IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

KYOWA HAKKA BIO, CO., LTD, BIOKYOWA, INC., KYOWA HAKKA BIO U.S. HOLDINGS, INC., and KYOWA HAKKO U.S.A., INC.,	:	
Plaintiffs,	:	**CIVIL ACTION**
v.	:	**NO. 17-313**
AJINOMOTO CO., INC., AJINOMOTO ANIMAL NUTRITION GROUP, INC., AJINOMOTO NORTH AMERICA, INC. AJINOMOTO HEARTLAND, INC. and AJINOMOTO WINDSOR, INC.,	:	
Defendants.	:	

Goldberg, J. **February 12, 2018**

MEMORANDUM OPINION

Plaintiffs Kyowa Hakko Bio Co., Ltd, BioKyowa, Inc., Kyowa Hakko Bio U.S. Holdings, Inc., and Kyowa Hakko U.S.A., Inc. (collectively, "Plaintiffs") allege infringement of their U.S. Patent No. RE 45,723, entitled "Process for Producing Amino Acids" by Defendants Ajinomoto Co., Inc., Ajinomoto Animal Nutrition Group, Inc., Ajinomoto North America, Inc., Ajinomoto Heartland, Inc., and Ajinomoto Windsor, Inc. (collectively, "Defendants"). Presently before me is Defendants' Motion to Dismiss the Complaint. For the following reasons, the Motion will be denied.

I. FACTUAL ALLEGATIONS IN THE COMPLAINT

A. The Parties

Plaintiffs Kyowa Hakko Bio, Co., Ltd. ("KHB") and BioKyowa ("BioKyowa") are biochemical companies that provide amino acids and other high value-added functional materials

for inclusion in pharmaceutical, medical treatment, healthcare, dietary supplement, and cosmetic products. Plaintiff Kyowa Hakko U.S.A., Inc. ("KHU") markets and sells the products of KHB and BioKyowa in the United States. BioKyowa and KHU are wholly owned subsidiaries of Plaintiff Kyowa Hakko Bio U.S. Holdings, Inc. ("KHH"). In turn, KHH is a wholly owned subsidiary of KHB. (Id. ¶¶ 8, 9, 11.)

Defendant Ajinomoto Heartland, Inc. ("AH") principally imports, manufactures, and sells animal nutrition products under the general direction of Defendants Ajinomoto Co., Ltd. ("AJ") and Ajinomoto Animal Nutrition Group, Inc. ("AANG"). Defendant Ajinomoto North America, Inc. ("ANA") is a wholly owned subsidiary of AJ and principally imports, manufactures, and sells cosmetic, human food, human nutritional, or pharmaceutical product applications under the general direction and control of AJ. Defendant Anjinomoto Windsor, Inc. ("AW") principally imports, manufactures, and sells food products. Defendants are all members of the Ajinomoto Group and are controlled and managed by AJ. (Id. ¶¶ 16–27.)

B. The Patent-In-Suit

The patent-in-suit, U.S. Patent No. RE 45,723 (the "'723 patent") was issued by the United States Patent and Trademark Office on October 6, 2015. Plaintiff Kyowa Hakka Bio Co., Ltd. ("KHB") is the owner, by valid assignment of the entire right, title, and interest in and to the '723 patent. KHB has authorized BioKwoya, Inc. ("BioKwoya") and KHU to use the inventions claimed in the '723 patent. (Id. ¶¶ 42–43, 46–47.)

Claim one of the '723 patent (as amended during reissue proceedings) sets forth a process for making amino acids, as follows:

> 1. A process for producing an amino acid, which comprises:
> [a] culturing a microorganism having an ability to produce the amino acid in a medium,

> [b] adding crystals of the amino acid having an average particle size of 7 to 50 μm to the medium at some time after the amino acid concentration in the medium reaches the saturation solubility and before crystals of the amino acid deposit in the medium so that the concentration of the crystals of the amino acid becomes 0.5 g/l or more,
> [c] culturing the microorganism having the ability to produce the amino acid in the medium,
> [d] allowing the crystals of the amino acid to grow to crystals of the amino acid having an average particle size of 30 μm or more and accumulate in the medium, and
> [e] recovering the crystals of the amino acid from the culture by separating the microorganism producing the amino acid and the accumulated crystals of the amino acid based on the difference in particle size or specific gravity between them.

(Id. ¶ 48.)

Claim 2 is the same as claim 1 except that, in claim 1, the "adding crystals" step [b] concludes "so that the concentration of the crystals of the amino acid becomes 0.5 g/l or more," while, in claim 2, the "adding crystals" step [b] concludes "so that the total surface area of the crystals of the amino acid in the medium becomes 0.02 m2/1 or more." (Id. ¶ 49.) Steps [b] - [e] of Claims 1 and 2 define a particular type of Direct Crystal Precipitation ("DCP") process. (Id. ¶ 50.)

C. Infringement Allegations and Procedural History

Plaintiffs filed their patent infringement suit on March 23, 2017. The Amended Complaint alleges that Defendants, acting as a single business enterprise, are liable for various acts of infringement through the sale of the "Accused Products," which are defined as

> the amino acids L-glutamine, L-glutamic acid, L-tryptophan, and L-valine, and monosodium glutamate (which is a sodium salt of L-glutamic acid) and other products incorporating one of those amino acids, which (a) were offered for sale, sold, made or used in the United States by one or more of the Defendants or entities under the control of a Defendant, and (b) . . . were made using a method as claimed or in equivalent to any of claims 1, 2, 7, and 8 of the '723 patent, either in the United States, or outside the United States and imported into the United States.

(Id. ¶ 2.) The Amended Complaint sets forth claims of direct infringement, vicarious infringement, inducement of infringement, and infringement by importing or selling the Accused Product into the United States. (Id. ¶¶ 64–67.)

