVIEW

The only actionable portions of the Motion raise grounds for dismissal pursuant to Federal Rule of Civil Procedure 12(b)(6).[1] When presented with a Rule 12(b)(6) motion to dismiss for failure to state a claim, a court conducts a two-part analysis. *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009). 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. *Id.* at 210-11. 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 *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678 (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007)). In assessing the plausibility of a claim, the court must "'accept all factual allegations as true, 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

DermAvance argues that, pursuant to Rule 12(b)(6), the allegations against it in the FAC must be dismissed, to the extent that Plaintiffs allege that it: (1) directly infringes the patents-in-

[1] DermAvance had also noted that in the "Jurisdiction and Venue" section of the FAC, Plaintiffs stated that they "will also seek a declaratory judgment pursuant to 28 U.S.C. §§ 2201-2202 that Defendants' future manufacture, use, offer for sale, sale in the U.S., or importation into the U.S. of DERMA VEIL" is infringing, (D.I. 33 at ¶ 11); to the extent such an assertion amounted to a "declaratory judgment claim[,]" DermAvance sought to dismiss that claim for lack of subject matter jurisdiction, pursuant to Rule 12(b)(1), (D.I. 41 at 10). Plaintiffs, however, confirmed that they are not presently asserting such a declaratory judgment claim. (D.I. 65 at 20) Thus, in this regard, DermAvance's Motion is DENIED as MOOT.

suit; or (2) induces infringement of the patents-in-suit. The Court will address these arguments in turn below.

A. Direct Infringement

DermAvance first argues that to the extent that the FAC alleges that it has directly infringed the patents-in-suit, those allegations must fail, because any U.S.-based infringing use of the inventions by DermAvance was statutorily protected by the safe harbor provision of 35 U.S.C. § 271(e)(1) ("Section 271(e)(1)"). (D.I. 41 at 8-10)[2] Section 271(e)(1) reads as follows:

> 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); *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 202 (2005) (noting that clinical trials for FDA approval fall within Section 271(e)(1)'s protection); *Abtox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1029 (Fed. Cir. 1997) (explaining that Section 271(e)(1) applies to all classes of medical devices). Here, DermAvance argues that Plaintiffs do "not allege (because [they] cannot) that DermAvance is 'using' DERMA VEIL for any other reason than as part of FDA-mandated clinical trials" (i.e., the trials referred to above in Section I). (D.I. 41 at 9)

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[2] Thus, in making this argument, DermAvance is invoking an affirmative defense. *See Classen Immunotherapies Inc. v. Somaxon Pharms.*, No. CV 12-06643-GAF-PLA, 2013 WL 9947386, at *2 n.1 (C.D. Cal. Apr. 11, 2013) (noting that Section 271(e)(1) is considered an affirmative defense to patent infringement); *Amgen, Inc. v. F. Hoffman-LaRoche Ltd.*, 456 F. Supp. 2d 267, 273 (D. Mass. 2006) (same). The Court may dismiss a claim pursuant to a Rule 12(b)(6) motion in light of an affirmative defense, but only where the well-pleaded factual allegations in the complaint, construed in the light most favorable to the plaintiff, suffice to establish the defense. *See Jones v. Bock*, 549 U.S. 199, 215 (2007); *Kabbaj v. Google, Inc.*, Civ. No. 13-1522-RGA, 2014 WL 1369864, at *2 n.2 (D. Del. Apr. 7, 2014).

In response, Plaintiffs assert that although the FAC does allege that DermAvance is "involved in a U.S. clinical trial for FDA approval[,]" the allegations in four paragraphs of the FAC (paragraphs 22, 50, 51 and 69) articulate how it is plausible that DermAvance is nevertheless using DERMA VEIL for purposes unrelated to the conduct of these clinical trials (such that Section 271(e)(1) would not protect such infringing acts). (D.I. 65 at 17)[3] However, having reviewed these paragraphs, the Court cannot conclude that in them, Plaintiffs press viable claims of direct infringement against DermAvance. More specifically:

