IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

JANSSEN BIOTECH, INC. and
NEW YORK UNIVERSITY

Plaintiffs,

v.

CELLTRION HEALTHCARE CO., LTD.,
CELLTRION, INC., and
HOSPIRA, INC.

Defendants.

Civil Action No. 1:15-cv-10698
Civil Action No. 1:16-cv-11117

CONFIDENTIAL

MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION FOR PARTIAL SUMMARY JUDGMENT OF NON-INFRINGEMENT OF U.S. PATENT NO. 7,598,083

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INTRODUCTION

Janssen's asserted patent directed to infliximab, the '471 patent, has been found invalid, leaving the '083 patent as the only patent left in dispute. As the Court has noted, the '083 patent is not directed to and "does not include any reference to infliximab." Dkt. 249 at 4.[1] Rather, the '083 patent recites a "soluble composition, suitable for producing a final volume of cell culture media" that can be used to culture cells. *Id*.; Dkt. 1-4 at claim 1, 1:13–14. Janssen's efforts to stop Remicade® competition based on the '083 patent must fail because Janssen's claims of direct infringement against Celltrion (Count 1 in Action No. 16-11117 (the "2016 Action")) and induced infringement against Celltrion and Hospira (Counts 2 and 3 in the 2016 Action) rely on theories that are contrary to law and that contradict undisputed facts.

First, on the issue of alleged direct infringement by Celltrion, Janssen impossibly asserts that Celltrion has directly infringed the '083 patent by purchasing certain compositions from HyClone Labs. Inc. ("HyClone"). It is undisputed that the compositions are made by HyClone alone—not Celltrion—in the United States. They are purchased and used by Celltrion in South Korea to make cell culture media, which are in turn used to grow cells that produce Celltrion's infliximab antibody. In a tortured theory of direct patent infringement, Janssen alleges that by providing design input when HyClone was developing the accused products and later purchasing the accused products from HyClone, Celltrion created an "agency" relationship with HyClone that gives rise to liability for direct infringement under 35 U.S.C. § 271(a). This theory fails based on the uncontroverted facts—specifically, the express and undisputed terms of the "Supply Agreement" between Celltrion and HyClone that govern their buyer-seller relationship. [redacted] SOF ¶ 24 (emphasis added). Janssen cannot create a

[1] Citations to docket entries refer to Action No. 15-10698 unless otherwise noted.

triable issue of fact based on allegations of agency that are refuted by the express terms of the parties' written agreement. Moreover, the law does not support a theory of direct infringement of a product claim based on an agency theory, or a "joint enterprise" theory, premised merely on purchase of a product, even crediting Janssen's allegation that the product is "custom-made." Janssen's Count 1 simply attempts to recast an allegation of indirect infringement under 35 U.S.C. § 271(b) as a claim for direct infringement under § 271(a). Permitting this theory to proceed would turn the Patent Act on its head by subverting its distinct forms of liability for infringement, and is erroneous as a matter of law.

Second, summary judgment should be granted in Defendants' favor on Janssen's Count 2 in the 2016 Action, which sets forth Janssen's claim that Celltrion induced infringement by virtue of its contract to purchase the accused HyClone products. Proof of inducement requires that Celltrion "knew of the patent," took active steps to encourage or bring about infringement, and knew while it was taking such active steps "that 'the induced acts constitute patent infringement.'" *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 765–66 (2011). This last requirement, critical here, is the requirement that there be specific intent to infringe. Janssen cannot establish specific intent as a matter of law because Janssen admits the accused products do not literally infringe the asserted claims in ***at least twelve different ways***. On this record, with so many differences between the accused product and the asserted claims, it cannot be disputed that Defendants have an objective, good-faith defense to non-infringement of the '083 patent, compelling summary judgment of no inducement.