Defendants moved to dismiss the Amended Complaint on August 21, 2017. Plaintiffs filed a response on September 5, 2017, Defendants submitted a reply brief on October 11, 2017, and Plaintiffs filed a notice of subsequent authority on October 31, 2017.

II. STANDARD OF REVIEW

Under Federal Rule of Civil Procedure 12(b)(6), a defendant bears the burden of demonstrating that the plaintiff has not stated a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6); see also Hedges v. United States, 404 F.3d 744, 750 (3d Cir. 2005). The United States Supreme Court has recognized that "a plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007) (quotations omitted). "[T]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice" and "only a complaint that states a plausible claim for relief survives a motion to dismiss." Ashcroft v. Iqbal, 556 U.S. 662, 678 (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." Id. A complaint does not show an entitlement to relief when the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct. Id.

The United States Court of Appeals for the Third Circuit has detailed a three-step process to determine whether a complaint meets the pleadings standard. Bistrian v. Levi, 696 F.3d 352 (3d Cir. 2014). First, the court outlines the elements a plaintiff must plead to state a claim for relief. Id. at 365. Next, the court must "peel away those allegations that are no more than

conclusions and thus not entitled to the assumption of truth." Id. Finally, the court "look[s] for well-pled factual allegations, assume[s] their veracity, and then 'determine[s] whether they plausibly give rise to an entitlement to relief.'" Id. (quoting Iqbal, 556 U.S. at 679). The last step is "a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." Id. (quoting Iqbal, 556 U.S. at 679).

Although the sufficiency of complaints involving claims of direct infringement were previously analyzed under Federal Rule of Civil Procedure 84 and the Appendix of Forms, those rules were abrogated effective December 1, 2015. Raindance Techs., Inc. v. 10x Genomics, Inc., No. 15-150, 2016 WL 927143, at *2 (D. Del. Mar. 4, 2016). It is now well established that both direct and indirect infringement claims are subject to the Twombly/Iqbal standard. IP Commc'n Solutions, LLC v. Viber Media (USA) Inc., No. 16-134, 2017 WL 1312942, at *2 (D. Del. Apr. 5, 2017); RAH Color Techs. LLC v. Ricoh USA Inc., 194 F. Supp. 3d 346, 350–51 (E.D. Pa. 2016).

III. DISCUSSION

A. Infringement Under the Doctrine of Equivalents

Defendants first move to dismiss Plaintiffs' cause of action for direct infringement. Upon review, I find that the Amended Complaint adequately states a claim upon which relief may be granted.

The direct infringement of a patent occurs when a party, without authority, "makes, uses, offers to sell, or sells any patented invention, within the United States. . . ." 35 U.S.C. § 271(a). A patentee may prove direct infringement under § 271(a) either by (1) demonstrating specific instances of direct infringement; or (2) showing that an accused device necessarily infringes on the patent. ACCO Brands, Inc. v. ABA Locks Mfrs. Co., 501 F.3d 1307, 1313 (Fed. Cir. 2007).

In order to plead a cause of action for direct infringement of a method claim, the complaint must allege that the accused infringer "perform[ed] all the steps of the claimed method, either personally or through another acting under his direction or control." Courtesy Prods, LLC v. Hamilton Beach Brands, Inc., 73 F. Supp. 3d 435, 439 (D. Del. 2014). In other words "[d]irect infringement requires a single party to perform every step of a claimed method." Forest Labs. Holdings Ltd. v. Mylan, Inc., 206 F. Supp. 3d 957, 973 (D. Del. 2016).

When literal infringement is not present, however, a Plaintiff may prove direct infringement via the doctrine of equivalents, i.e., where the accused product is the substantial equivalent of the patented invention. See Warner–Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 24 (1997). "Application of the doctrine of equivalents may allow a patentee to recover for infringement even though the accused device falls outside of the literal scope of the claims, but only where the differences between the innovation and the accused products are insubstantial." Highland Tank & Mfg. Co. v. PS Int'l, Inc., 742 F. Supp. 2d 722, 728 (W.D. Pa. 2010).

To determine whether an accused device infringes under the doctrine of equivalents, a court examines the differences between the claimed invention and the accused device. Dawn Equip. Co. v. Kentucky Farms, Inc., 140 F.3d 1009, 1015–16 (Fed. Cir. 1998). This inquiry generally involves determining whether "the element of the accused device at issue performs substantially the same function in substantially the same way, to achieve substantially the same result, as the limitation at issue in the claim." Id. at 1016 (describing the "function/way/result" inquiry). Each element contained in a patent claim is deemed material to defining the scope of patented invention. Thus, the doctrine of equivalents must be applied to individual elements of claim, not to the invention as a whole. Warner–Jenkinson, 520 U.S. at 29.

The Amended Complaint here sets forth a direct infringement claim by alleging that:

> 65. Upon information and belief, the process used by ANA to produce glutamic acid at its plant in Eddyville, Iowa includes steps literally corresponding to each of steps [a] and [c]–[e] of claims 1 and 2 of the '723 patent . . . .
>
> 66. Upon information and belief, the process used by ANA to produce glutamic acid at its plant in Eddyville, Iowa includes a step literally corresponding to or the equivalent of adding seed crystals of glutamic acid to cause precipitation of glutamic acid crystals as claimed in step [b] of claims 1 and 2 of the '723 patent . . . .

(Am. Compl. ¶¶ 65–66.) Defendants do not dispute the sufficiency of the allegation, in paragraph sixty-five, that their process of producing glutamic acid literally infringes on steps [a] and [c] to [e] of claims 1 and 2 of the '723. Rather, Defendants challenge Plaintiffs' contention, in paragraph sixty-six, that Defendants' process infringes on step [b] of the patent under the doctrine of equivalents. They specifically assert that (1) Plaintiffs fail to properly plead an allegedly equivalent step practiced by Defendants under the Twombly/Iqbal standard,[1] and (2) the doctrine of prosecution history estoppel bars Plaintiffs' equivalency argument.