- With regard to paragraph 22, here, all that is alleged is that DermAvance "uses U.S. clinical trials and research data to market and sell U.S. manufactured DERMA VEIL in foreign countries." (D.I. 33 at ¶ 22) Although Plaintiffs argue that the allegation that "DermAvance uses DERMA VEIL for 'research data' unrelated to data collected for the clinical trial, in connection with its foreign promotional activities of DERMA VEIL" is sufficient, (D.I. 65 at 17), such conduct does not fall outside of Section 271(e)(1)'s safe harbor. In *Abtox, Inc. v. Exitron Corp.*, 122 F.3d 1019 (Fed. Cir. 1997), the United States Court of Appeals for the Federal Circuit explained that so long as the otherwise infringing act (here, DermAvance's use of the product during the clinical trials) is itself performed solely for uses reasonably related to FDA approval, then DermAvance is permitted under Section 271(e)(1) to "use its data from the tests for more than FDA approval." 122 F.3d at 1030; *see also Classen Immunotherapies Inc. v. Elan Pharms., Inc.*, 786 F.3d 892, 898 (Fed. Cir. 2015) ("[S]ubsequent disclosure or use of *information* obtained from an exempt clinical study, even for purposes other than regulatory approval, does not repeal that exemption of the clinical study, provided that the subsequent disclosure or use is itself not an *act of infringement* of the asserted claims.") (emphasis in original).

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[3] Prior to reading the briefing, the Court would not actually have thought that Plaintiffs even intended to allege that DermAvance directly infringes the patents-in-suit. This is because in the two infringement counts in the FAC, Plaintiffs call out DermAvance by name only in paragraphs in which Plaintiffs allege induced infringement. (D.I. 33 at ¶¶ 76, 85) Conversely, in the paragraphs in the counts where Plaintiffs most clearly set out the direct infringement allegations, Plaintiffs call out five Defendants by name, but none of those are DermAvance. (*Id.* at ¶¶ 73, 81; *see also* D.I. 68 at 2)

- With regard to paragraph 50, Plaintiffs note that therein, they allege that DermAvance agrees "to conduct[] workshops regularly to instruct Customers on the proper preparation, application, and use object of DERMA VEIL[,]" (D.I. 33 at ¶ 50 (internal quotation marks and citation omitted), and argue that such activities "plausibly involve using DERMA VEIL outside of clinical trial purposes[,]" (D.I. 65 at 17). But paragraph 50, as DermAvance notes, (D.I. 68 at 3), suggests that the conduct being referred to here is that which took place as part of "DermAvance's marketing and advertising . . . in Asia[,]" (D.I. 33 at ¶ 50), and that could not amount to U.S.-based infringement activity.

- With regard to paragraph 51, Plaintiffs there allege only that pursuant to the agreement between Medinter and DermAvance, DermAvance has agreed to "furnish[] information to Medinter concerning [c]ustomers' requirements and other matters" that may enhance the product's later sales in the United States. (D.I. 33 at ¶ 51) The furnishing of "information," of course, is not itself infringing activity. And to the extent that Plaintiffs are suggesting that this allegation plausibly suggests infringing *use of the product at issue* in the United States, (D.I. 65 at 17), the Court disagrees. No such facts are suggested or stated in the paragraph.

- As to paragraph 69, there Plaintiffs allege that Medinter manufactures an amount of DERMA VEIL in the United States that "significantly exceeds the amount required for the conduct of the U.S. clinical trial to support FDA approval." (D.I. 33 at ¶ 69) As DermAvance notes, however, (D.I. 68 at 3), this paragraph only references actions allegedly taken by *Medinter*. Contrary to Plaintiffs' argument, the paragraph does not plausibly suggest that "*DermAvance* [is] otherwise stockpiling DERMA VEIL for reasons unrelated to the clinical trial." (D.I. 65 at 17 (emphasis added)) If Plaintiffs had possession of facts indicating that DermAvance was taking such actions, they would presumably have pleaded them.

For these reasons, the Court grants DermAvance's Motion as it relates to claims of direct infringement.

B. Induced Infringement

DermAvance also challenges Plaintiffs' induced infringement allegations. Although the FAC's infringement counts assert that DermAvance "actively and knowingly encouraged"

Medinter to manufacture DERMA VEIL in the United States "for international commercial sale and distribution[,]" (D.I. 33 at ¶¶ 76, 85), DermAvance asserts that there are "no plausible facts" pleaded to support the idea that it "encouraged Medinter to make DERMA VEIL for export abroad[,]" (D.I. 41 at 15). Here, the Court disagrees with the movant.

Pursuant to 35 U.S.C. § 271(b) ("Section 271(b)"), "[w]hoever actively induces infringement of a patent shall be liable as an infringer." In order to prove induced infringement, the patentee "must show direct infringement, and that the alleged infringer knowingly induced infringement and possessed specific intent to encourage another's infringement." *Toshiba Corp. v. Imation Corp.*, 681 F.3d 1358, 1363 (Fed. Cir. 2012) (internal quotation marks and citations omitted); *Symantec Corp. v. Comput. Assocs. Int'l, Inc.*, 522 F.3d 1279, 1292-93 (Fed. Cir. 2008) ("Thus, 'inducement requires evidence of culpable conduct, *directed to encouraging* another's infringement, not merely that the inducer had knowledge of the direct infringer's activities.'") (emphasis added) (citation omitted).