Moreover, even assuming that Janssen's theory of infringement in this case had any merit (it does not), there would be no dispute of material fact that Celltrion lacked knowledge that the induced acts constitute patent infringement. *Global-Tech*, 563 U.S. at 766. Janssen's sole theory

that the accused HyClone products infringe the ’083 patent is a tortuous, twelve-way doctrine of equivalents (“DOE”) argument. Specifically, Janssen alleges that despite the accused products being literally outside the scope of the asserted claims in at least twelve different ways, the products are nonetheless “equivalent” to the claimed products in all of those at least twelve different ways. No. 16-11117 Dkt. 1 at ¶¶ 71, 82–94. This theory—and indeed, Janssen’s ability to even plead direct infringement—required Janssen to perform complicated and expensive testing aiming to demonstrate that the accused products are somehow “equivalent” to the claimed compositions. *Id.* Setting aside the various deficiencies in the testing that result in a failure to show equivalence, which are not the subject of this motion, there is no evidence that Celltrion performed such testing or had reason to believe that HyClone’s compositions infringed under Janssen’s unprecedented and strained approach to the DOE. Summary judgment of non-infringement should be granted on Count 2.

Finally, the Court should grant summary judgment on Janssen’s Count 3, which claims that Hospira has induced infringement of the ’083 patent. Count 3 fails for the same reasons as Janssen’s inducement claim against Celltrion—namely, that Janssen’s allegation of direct infringement is subject to an objective, good-faith non-infringement defense, and Janssen cannot show knowledge that the induced acts constitute patent infringement. Moreover, Janssen cannot show that Hospira “actively induced” direct infringement under 35 U.S.C. § 271(b). That is, it cannot show that Hospira took any affirmative steps to encourage or bring about alleged infringement by Celltrion or HyClone. Nor could Janssen allege such facts, because it is undisputed that Hospira has no involvement with the purchase or use of the accused HyClone products, and has no connection to them at all. Hospira simply sells and distributes the

infliximab drug that Celltrion manufactures. Summary judgment of no inducement should be granted on Count 3 as well.[2]

BACKGROUND

That only patent left in dispute in this litigation is U.S. Patent No. 7,598,083 (the "'083 patent"), entitled "Chemically Defined Compositions." SOF ¶ 9. The '083 patent, referred to by the parties at times as the "soup patent," does not claim or disclose the infliximab antibody in Janssen's drug Remicade®, or in the Defendants' biosimilar drug Inflectra®. SOF ¶¶ 11–13. Rather, it pertains to soluble compositions that are suitable for producing final volumes of cell culture media in which cells can be grown. *Id.*

The dispute over the '083 patent centers on two compositions made by third party HyClone in the United States. SOF ¶ 14. In 2013, Defendant Celltrion, Inc., based in South Korea, entered into a "Supply Agreement" with HyClone to purchase the compositions, and Celltrion has [redacted] in South Korea to produce cell culture media used to grow cells that produce the infliximab antibody in Inflectra®, also marketed in some countries as Remsima®. SOF ¶¶ 8, 21. Hospira has entered into an agreement with Celltrion to distribute and market Inflectra®, including in the United States. SOF ¶ 4. Janssen claims that HyClone has infringed the '083 patent because the compositions it makes in the United States allegedly practice the patent, and has sued HyClone for infringement of the '083 patent in a separate litigation in a different court. SOF ¶¶ 14, 20. In an extraordinary attempt to also hold Celltrion and Hospira liable for HyClone's alleged infringement, Janssen asserts here that Celltrion, by virtue of its contractual relationship with HyClone, is somehow vicariously liable as a direct infringer or has induced HyClone's alleged direct infringement in the United States.

[2] Count 6 of Janssen's complaint in the 2015 Action, which alleges technical infringement based on the filing of Celltrion's biosimilar application, fails as a matter of law for the same reasons.

Janssen further alleges that Hospira, by virtue of its agreement to market and distribute biosimilar infliximab, also induced HyClone's alleged infringement. SOF ¶¶ 18–19. Applying the law to undisputed facts, each of Janssen's claims fails.