1. Failure to Plead Factual Allegations to Establish Equivalency

Defendants first contend that Plaintiffs fail to set forth any factual allegations identifying a step practiced by Defendants that is allegedly equivalent to step [b] of the '723 patent. They argue that the Amended Complaint "does little more than merely toss the word 'equivalent' about the amended complaint" and make threadbare allegations of equivalency. (Defs.' Mem. Supp. Mot. to Dismiss p. 8.) According to Defendants, Plaintiffs' pleadings are insufficient to

[1] Plaintiffs argue that Defendants ignore the proper legal standards for evaluating a motion to dismiss as they fail to cite the Third Circuit case of Fowler v. UPMC Shayside, 578 F.3d 203, 210–11 (3d Cir. 2009). Fowler, however, is an application of the Twombly/Iqbal standards which are properly cited in Defendants' Memorandum.

allow the Court to infer more than the mere possibility of infringement under the doctrine of equivalents. (Id. at pp. 8–9.)

Considering this argument under the Rule 12(b)(6) pleading standards, I disagree. As set forth above, Plaintiffs plead that "the process used by ANA to produce glutamic acid at its plant in Eddyville, Iowa includes a step literally corresponding to or the equivalent of adding seed crystals of glutamic acid to cause precipitation of glutamic acid crystals as claimed in step [b] of claims 1 and 2 of the '723 patent." (Am. Compl. ¶ 66.) Although Plaintiffs do not definitively identify an equivalent step practiced by Defendants, the Amended Complaint asserts that "[u]pon information and belief, if the term 'particle size' in the context of the '723 patent is interpreted as meaning 'the diameter of a spherical particle having the same particle volume as the particle being measured,' Ajinomoto's process for L-glutamic acid that is referred to in the Response Letter [prepared by Defendants' attorney] infringes at least one claim of the '723 patent, either literally or under the Doctrine of Equivalents." (Id. ¶ 90.) The Amended Complaint then provides:

> 105. In particular, there is a substantial likelihood that the Accused Products were made by a process including step [b], using seed crystals having an average particle size of 7 µm to 50 µm to cause precipitation as claimed in that step, or an equivalent of that step, because Defendants knew of the '723 patent's disclosure that step [b] is superior to using other materials or methods to initiate precipitation, such as surfactants, or adjusting the temperature or pH of the culture medium, because those other materials and methods do not suppress the growth of microcrystals, and are therefore less efficient.
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> . . .
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> 107. There is a substantial likelihood that the Accused Products were made by a process including steps [b]–[e] or equivalent steps because that process is not only less likely to produce undesired microcrystals, but it also produces larger crystals following growth in step [d], which makes it easier to recover a high percentage of the amino acid in the resulting crystals in step [e].
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> . . .

> 109. There is a substantial likelihood that the Accused Products were made by a process using crystals having a maximum average particle size of 50 µm or less to cause precipitation as claimed in step [b] or an equivalent, as compared with using larger crystals, because (1) the rate of growth of crystals in step [d] is dependent on the surface area of the added crystals, and (2) the surface area per unit volume of the added crystals decreases as average particle size increases, so—all other factors being equal—smaller crystals of a given total volume will have more total surface area and will permit faster growth as compared with larger crystals having the same total volume.
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> 110. There is a substantial likelihood that the Accused Products were made by a process in which the crystals were added to the medium in the size range claimed in step [b] of claims 1 and 2, "at some time after the amino acid concentration in the medium reaches the saturation solubility and before crystals of the amino acid deposit in the medium," or an equivalent step, because that is an optimum condition for causing precipitation and permitting the microorganism to continue producing the amino acid in step [c].

(Am. Compl. ¶¶ 105, 107, 109–10.)

At this stage of the litigation, such allegations are sufficient to survive Twombly/Iqbal scrutiny. The Amended Complaint describes the patent, alleges that the Accused Products literally infringe on all but one step of the patent-in-suit, and asserts that the Accused Products infringe on the remaining step under the doctrine of equivalents. Plaintiffs appropriately justify their inability to specifically plead the exact processes used by Defendants by alleging that "Defendants have not publically disclosed the processes they use to make their Accused Products" and, therefore, that information is not reasonably available to Plaintiffs. (Id. ¶ 78); see DermaFocus LLC v. Ulthera, Inc., 201 F. Supp. 3d 465, 469 (D. Del. 2016) (recognizing that, in patent cases, it is often not possible for a plaintiff to describe its case with particularity in the complaint if it lacks access to the accused method).[2] Accordingly, I find that Defendants have

[2] As concisely stated in DermaFocus,

given reasonable notice of a plausible claim of direct infringement of claims 1 and 2 of the '723 patent by manufacture of the Accused Products and will deny the Motion to Dismiss on this ground.

2. Prosecution History Estoppel

Alternatively, Defendants argue that Plaintiffs' equivalency pleading is deficient in light of the doctrine of prosecution history.

Prosecution history estoppel is a doctrine that limits a plaintiff's use of the doctrine of equivalents to establish infringement. In Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd., 535 U.S. 722 (2002), the Supreme Court stated:

> Prosecution history estoppel ensures that the doctrine of equivalents remains tied to its underlying purpose. Where the original application once embraced the purported equivalent but the patentee narrowed his claims to obtain the patent or to protect its validity, the patentee cannot assert that he lacked the words to describe the subject matter in question. The doctrine of equivalents is premised on language's inability to capture the essence of innovation, but a prior application describing the precise element at issue undercuts that premise. In that instance the prosecution history has established that the inventor turned his attention to the subject matter in question, knew the words for both the broader and narrower claim, and affirmatively chose the latter.

> In the context of patent litigation, it is logical to presume that a defendant has greater access to and, therefore, more information about its accused method. The degree of public information about any accused method varies widely, as does the degree of specificity with which any asserted invention is claimed. Given the focus of the above articulated standard of review on reasonable notice of plausible claims under the circumstances, the question a court must address with each case is whether the plaintiff at bar has provided sufficient information to allow the court to determine plausibility and to allow the named defendant to respond to the complaint.