Here, contrary to DermAvance's arguments, there are facts pleaded in the FAC that plausibly suggest that DermAvance was inducing infringement. Inducement, after all, is a fairly wide-ranging term. A person induces infringement under Section 271(b) simply by "actively and knowingly aiding and abetting another's direct infringement." *C.R. Bard, Inc. v. Advanced Cardiovascular Sys., Inc.*, 911 F.2d 670, 675 (Fed. Cir. 1990); *see also Hockerson-Halberstadt, Inc. v. JSP Footwear, Inc.*, 104 F. App'x 721, 724 (Fed. Cir. 2004). While an affirmative act of some kind, knowingly taken, is required to make out a claim of inducement, one can be guilty of inducement if one engages in any one of a "broad . . . range of actions" by which one "in fact causes, or urges, or encourages, or aids another to infringe a patent." *Tegal Corp. v. Tokyo Electron Co., Ltd.*, 248 F.3d 1376, 1378-79 (Fed. Cir. 2001).

In the FAC, Plaintiffs note that DermAvance and Medinter (the U.S.-based manufacturer of DERMA VEIL) already have a working relationship—that is, they have a written agreement to work together to try to sell DERMA VEIL in the United States (pending FDA approval of the product). (D.I. 33 at ¶ 49 & ex. J) And Plaintiffs go on to explain why it is that DermAvance and its founder, President and Chief Executive, Keith Greathouse, would be financially motivated to encourage Medinter to manufacture more of the product for distribution internationally. There, they plead that DermAvance would be incentivized to do so because maximizing the "international sale and distribution of DERMA VEIL so that it receives international recognition and success" will—if and when DERMA VEIL eventually receives FDA approval in the United States—enable DermAvance to "benefit from increased U.S. sales" and "potentially maximize profits" in the United States. (*Id.* at ¶¶ 59-60) Plaintiffs also plead that Mr. Greathouse "has been promoting the sale of DERMA VEIL in Asia, including Hong Kong and Taiwan, since at least 2014" and "actively travels internationally to advertise and promote" DERMA VEIL. (*Id.* at ¶¶ 56-58 & exs. K-L) And, with all of that as backdrop, Plaintiffs go on to allege that Mr. Greathouse or other DermAvance employees have "encouraged Medinter [], through non-public written or verbal communications, to increase its United States manufacture of infringing DERMA VEIL for international distribution to boost the global recognition of DERMA VEIL[.]" (*Id.* at ¶ 60) It does thus seem plausible that Mr. Greathouse (who we know has already been advocating for enhanced DERMA VEIL usage internationally, and who, along with DermAvance, has a future financial incentive to do so) and DermAvance employees working with him would have actually engaged in this type of encouragement. *Cf. Trs. of Columbia Univ. v. Roche Diagnostics GmbH*, 272 F. Supp. 2d 90, 106 (D. Del. 2002) ("As long as [the alleged induced infringer] encouraged [the alleged direct

infringer] to take actions that it knew or should have known would infringe the [patents-in-suit] with the requisite specific intent, [the alleged induced infringer] is liable under Section 271(b).")

It is true, as DermAvance notes, that Plaintiffs' articulation of their inducement allegations requires the Court to take a few different logical steps. (D.I. 68 at 5-10) But in the Court's view (for the reasons set out above), the inferences necessary to each of those steps are reasonable inferences. For that reason, the Court orders that DermAvance's Motion is denied to the extent it relates to the allegations of indirect infringement.

IV. CONCLUSION

For the reasons set out above, the Court orders that the Motion is GRANTED-IN-PART and DENIED-IN-PART. More specifically, the Motion is GRANTED as to Plaintiffs' allegations of direct infringement against DermAvance and DENIED as to Plaintiffs' allegations of indirect infringement against DermAvance. It is DENIED as MOOT with regard to DermAvance's arguments regarding Rule 12(b)(1). An appropriate Order will issue.

Because this Memorandum Opinion may contain confidential information, it has been released under seal, pending review by the parties to allow them to submit a single, jointly-proposed, redacted version (if necessary) of the Memorandum Opinion. Any such redacted version shall be submitted no later than **February 20, 2020**, for review by the Court, along with a motion for redaction that includes a clear, factually detailed explanation as to why disclosure of any proposed redacted material would "work a clearly defined and serious injury to the party seeking closure." *Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 786 (3d Cir. 1994) (internal quotation marks and citation omitted). The Court will subsequently issue a publicly-available version of its Memorandum Opinion.