LEGAL STANDARD FOR SUMMARY JUDGMENT

"The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). "To be genuine, a factual dispute must be built on a solid foundation—a foundation constructed from materials of evidentiary quality." *Nieves-Romero v. United States*, 715 F.3d 375, 378 (1st Cir. 2013). Though all facts are to be taken in the light most flattering to the nonmoving party, "'[c]onclusory allegations, empty rhetoric, unsupported speculation, or evidence which, in the aggregate, is less than significantly probative' will not suffice to ward off a properly supported summary judgment motion." *Id*. (citations omitted). "A plaintiff's failure to produce any evidentiary proof concerning one of the essential elements of his claim is grounds for summary judgment." *Jakobiec v. Merrill Lynch Life Ins. Co.*, 711 F.3d 217, 226 (1st Cir. 2013). There are two phases of a summary judgment inquiry: "First, the movant must make a preliminary showing that there is no genuine issue of material fact which requires resolution in the crucible of a trial. Once this showing has been made, the burden shifts to the nonmovant to demonstrate, through specific facts, that a trialworthy issue remains." *Cadle Co. v. Hayes*, 116 F.3d 957, 960 (1st Cir. 1997). For any "issues on which the nonmovant has the burden of proof, the movant need do no more than aver 'an absence of evidence to support the nonmoving party's case.'" *Mottolo v. Fireman's Fund Ins. Co.*, 43 F.3d 723, 725 (1st Cir. 1995).

ARGUMENT

The Court should grant Defendants' motion for summary judgment because Janssen's theories of infringement are contrary to law and contradicted by the undisputed facts. Count 1

alleges direct infringement by Celltrion under a vicarious liability theory. It fails because it is contradicted by the undisputed language of the contract governing HyClone and Celltrion's relationship, and because such a theory, if permitted, would contradict and subvert the specific, well-established statutory bases of infringement under the Patent Act. For Counts 2 and 3, alleging inducement by Celltrion and Hospira, respectively, there can be no dispute of material fact that Defendants lack the requisite specific intent to infringe, and that Hospira has not engaged in any acts that constitute "active inducement" of direct infringement. Accordingly, all of Janssen's claims for infringement of the '083 patent fail as a matter of law.

I. Summary Judgment Should be Awarded on Count 1 Because The Undisputed Record Does Not Support A Claim Of Vicarious Liability By Celltrion

Janssen's Count 1 in the 2016 Action alleges that Celltrion directly infringes the '083 patent under a vicarious liability theory. There is no triable question of fact under this Count.

A. Based On The Undisputed Facts, Janssen Cannot Establish That HyClone Is Celltrion's Agent Or Is Engaged In A Joint Enterprise

Janssen alleges that Celltrion is vicariously liable for direct infringement of the '083 patent by virtue of its "directing and controlling ***its agent*** HyClone's development of the infringing media" and because of its "participating in a contractual relationship pursuant to which HyClone continues to manufacture the infringing media." No. 16-11117, Dkt. 1 at ¶ 103 (emphasis added). However, the only material and undisputed evidence of the relationship between HyClone and Celltrion—the actual contract governing that relationship—clearly establishes that HyClone is ***not*** Celltrion's agent. [redacted] [redacted] SOF ¶ 24 (emphasis added). Under these facts, Janssen's assertion of vicarious liability of direct infringement fails as a matter of law.

When considering whether one entity may be held liable for the direct infringement of another entity under 35 U.S.C. § 271(a), the statutory section for direct infringement, the Federal Circuit has applied "general principles of vicarious liability" and "traditional agency principles." *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 797 F.3d 1020, 1022–23 (Fed. Cir. 2015) (en banc) (citing *BMC Res., Inc. v. Paymentech, L.P.*, 498 F.3d 1373, 1379–81 (Fed. Cir. 2007)).[3] The Federal Circuit also has applied agency principles of the state whose law governed the contract in question, where the parties agreed that the state law applied. *See Ericsson, Inc. v. D-Link Sys., Inc.*, 773 F.3d 1201, 1235 (Fed. Cir. 2014). Here, the contract between Celltrion and HyClone states their relationship is governed by New York law. SOF ¶ 23. Under New York law, and under federal common law agency principles and the Restatement of Agency, the express contract terms dictate that Janssen cannot establish that HyClone is Celltrion's agent.

"Agency is the fiduciary relationship that arises when one person (a 'principal') manifests assent to another person (an 'agent') that the agent shall act on the principal's behalf and subject to the principal's control, and the agent manifests assent or otherwise consents so to act." Restatement (Third) Of Agency § 1.01 (2006); *Maurillo v. Park Slope U-Haul*, 194 A.D.2d 142, 146 (N.Y. App. Div. 1993). Thus, where an agency relationship is alleged, the first inquiry is whether the alleged principal controls the alleged agent. *See id.*; *Centillion Data Sys., LLC v. Qwest Commc'ns Int'l, Inc.*, 631 F.3d 1279, 1286–87 (Fed. Cir. 2011) (discussing direction and