DermaFocus, 201 F. Supp. 3d at 469; see also United States Gypsum Company v. New NGC, Inc., No. 17-130, 2017 WL 2538569, at *3 (D. Del. Aug. 18, 2017).

Id. at 734–735.

The prosecution history of a patent, as the public record of the patent proceedings, serves the important function of identifying the boundaries of the patentee's property rights. Id.at 733–34. Once a patentee has narrowed the scope of a patent claim as a condition of receiving a patent, the patentee may not recapture the subject matter surrendered. Id. In order for prosecution history estoppel to apply, however, there must be a deliberate and express surrender of subject matter. See Southwall Tech., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1580 (Fed. Cir. 1995).

Here, the allegedly-infringing equivalent is the "average particle size" recited in the claims at step [b]. Defendants contend that during the prosecution of the '723 patent, Plaintiffs narrowed the range of the average particle size of the seed crystals from "1 to 120" microns to "7 to 50" microns and restricted step [b] temporally so that adding the seed crystals occurs "at some time after the amino acid concentration in the medium reaches the saturation solubility and before crystals of the amino acid deposit in the medium." (Am. Compl., Ex. 1, col. 10:51–54.) Defendants also allege that Plaintiffs narrowed step [d] of claims 1 and 2 to recite "an average particle size of 30 μm or more." (Id. at col 10:60–61, 11:14–15.) Defendants further argue that, according to the '723 patent file history, these narrowing amendments were made because the original patent was partially invalid by reason of the patentee claiming more than it had a right to claim in the patent. Relying on the doctrine of prosecution history estoppel, Defendants conclude that Plaintiffs—having narrowed the range of the average particle size of the seed crystals—cannot base infringement of the process claimed in step [b] of the '723 patent on the doctrine of equivalents.

Defendants' argument is premature at this stage of the litigation. The presumption of surrender from a patentee's decision to narrow his claim "may be rebutted if the patentee can demonstrate that: (1) 'the alleged equivalent would have been unforeseeable at the time . . . the narrowing amendment' was made; (2) 'the rationale underlying the narrowing amendment bore no more than a tangential relation to the equivalent at issue'; or (3) 'there was "some other reason" suggesting that the patentee could not reasonably have been expected to have described the alleged equivalent.'" Honeywell Int'l Inc. v. Hamilton Sundstrand Corp., 370 F.3d 1131, 1140 (Fed. Cir. 2004) (quotations omitted). Thus, the scope of estoppel depends on factual questions regarding the prosecution history, which may preclude a disposition of the issue not only on a motion to dismiss, but on summary judgment. Hormone Research Found., Inc. v. Genentech, Inc., 904 F.2d 1558, 1564 (Fed. Cir. 1990). When deciding issues regarding foreseeability and rationale, "a district court may hear expert testimony and consider other extrinsic evidence relating to the relevant factual inquiries," including "the state of the art and the understanding of a hypothetical person of ordinary skill in the art at the time of the amendment." DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc., 567 F.3d 1314, 1324 (Fed. Cir. 2009).

Defendants offer cursory arguments for why none of the three potential bases for rebuttal of the presumption apply. Such factual issues, however, are not proper at the motion to dismiss stage without a developed evidentiary record. Plaintiffs are entitled to discovery about the details of Defendants' processes before identifying the precise equivalency and applicable ways for overcoming the presumption. Accordingly, I will deny Defendants' Motion to Dismiss Plaintiffs' doctrine of equivalents cause of action.

B. Infringement of an Imported Product Under 35 U.S.C. § 271(g)

Defendants next seek dismissal of Plaintiffs' infringement action brought under 35 U.S.C. § 271(g).

Section 271(g) provides, in pertinent part:

> [w]hoever without authority imports into the United States or offers to sell, sells, or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, offer to sell, sale, or use of the product occurs during the term of such process patent. In an action for infringement of a process patent, no remedy may be granted for infringement on account of the noncommercial use or retail sale of a product unless there is no adequate remedy under this title for infringement on account of the importation or other use, offer to sell, or sale of that product. A product which is made by a patented process will, for purposes of this title, not be considered to be so made after—
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> (1) it is materially changed by subsequent processes; or
>
> (2) it becomes a trivial and nonessential component of another product.

35 U.S.C. § 271(g). By its terms, section 271(g) prohibits the unauthorized importation into the United States, or sale or use within the United States, of a "product which is made by a process patented in the United States." Momenta Pharms., Inc. v. Teva Pharms. USA, Inc., 809 F.3d 610, 615 (Fed Cir. 2015) (quoting 35 U.S.C. § 271(g) (emphasis omitted)).

Here, the Amended Complaint sets forth the following allegations in support of a § 271(g) claim:

> 36. On information and belief, each of the Defendants ANA and AW, directly or indirectly through their agents, have committed infringing activities in Delaware and in the United States by making, using, marketing, offering for sale, selling, and importing Accused Products; by offering such Accused Products for sale and placing them into the stream of commerce with the awareness, knowledge, and intent that they would be used, offered

> for sale, and/or sold by others in this judicial district and/or purchased by consumers in this judicial district.
>
> 37. On information and belief, Defendant AJ, directly and vicariously through its agents, including ANA and AW, has committed infringing acts in Delaware and in the United States by making, using, marketing, offering for sale, selling, and importing Accused Products; by offering such Accused Products for sale and placing them into the stream of commerce with the awareness, knowledge, and intent that they would be used, offered for sale, and/or sold by others in this judicial district and/or purchased by consumers in this judicial district.
> . . .
>
> 55. One or more of the Defendants has infringed claims 1 and 2 of the '723 patent under 35 U.S.C. § 271(g) by importing the Accused Products into the United States or by making, selling, offering for sale, or using the Accused Products in the United States after they have been imported, using the patent process or equivalent steps.
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> 56. One or more of the Defendants has vicariously infringed claims 1 and 2 of the '723 patent under 35 U.S.C. § 271(a) and (g) by directing one of its agents to use the patented process or equivalent steps to make, use[,] sell and offer for sale Accused Products in the United States.

(Am. Compl. ¶¶ 36–37, 55–56.)

Defendants challenge the sufficiency of these allegations on two grounds. First, they contend that Plaintiffs fail to identify any foreign manufacturer despite the fact that 35 U.S.C. § 271(g) protects only against products made abroad by a process patented in the United States. Second, they argue that the "materially changed" exception in § 271(g)(1) applies. For the following reasons, I find no merit to either of these arguments.

1. Failure to Identify a Foreign Manufacturer

Defendants' first argument asserts that § 271(g) requires an allegation that the Accused Product was manufactured or practiced outside the United States. Because the Amended

Complaint makes no such allegation, Defendants urge that this cause of action must be dismissed.

Defendants' interpretation of this provision is not correct. "The plain language of Section 271(g) is not limited to instances where the manufacture of the product via an infringing process is performed abroad." United Gen. Supply Co., Inc. v. 2nds in Bldg. Materials, Inc., No. 15-1975, 2017 WL 524720, at *2 (W.D. La. Feb. 2, 2017). To the contrary, the statute is phrased in the disjunctive and establishes liability for whomever, without authority, either (a) imports into the United States or (b) offers to sell, sells, or uses within the United States, a product which is made by a process patented in the United States. Id. "Canons of construction ordinarily suggest that terms connected by a disjunctive be given separate meanings, unless the context dictates otherwise[.]" Reiter v. Sonotone Corp., 442 U.S. 330, 339 (1979); see also McRO, Inc. v. Namco Bandai Games Am., Inc., 23 F. Supp. 3d 1113, 1118 (C.D. Cal. 2013) (reading § 271(g) in the disjunctive to find that "the plain language of the statute is not limited to circumstances in which the manufacture of the product via an infringing process is performed abroad"); Avery Dennison Corp. v. UCB Films PLC, No. 95-6351, 1997 WL 665795, at *1–2 (N.D. Ill. Oct. 20, 1997) (holding that the plain language of § 271(g) makes no distinctions as to where the steps of a process patent are performed; it is only concerned with importation, sale, or use of the end product).[3]

[3] Defendants rely on isolated statements made by the Federal Circuit that "35 U.S.C. § 271(g) imposes liability for infringement by importation, sale, or use in the United States of a product made abroad by a process patented in the United States." Ajinomoto Co. v. Archer-Daniels-Midland Co., 228 F.3d 1338, 1347 (Fed. Cir. 2000) (emphasis added); see also Eli Lilly & Co. v. Am. Cyanamid Co., 82 F.3d 1568, 1571 (Fed. Cir. 1996) ("The Process Patent Amendments Act makes it an act of infringement to import, sell, offer to sell, or use in this country a product that was made abroad by a process protected by a U.S. patent.") (emphasis added). Neither case, however, addressed the applicability of § 271(g) to domestic manufacturing as the facts in those cases concerned products produced abroad. Eli Lilly focused on only the "materially changed"

The legislative history of § 271(g) further demonstrates that it was "meant to give relief to process patent holders when the resulting products of their patented process are used within the United States—regardless of where the process is practiced." Zoltek Corp. v. United States, 672 F.3d 1309, 1315 (Fed. Cir. 2012) (emphasis added). The offending conduct that Congress sought to punish by the addition of this statute was "the importation of a product made through the use of a protected process patent or its subsequent sale within the United States." Id. at 1324. Congress still intended to apply § 271(g) to domestic sellers of infringing goods together with manufacturers and importers of such goods. See Shamrock Techs., Inc. v. Precision Micron Powders, Inc., No. 91-0869, 1991 WL 335362, at *2 n.4 (E.D.N.Y. Aug. 8, 1991) (citing H.R. Rep. No. 60, 100th Cong., 1st Sess., at 3 (1987) (stating that the purpose of section 271(g) is to provide "meaningful protection to owners of patented processes" because prior to its enactment there was "no remedy against parties who use or sell the product, regardless where it is made"); S. Rep. No. 83, 100th Cong., 1st Sess. 46 (1987) (Section 271(g) "was crafted to apply equally to the use or sale of a product made by a process patented in this country whether the product was made (and the process used) in this country or in a foreign country"); H.R. Conf. Rep. No. 576, 100th Cong., 2d Sess. 1085–86 (1988), reprinted in 1988 U.S.C.C.A.N. 2118–19 (stating that both the House and Senate bills provide that "using, selling, or importing a product made in violation of a U.S. process patent is an act of patent infringement")).

Here, Plaintiffs rely on the second clause of § 271(g)—whoever "offers to sell, sells, or uses within the United States, a product which is made by a process patented in the United States." Under that provision, the Amended Complaint need not allege facts that the offending

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provision of § 271(g)(1), a provision not at issue here. Eli Lilly, 82 F.3d at 1571–72. Ajinomoto simply held that when manufacturing occurs abroad, there is no liability until importation, sales or offers for sale in the United States. Ajinomoto, 228 F.3d at 1347.

process was practiced for a product manufactured outside the United States or that Defendants imported that product.