[3] *Akamai* held that a party could not avoid direct infringement liability in the context of a multi-step *method patent* by contracting with another party to perform one or more of the multiple claimed steps. *Akamai*, 797 F.3d at 1025. *Akamai* does not support the possibility of vicarious liability for direct infringement of claims directed to a product or composition, such as the '083 patent claims. *See Akamai Techs., Inc v. Limelight Networks, Inc.*, 786 F.3d 899, 910 (Fed. Cir.), *on reh'g en banc sub nom. Akamai Techs.*, 797 F.3d 1020, and *reh'g en banc granted, opinion vacated sub nom. Akamai Techs., Inc. v. Limelight Networks, Inc.*, 612 F. App'x 617 (Fed. Cir. 2015) ("only method claims can raise an issue of divided infringement"). Moreover, there is no dispute that Celltrion did not actually make the accused products or any part of them. SOF ¶ 18.

control); *Muniauction, Inc. v. Thomson Corp*., 532 F.3d 1318, 1329 (Fed. Cir. 2008) (same). Further, "[i]t is axiomatic…that the formation of an agency relationship requires the consent of both parties thereto." *All Boys Music, Ltd. v. DeGroot*, No. 89 CIV. 8258 (LMM), 1992 WL 51502, at *12 (S.D.N.Y. Mar. 9, 1992); *see also Ericsson, Inc*. 773 F.3d at 1236 (agency requires "(1) the principal manifested intent to grant authority to the agent, and (2) the agent agreed or consented to the agency relationship"); Restatement (Third) Of Agency § 1.01 (2006).

Critically, the agreement between Celltrion and HyClone establishes as a matter of law that HyClone is not Celltrion's agent. Celltrion's contract with HyClone is a "Supply Agreement" in which HyClone, [redacted] SOF ¶ 24. [redacted]

Id. (emphasis added).[4]

The Celltrion-HyClone agreement demonstrates that Celltrion does *not* control HyClone, and that neither party consented to such control. [redacted] Courts applying New York law have held that "[w]here an

[4] Although Janssen defines both Celltrion entities together as "Celltrion" (No. 16-11117, Dkt. 1 at 1), [redacted]. *See* SOF ¶ 21.

agreement specifically precludes the creation of an agency relationship, courts will not create one." *Tellium, Inc. v. Corning Inc.*, No. 03 CIV. 8487 (NRB), 2004 WL 307238, at *6 (S.D.N.Y. Feb. 13, 2004); *see also Encyclopedia Brown Prods., Ltd. v. Home Box Office, Inc.*, 25 F. Supp. 2d 395, 402–03 (S.D.N.Y. 1998) (no agency relationship where parties' agreement disclaimed one); *Butto v. Collecto Inc.*, 802 F. Supp. 2d 443, 449 (E.D.N.Y. 2011) (same); *Bellino Schwartz Padob Advert., Inc. v. Solaris Mktg. Grp., Inc.*, 222 A.D.2d 313, (N.Y. App. Div. 1995) (same). Under the Restatement of Agency, although statements disclaiming an agency relationship are not alone determinative, they are "relevant to determining whether the parties consent to a relationship of agency." Restatement (Third) Of Agency § 1.02 (2006), Cmts. "[O]ther indicia of consent" may be relevant as well. *Id.* When, as here, [redacted] summary judgment of no agency is appropriate. *See, e.g., In re Air Crash near Clarence Ctr.*, 18 N.Y.S.3d 500, 504 (N.Y. Sup. Ct. 2014) (finding no vicarious liability on summary judgment based on theories of agency and joint venture refuted by express contract stating "[n]othing in this Agreement shall be interpreted or construed as establishing between the parties a partnership, joint venture or other similar arrangement.").

Indeed, numerous parts of the Celltrion-HyClone contract confirm [redacted] and that no agency relationship exists. [redacted] SOF ¶ 25. As Janssen admits, HyClone did not even disclose the complete compositions of the accused media to any Celltrion employees until December 2013,

years after Celltrion began purchasing and using the media. No. 16-11117 Dkt. 1 at ¶¶ 75, 78–79; SOF ¶ 30.

Likewise, under the agreement, [redacted] SOF ¶ 26. In other words, even where, as here, the compositions allegedly contain some "customized" elements, [redacted] *Id.; see also* SOF ¶¶ 27–28. If HyClone were an agent of Celltrion and Celltrion controlled HyClone, [redacted] *Cf. Cahill v. Regan*, 4 A.D.2d 328, 329 (2d App. Div. 1957), *aff'd*, 157 N.E.2d 505 (N.Y. 1959) ("[I]f the employee is hired to invent, or is assigned the duty of devoting his efforts to a particular problem, a resulting invention belongs to the employer."). Each of the above provisions in the Celltrion-HyClone contract, [redacted] likewise show as a matter of law that the parties are independent entities in an arm's-length buyer-seller arrangement, and demonstrate that Celltrion does not control HyClone. SOF ¶ 29.

Although Janssen alleges that Celltrion exercised "control" over the "development" of the accused compositions and "over the formulation of the media," and that HyClone developed the media "[a]t Celltrion's direction and under Celltrion's control" (No. 16-11117 Dkt. 1 at ¶¶ 72, 101), these allegations are directly contradicted by the express and controlling language of the parties' contract. Under clear law, Janssen cannot create a genuine dispute of material fact or raise a triable issue by disagreeing with the unambiguous contract governing the parties' relationship. *See, e.g., Cargill, Inc. v. Canbra Foods, Ltd.*, 476 F.3d 1359, 1369–70 (Fed. Cir. 2007) (affirming summary judgment of invalidity where patentee attempted to avoid that result

by raising alleged fact disputes contradicting the "unambiguous" written instrument at issue); *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 424 F.3d 1276, 1281–84 (Fed. Cir. 2005) (affirming summary judgment of invalidity where patentee attempted to avoid that result by raising alleged fact disputes contradicting the "plain language" of the written instrument at issue).

In short, based on the express terms of the Celltrion-HyClone agreement, Janssen cannot establish the key missing element of an agency relationship required for its direct infringement theory against Celltrion. The Federal Circuit has affirmed summary judgment of no infringement based on a patentee's theory of vicarious liability of direct infringement of a method patent where the alleged joint actors had a Memorandum of Understanding ("MOU") lacking "any express or implicit agreement" that the parties acted on one another's behalf or were "subject to [the other's] control, as an agency relationship would require." *Travel Sentry, Inc. v. Tropp*, 497 F. App'x 958, 962 (Fed. Cir. 2012) (citing *Dixson v. United States*, 465 U.S. 482, 505 (1984) (quoting Restatement (Second) of Agency § 1 (1957))). Here, the parties have more than an MOU; they have an express agreement setting out [redacted]

Finally, although Janssen's Complaint in the 2016 Action does not state a claim for direct infringement by Celltrion under a "joint enterprise" theory (No. 16-11117 Dkt. 1 at ¶¶ 100–107), Janssen has indicated, including during the October 6, 2016 status conference with the Court, that it intends to attempt to show infringement under such a theory. Infringement of a product claim by a "joint enterprise" under the circumstances here is not a legally cognizable theory of direct infringement, as discussed in more detail below. But even assuming it were a valid theory, the Celltrion-HyClone agreement also forecloses the possibility of a joint enterprise, for the same reasons set forth above. Where the Federal Circuit has recently found infringement by a joint

enterprise possible, in the limited context of a method patent, it has applied principles of mutual agency, requiring "an equal right [by all alleged members of the joint enterprise] to a voice in the direction of the enterprise, which gives an equal right of control." *Akamai*, 797 F.3d at 1023 (citing Restatement (Second) of Torts § 491 cmt. b, c ("The law…considers that each is the agent or servant of the others, and that the act of any one within the scope of the enterprise is to be charged vicariously against the rest."). Because the Celltrion-HyClone agreement [redacted] they also cannot be part of a joint enterprise. SOF ¶¶ 21–30. Based on the undisputed evidence of HyClone and Celltrion's relationship, Count 1 must fail.

B. Permitting a Claim for Direct Infringement Liability Under the Undisputed Facts Would Conflict With and Subvert the Patent Act

Janssen's agency theory of direct liability by Celltrion—and its joint infringement theory, to the extent it maintains one—also are unsupported by Federal Circuit precedent, and fail based on firmly rooted principles of patent law.