2. Failure to Allege No Material Change

In a second effort to have the § 271(g) claim dismissed, Defendants posit that § 271(g)(1) requires that the accused product not have been "materially changed" by subsequent processes, which is an express statutory exception to § 271(g) liability. Defendants contend that Plaintiffs have not met their pleading burden because Plaintiffs have failed to allege that the accused product here is not "materially changed" from the corresponding amino acid,

This argument is premature. The limits on liability set forth in § 271(g)(1) and (2) have been characterized by the Federal Circuit as "defenses" or "exceptions" not as elements of a § 271(g) claim that must be affirmatively pled. See Kinik Co. v. Int'l Trade Comm'n, 362 F.3d 1359, 1362 (Fed. Cir. 2004). This is particularly true with the "materially changed" provision since it involves factual issues not appropriate for resolution in a Rule 12(b)(6) motion. See Biotec Biologische Naturverpackungen GmbH & Co. KG v. Biocorp, Inc., 249 F.3d 1341, 1352 (Fed. Cir. 2001) ("Whether a change in a product is material is a factual determination, and is properly for the trier of fact."); Janssen Pharmaceutica, N.V. v. Mylan Pharm. Inc., No. 15-760, 2016 WL 5723652, at *2 (D. Del. Sept. 29, 2016) ("To the extent defendants are arguing a material-change defense . . . such a defense presents a factual dispute not for resolution on the pleadings."); Millennium Cryogenic Techs., Ltd. v. Weatherford Artificial Lift Sys., Inc., No. 12-890, 2012 WL 12894799, at *2 (S.D. Tex. Sept. 5, 2012) (holding that the issue of a § 271(g)(1) material change should not be resolved in the context of a Rule 12(b)(6) motion to dismiss).

Plaintiffs have adequately pled a plausible claim for relief under § 271(g).

C. Inducement of Infringement

Defendants next seek dismissal of Plaintiffs' inducement of infringement claim. Under 35 U.S.C. § 271(b), "[w]hoever actively induces infringement of a patent shall be liable as an infringer." Id. "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." DSU Med. Corp. v. JMS Co., 471 F.3d 1293, 1306 (Fed. Cir. 2006) (en banc in relevant part). To prevail on a claim of induced infringement, the patentee "must show [(1)] direct infringement, and [(2)] 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) (quoting i4i Ltd. P'ship v. Microsoft Corp., 598 F.3d 831, 851 (Fed. Cir. 2010)).

Defendants aver that the Complaint fails to either plead that they possessed the specific intent to induce infringement or identify a party that they have allegedly induced to infringe.

1. Specific Intent

"[L]iability for induced infringement can only attach if the defendant knew of the patent and knew as well that 'the induced acts constitute patent infringement." Commill USA, LLC v. Cisco Sys., Inc., 135 S. Ct. 1920, 1926 (2015) (citing Global-Tech Appliances, Inc. v. SEB S.A., 563 U.S. 754, 763 (2011)). The knowledge requirement must be met by a showing of either actual knowledge or willful blindness. Global–Tech, 563 U.S. at 766. "[A] willfully blind defendant is one who takes deliberate actions to avoid confirming a high probability of wrongdoing and who can almost be said to have actually known the critical facts." Id. at 769. At the pleading stage, "the question before the Court on defendants' motions to dismiss is whether [the plaintiff] has plead sufficient facts . . . for the Court to infer that the defendants had

knowledge of [the plaintiff's] patents and that their products infringed on those patents." MONEC Holding AG v. Motorola Mobility, Inc., 897 F. Supp. 2d 225, 229 (D. Del. 2012) (quotations omitted) (emphasis in original); see also In re Bill of Lading Transmission & Processing Sys. Patent Litig., 681 F.3d 1323, 1339 (Fed. Cir. 2012) ("To survive . . . a motion to dismiss, therefore, [the plaintiff's] amended complaint[ ] must contain facts plausibly showing that [the defendant] specifically intended [its] customers to infringe the [patents-in-suit] and knew that the customer's acts constituted infringement."). Mere knowledge of acts alleged to constitute infringement is not sufficient; rather the plaintiff must show "specific intent and action to induce infringement." Eli Lilly & Co. v. Teva Parenteral Meds., Inc., 845 F.3d 1357, 1368 (Fed. Cir. 2017) (citations omitted).

Courts have repeatedly found that pleading the existence of a direct infringer, the defendant's knowledge of the patent, and the defendant's specific intent to induce infringement is sufficient to sustain a § 271(b) claim under the Twombly/Iqbal standards. See, e.g., Intellectual Ventures I LLC v. Nikon Corp., 935 F. Supp. 2d 787, 795 (D. Del. 2013) (finding allegations that defendants knew of the patents-in-suit and indirectly infringed them by "contracting with others to market and sell infringing products with the knowledge and intent to facilitate infringing sales of the products by others within this District and by creating and/or disseminating instructions and other materials for the products with like mind and intent" sufficient to plead intent to infringe); Telecomm Innovations, LLC v. Ricoh Co., Ltd., 966 F. Supp. 2d 390, 394–95 (D. Del. 2013) (finding intent sufficiently pled when plaintiffs alleged that defendants had knowledge of the patent and provided technical support to customers in such a way as to infringe the patent); Fairchild Semiconductor Corp. v. Power Integrations, Inc., 935 F. Supp. 2d 772, 778 (D.. Del. 2013) (finding sufficient allegations that defendant, acting with

knowledge of the patent-in-suit, included the infringing technology in a product which would then be used by customers); Netgear, Inc. v. Ruckus Wireless, Inc., 852 F. Supp. 2d 470, 475–76 (D. Del. 2012) (holding that the plaintiff sufficiently pled induced infringement because it had pled or otherwise plausibly inferred a direct infringer, defendant's knowledge of the patent-in-suit, and defendant's specific intent to induce the infringement "by its activities relating to the marketing and distribution" of its products).

Here, the Amended Complaint asserts that Defendant AJ was aware of the '723 patent in November 2014—twenty-seven months before this action was initiated—and Defendant ANA was aware of the '723 patent in June 2016—seven months before this action was initiated. (Am. Compl. ¶¶ 81–82.) The Amended Complaint goes on to allege that these Defendants are wholly owned subsidiaries of and are controlled and managed by Defendant AJ. (Id. ¶¶ 22-23.) As the Defendants function as an "integrated organization" and a "single business enterprise" in the manufacture, importation, and sale of the Accused Products, Plaintiffs assert that one Defendant's knowledge of the patent can be imputed to the others. (Id. ¶ 24.)