The Patent Act codified in Title 35 expressly includes two ways in which a person who has not engaged in acts of direct infringement may be found liable for patent infringement: "actively induc[ing] infringement of a patent" by another, under 35 U.S.C. § 271(b), and contributory infringement under 35 U.S.C. § 271(c). Under Congress's regime, "direct infringement, and the two types of indirect infringement—contributory and induced—are 'distinct concepts with distinct standards.'" *Zoetis LLC v. Roadrunner Pharm., Inc.*, No. 15-3193, 2016 WL 755622, at *4 (D.N.J. Feb. 25, 2016) (quoting *In re Bill of Lading Transmission and Processing Sys. Patent Litig.*, 681 F.3d 1323, 1333 (Fed. Cir. 2012)). The Federal Circuit has instructed that courts should not "expand[] the rules governing direct infringement to reach

independent conduct of multiple actors," because to do so "would subvert the statutory scheme for indirect infringement." *BMC*, 498 F.3d at 1381.

HyClone and Celltrion's relationship is one of "mere 'arms-length cooperation'" between independent entities that should not "give rise to direct infringement" by Celltrion. *Muniauction*, 532 F.3d at 1329 (internal citations omitted). Permitting Celltrion to be held liable for HyClone's manufacture of the accused products Celltrion purchases, either under an agency theory or under a joint enterprise theory, would impermissibly "expand[] the rules governing direct infringement to reach independent conduct of multiple actors" in a way that would improperly "subvert the statutory scheme for indirect infringement." *BMC*, 498 F.3d at 1381. As one court has acknowledged, "[t]o allow a vicarious liability claim based solely on a customer relationship[] . . . would run afoul of the Federal Circuit's warning in *BMC* that 'expanding the rules governing direct infringement to reach independent conduct of multiple actors would subvert the statutory scheme for indirect infringement.'" *Joao Control & Monitoring Sys. of Cal., LLC v. Sling Media, Inc*., No. C-11-6277 EMC, 2012 WL 3249510, at *7 (N.D. Cal. Aug. 7, 2012) (quoting *BMC*, 498 F.3d at 1381). Defendants are aware of no case finding direct infringement, either under an agency theory or a joint enterprise theory of liability, under the undisputed facts present in this case—that is, where one party is alleged to vicariously infringe a patent on a product by entering into an agreement to purchase it. This is not surprising. To permit a claim for direct liability in such circumstances would fly in the face of the statutory regime for indirect infringement, under which Congress and the courts have established specific and stringent requirements related to the type of "active" conduct and specific intent that must be shown before a litigant may be held liable for acts of alleged direct infringement that take place entirely at the hands of a third party. To countenance Janssen's

vicarious direct liability theory here would turn 35 U.S.C. § 271 on its head and subject countless purchasers of goods to liability for patent infringement without any requirement that they know that the goods in question infringe, or even have knowledge of the patent alleged to be infringed.

Because Janssen's theory of direct infringement by Celltrion contradicts the undisputed evidence and is legally unsupported, summary judgment on Count 1 should be granted.

II. Count 2 Fails As a Matter Of Law Because There Is No Genuine Dispute That Celltrion Lacks The Requisite Intent to Induce

Count 2 alleges that Celltrion has induced HyClone to infringe the '083 patent, in violation of 35 U.S.C. § 271(b), which imposes liability for persons who "actively induce[] infringement of a patent." To prove this claim, Janssen must show that Celltrion had both "specific intent and action to induce infringement." *Takeda Pharm. U.S.A., Inc. v. W.-Ward Pharm. Corp.*, 785 F.3d 625, 631 (Fed. Cir. 2015). Janssen cannot prove specific intent by Celltrion to induce direct infringement of the '083 patent, and Janssen's Count 2 must fail.

The Supreme Court has held twice in recent years that a party cannot violate § 271(b) without both (1) "knowledge of the existence of the patent that is infringed" and (2) "knowledge that the induced acts constitute patent infringement" at the time of the alleged acts of inducement. *Global-Tech*, 563 U.S. at 765–66; *see also Commil USA, LLC V. Cisco Sys., Inc.*, 135 S. Ct. 1920, 1926 (2015). This, of course, means that a party cannot be liable for induced infringement if "he did not know the acts were infringing" at the time when he is alleged to have committed the acts amounting to active inducement. *Id.* at 1928; *see also Global-Tech*, 563 U.S. at 760; *see also Ecolab, Inc. v. FMC Corp.*, 569 F.3d 1335, 1351 (Fed. Cir. 2009). A good-faith belief of non-infringement defeats an allegation that an accused inducer lacked the intent required to be held liable for induced infringement. *Commil USA, LLC v. Cisco Sys., Inc.*, 720

F.3d 1361, 1367–68 (Fed. Cir. 2013), *vacated in part*, 135 S. Ct. 1920; *see also Global-Tech*, 563 U.S. at 766.

Here, Janssen cannot establish that Celltrion had "knowledge that the induced acts constitute patent infringement," as a matter of law, because Janssen ***admits*** that at least twelve claim limitations of the asserted claims of the '083 patent are not literally met by the accused products made by HyClone. Claim 1 of the '083 patent recites "[a] soluble composition, suitable for producing a final volume of cell culture media, wherein the composition comprises the following components in the following amounts per liter of the final volume of cell culture media," and lists 61 different ingredients present in specified concentration ranges. SOF ¶ 11. Claim 2 is dependent upon claim 1 and therefore also requires the 61 ingredients in specific concentration ranges, and also adds the requirement of "a buffering molecule with a pKa between 5.9 and 7.8 and a cell protectant." SOF ¶ 12. It is undisputed that at least twelve of the claimed ingredient concentrations are ***not*** present in the accused HyClone products that Celltrion has purchased and used. Indeed, Janssen has admitted that "it is true that twelve ingredients fall outside the literal ranges of" claim 1 of the '083 patent, and thus, "10% of the limitations (12 out of 122) are not met literally." SOF ¶ 15. Thus, even assuming that Celltrion knew the ingredients and concentrations of the accused HyClone products, Janssen could not establish that Celltrion specifically intended to infringe any '083 patent claim.

As noted already, because the accused products are literally outside of the scope of the asserted claims in at least twelve different ways, Janssen's direct infringement theory is, and must be, premised entirely on the DOE, under which "a product or process that does not literally infringe upon the express terms of a patent claim may nonetheless be found to infringe if there is 'equivalence' between the elements of the accused product or process and the claimed elements

of the patented invention." *Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 21 (1997) (citation omitted). Defendants are aware of no case in the more than five years since the Supreme Court decision in *Global-Tech* in which inducement was found based solely on infringement under the DOE, and are aware of no case finding infringement under the DOE where twelve limitations of the asserted claims were not present in the accused product.

Moreover, the Supreme Court has warned "that the doctrine of equivalents, when applied broadly, conflicts with the definitional and public-notice functions of the statutory claiming requirement." *Warner-Jenkinson*, 520 U.S. at 29. For this reason, "the doctrine, even as to an individual element, is not allowed such broad play as to effectively eliminate that element in its entirety." *Id.* "Thus, if a…finding of infringement under the doctrine of equivalents 'would entirely vitiate a particular claimed element,' then the court should rule that there is no infringement." *Lockheed Martin Corp. v. Space Sys./Loral, Inc*., 324 F.3d 1308, 1321 (Fed. Cir. 2003) (citations omitted). Janssen's DOE infringement theory runs afoul of this critical and well-established limitation on the DOE. The accused products, according to Janssen's own analysis, contain recited ingredients in concentrations that are in some cases more than twice the upper limit, or less than half of the lower limit, of the recited concentration range. SOF ¶ 16. Thus, in claiming that the accused products infringe the '083 patent under the DOE, Janssen stretches limitations of the claims so far as to render them nullities, running afoul of the rule that "a potential competitor is entitled to fair notice of what will infringe a patent under the doctrine of equivalents...." *Biogen, Inc. v. Berlex Labs.*, Inc., 113 F. Supp. 2d 77 (D. Mass. 2000).

Finally, to attempt to establish direct infringement under the DOE—indeed, even to attempt to plead direct infringement under the DOE in its complaint—Janssen had to perform elaborate, $1 million tests on the accused products, kept confidential in discovery, in an effort to

compare them to the compositions claimed in the '083 patent. *See* No. 16-1117 Dkt. 1 at ¶¶ 82–94; SOF ¶ 17. But Janssen has put forth no evidence that Celltrion performed the same or comparable testing or had any reason to believe that HyClone's compositions could be alleged by Janssen to constitute infringement under its complex, twelve-way DOE theory. Thus, even under an assumption that Janssen's DOE theory of infringement has merit (it does not), Janssen cannot prove inducement, because it cannot provide any evidence that Defendants knew and specifically intended that the accused products infringe under Janssen's DOE theory.