The Amended Complaint then sets forth facts from which to infer that Defendants specifically intended that its agents infringe the '723 patent. In particular, Plaintiffs allege:

> 38. On information and belief, Defendant AJ has induced acts of infringement of the '723 patent in Delaware and in the United States by its agents, including ANA and AW, by making, using, marketing, offering for sale, selling, and importing Accused Products; by offering such Accused Products for sale and placing them into the stream of commerce with the awareness, knowledge, and intent that they would be used, offered for sale, and/or sold by others in this judicial district and/or purchased by consumers in this judicial district, all with the knowledge of the '723 patent and with knowledge or willful blindness to the act that the induced acts infringe one or more claims of the '723 patent.
>
> 39. For example without limitation, upon information and belief, Defendants manufacture the Accused Product L-glutamic

> acid . . . offer such products for sale throughout the United States on websites controlled by AJ or ANA or both; and sell such products in Delaware and elsewhere in the United States through ANA and other agents.
>
> . . .
>
> 60. On information and belief, AJ has induced infringement of one or more of claims 1 and 2 of the '723 patent, in violation of 35 U.S.C. § 271(b), by specifying and controlling the method for making Accused Products that are imported into the United States or made in the United States by its agents, including one or more of the other Defendants and by inducing them to sell or offer to sell the Accused Products into the United States, or import the Accused Products in the United States, all with knowledge of the '723 patent and with knowledge or willful blindness to the fact that the induced acts infringe one or more claims of the '723 patent.
>
> . . .
>
> 68. On information and belief, ANA has induced infringement of claims 1 and 2 of the '723 patent, in violation of 35 U.S.C. § 271(b), by specifying and controlling the method for making Accused Products imported into the United States or made in the United States by its agents, including one or more of the other Defendants, and by inducing them to sell the Accused Products in the United States or import the Accused Products into the United States, all with knowledge of the '723 patent and with knowledge or willful blindness to the fact that the induced acts infringe one or more claims of the '723 patent.
>
> . . .
>
> 70. On information and belief, AW has induced infringement of claims 1 and 2 of the '723 patent, in violation of 35 U.S.C. § 271(b), by inducing its agents to sell the Accused Product monosodium glutamate in the United States, or import the Accused Products into the United States, all with knowledge of the '723 patent and with knowledge or willful blindness to the fact that the induced acts infringe one or more claims of the '723 patent.

(Am. Compl. ¶¶ 38–39, 60, 68, 70.)

These allegations are sufficient, at this stage of the litigation, to allow an inference of intent. The Amended Complaint specifically pleads Defendants' knowledge of the patent-in-suit and that, despite this knowledge, Defendants induced their agents to import, offer to sell, or sell the Accused Products in the United States. Consistent with the aforementioned jurisprudence,

Plaintiffs' claims of induced infringement are facially plausible and provide Defendants with adequate notice of the claim against them.

2. Identity of Direct Infringers

Defendants also allege that the inducement of infringement claim, as set forth against Defendant AW, must fail because the Amended Complaint does not adequately identify a party that AW has induced to infringe.

A plaintiff need not specifically identify the individuals or companies who are induced to infringe, as this is a "proper question for discovery." Minkus Elec. Display Sys., Inc. v. Adaptive Micro Sys. LLC, No. 10–666, 2011 WL 941197, at *3 (D. Del. Mar. 16, 2011). A plaintiff must only "plead[] facts sufficient to allow an inference that at least one direct infringer exists." Bill of Lading, 681 F.3d at 1336. Such an inference is permissible from generalized allegations regarding the identity of the direct infringers. See, e.g., Telecomm Innovations, 966 F. Supp. 2d at 394 (finding allegation that "[d]efendants' customers and others have infringed and are continuing to infringe" was sufficient to allow an inference that at least one direct infringer exists); E.I. Du Pont de Nemours and Co. v. Heraeus Holding GmbH, No. 11-773, 2012 WL 4511258, at *4 (D. Del. Sept. 28, 2012) (finding that allegation that accused method is used by defendant's customers sufficient to allow an inference that at least one direct infringer exists).

The Amended Complaint alleges that, with respect to Defendant AW:

> AW has induced infringement of claims 1 and 2 of the '723 patent, in violation of 35 U.S.C. § 271(b), by inducing its agents to sell the Accused Product monosodium glutamate in the United States, or import the Accused Products into the United States, all with knowledge of the '723 patent and with knowledge or willful blindness to the fact that the induced acts infringe one or more of the other Defendants, and by inducing them to sell the Accused Products in the United States, or import the Accused Products into

> the United States, all with the knowledge of the '723 patent and with knowledge or willful blindness to the fact that the induced acts infringe one or more claims of the '723 patent.

(Am. Compl. ¶ 68.)

Defendants contend that this allegation is insufficient because it identifies the category of direct infringers vaguely as "agents," but does not otherwise define who the agents are or their relationship with AW. Defendants further posit that Plaintiffs use the term "agent" inconsistently in the Amended Complaint, as it refers to AW and ANA as agents of AJ, and then references AW's own "agents" without defining them. Absent any specificity, Defendants claim they are left to guess as to the scope of this claim.

Defendants demand too much at this pleading stage of the litigation. As noted above, a plaintiff need only plead facts to allow an inference that one direct infringer exists. Such an inference is permissible in this case from Plaintiffs' assertion that AW's "agents"—whether sales agents or some other independent agents—directly infringed the patent-in-suit and were induced to do so by AW. To the extent Defendants remain unclear as to which "agents" were induced by AW, they may explore this topic during discovery.

D. Willful Infringement

In their final argument, Defendants move to dismiss Plaintiffs' claim of willful infringement.

Pursuant to § 284 of the Patent Act, once infringement has been established, the court "may increase the damages up to three times the amount found or assessed." 35 U.S.C. § 284. In 2016, the Supreme Court abrogated the Federal Circuit's previous two-part test for proving willful infringement. Halo Elecs., Inc. v. Pulse Elecs., Inc., 136 S. Ct. 1923 (2016). "In so doing, the Court invited district courts to exercise discretion in evaluating whether to award

enhanced damages under 35 U.S.C. § 284." Progme Corp. v. Comcast Cable Commc'n LLC, No. 17-1488, 2017 WL 5070723, at *12 (E.D. Pa. Nov. 3, 2017). The Supreme Court explained that enhanced damages are "designed as a 'punitive' or 'vindictive' sanction for egregious infringement behavior," commonly described as "willful, wanton, malicious, bad faith, deliberate, consciously wrongful, flagrant, or . . . characteristic of a pirate." Halo Elecs, 136 S. Ct. at 1932. "[C]ulpability is generally measured against the actor's knowledge of the actor at the time of the challenged conduct." Id. at 1933 (citations omitted). A patent infringer's subjective willfulness, whether intentional or knowing, "may warrant enhanced damages, without regard to whether his infringement was objectively reckless." Id. at 1933. The Supreme Court stressed that the award of enhanced damages was discretionary and directed that the court "take into account the particular circumstances" in its determination of whether enhanced damages are appropriate, which have been historically "reserved for egregious cases typified by willful misconduct." Id. at 1933–34.

Mere formulaic pleading of willful infringement will not survive a Rule 12(b)(6) motion. See Varian Med. Sys., Inc. v. Elekta AB, No. 15-871, 2016 WL 3748772, at *8 (D. Del. July 12, 2016) (finding allegations insufficient to plead willful infringement where the complaint provided "a formulaic recitation of the pre-Halo elements of a willful infringement claim"); Princeton Digital Image Corp. v. Ubisoft Entm't SA, No. 13-335, 2016 WL 6594076, at *11 (D. Del. Nov. 4, 2016) (dismissing willful infringement claim where the complaint failed to sufficiently allege that, prior to the service of the original complaint, defendants had knowledge of the patent-in-suit).

Nonetheless, even after Halo, broader allegations of willfulness without a specific showing of egregiousness are sufficient to withstand a motion to dismiss. Bio-Rad Labs Inc. v.

Thermo Fisher Scientific Inc., 267 F. Supp. 3d 499, 501 (D. Del. 2017) ("At the pleading stage, it is not necessary to show that the case is egregious."); DermaFocus LLC v. Ulthera, Inc., 201 F. Supp. 3d 465, 473 (D. Del. 2016) (holding that general allegations of willful infringement are sufficient under Halo to withstand a motion to dismiss). Thus, where a complaint permits an inference that the defendant was on notice of the potential infringement and still continued its infringement, the plaintiff has pled a plausible claim of willful infringement. See, e.g., Green Pet Shop Enterprises, LLC v. Telebrands Corp., No. 17-6179, 2018 WL 547544, at *2 (D.N.J. Jan. 24, 2018) (holding that allegations of receipt of a detailed cease-and-desist letter, followed by continued infringement, make plausible an inference of subjective willfulness); Telebrands Corp. & Prometheus Brands, LLC v. Everstar Merchandise Co., Ltd., No. 17-2878, 2018 WL 585765, at *8 (D.N.J. Jan. 29, 2018) (allegations that defendants had notice of the patent-in-suit since their receipt of the complaint and yet still created and sold the allegedly infringing product are sufficient to establish a plausible entitlement to enhanced damages); Progme Corp. v. Comcast Cable Commc'ns LLC, No. 17-1488, 2017 WL 5070723, at *12 (E.D. Pa. Nov. 3, 2017) ("To the extent that [Defendant] has persisted in its alleged infringement of the '425 Patent after Plaintiff filed its complaints, this conduct could possibly amount to willful infringement. At this stage in the litigation, I will not deny Plaintiff the possibility of collecting enhanced damages related to [Defendant's] post-suit conduct.").

I find that, taking the allegations in the Amended Complaint as true, Plaintiffs create a sufficient inference of egregiousness to allow their willful infringement claim to proceed past the pleading stage. As set forth above, the Amended Complaint alleges that Defendants knew about the '723 patent and actually approached Plaintiffs about obtaining a license under that agreement. (Am. Compl. ¶ 81.) Thereafter, Plaintiffs—concerned about potential

infringement—requested that Defendants disclose, under a non-disclosure agreement, the process used to manufacture their Accused Products. (Id.) Defendants allegedly ignored Plaintiff's request for disclosure and simply said that their process did not infringe on step [b] of Plaintiffs' patented process because the average particle size of the crystals added to the amino acid was bigger than that claimed by the patent. (Id. ¶ 84–85.) Defendants did not address any of the other limitations of the '723 patent. (Id. ¶ 86.) Nor did Defendants indicate their basis for their interpretation of "average particle size" in the '723 patent. (Id. ¶¶ 87–88.) Based on these allegations, the Amended Complaint concludes that "[o]ne or more of the Defendants has induced infringement of claims 1 and 2 of the '723 patent under 35 U.S.C. § 271(b) by directing one of its agents to use the patented process or equivalent steps to make Accused Products in the United States, or has induced one of its agents to import the Accused Products in the United States, "*all with knowledge of the '*723 patent and with knowledge or willful blindness to the act that the induced acts infringe one or more claims of the '723 patent." (Id. ¶ 57 (emphasis added).) Such allegations are more than the formulaic recitation found to be insufficient under Twombly and Iqbal and sufficiently permit a plausible inference of subjective willfulness.

IV. CONCLUSION

In light of the foregoing, I conclude that the claims of infringement set forth in the Amended Complaint adequately state a claim upon which relief may be granted. Accordingly, I will deny Defendants' Motion to Dismiss in its entirety.