The foregoing undisputed facts—that the accused products are literally outside of the scope of the asserted claims in at least twelve different ways, that Janssen's DOE theory is one of unprecedented breadth and is contrary to Supreme Court precedent, and that Janssen's attempt to plead a DOE claim involved complicated testing which, setting aside its shortcomings, Celltrion is not alleged to have carried out—prevent Janssen, as a matter of law, from claiming that Celltrion lacks a good-faith belief of non-infringement. Under such circumstances, there can be no inducement. Summary judgment on Count 2 must be granted.

III. Count 3 Fails As A Matter Of Law Because There Is No Genuine Dispute That Hospira Lacks The Requisite Intent To Induce, And Because There Is No Genuine Dispute That Hospira Does Not "Actively Induce"

Janssen's Count 3 alleges that Hospira has induced infringement by Celltrion and HyClone under 35 U.S.C. § 271(b). Janssen's allegation of inducement by Hospira fails as a matter of law for at least the same reason its allegation of inducement by Celltrion fails: Janssen's allegation that Hospira had "actual knowledge, or was willfully blind to the fact that, Celltrion's custom-made media infringe claims 1-2 of the 083 patent" is unsupported, and indeed, contradicted, by the undisputed evidence. No. 16-11117 Dkt. 1 at ¶ 117. As explained above in Section II, Janssen admits at least twelve limitations of the asserted claims are not met by the accused HyClone products. The only purported basis for direct infringement—that the

accused compositions are different than the claimed compositions in at least twelve different ways but are nonetheless "equivalent" to the claimed compositions in those at least twelve ways—is unprecedented, contrary to established law, and in and of itself creates an objective, good-faith non-infringement defense. Moreover, as explained above, Janssen has no evidence showing the requisite knowledge of infringement and specific intent to infringe even under its twelve-way DOE theory. For the reasons set forth in Section II, Janssen cannot establish that Hospira had the requisite "knowledge that the induced acts constitute patent infringement." *Global-Tech*, 563 U.S. at 765–66. The inducement claim fails as a matter of law.

Janssen's claim that Hospira induces infringement also fails for the additional reason that Janssen has provided no evidence that any conduct by Hospira constitutes "actively induc[ing]" infringement under 35 U.S.C. § 271(b). The "adverb 'actively'" in § 271(b) "suggests that the inducement must involve the taking of affirmative steps to bring about" the infringement. *Global-Tech*, 563 U.S. at 760. Inducement based on "active steps taken to encourage direct infringement" can be found, for example, where the alleged inducer provides "instructi[ons on] how to engage in an infringing use" or where there is "evidence [of] intent to encourage infringement." *Takeda*, 785 F.3d at 630-631 (citations and quotations omitted). Put differently, "inducement requires evidence of culpable conduct, directed to encouraging another's infringement." *DSU Med. Corp. v. JMS Co. Ltd.*, 471 F.3d 1293, 1306 (Fed. Cir. 2006) (en banc). It is not sufficient that the alleged inducer "merely…had knowledge of the direct infringer's activities." *Id.* (citations omitted).

Janssen claims in Count 3 that Hospira "actively induced" infringement by Celltrion and HyClone "by entering into one or more agreements with Celltrion to market and distribute" biosimilar infliximab and that "Hospira has ordered and sold its infliximab products outside of

the United States," knowing that infliximab is made using media (or more accurately, components of media) "made in the United States." No. 16-11117, Dkt. 1 at ¶ 118.[5] These alleged facts, even taken as true, cannot be "active" or "affirmative steps to bring about" the alleged infringement. Janssen has not put forth any evidence that Hospira has encouraged or instructed HyClone to make the accused products, or encouraged or instructed Celltrion to purchase or use the accused products, much less that Hospira had any intent to encourage or instruct that such activities take place. Indeed, [redacted] SOF ¶¶ 31–33; *epicRealm, Licensing, LLC v. Autoflex Leasing, Inc.*, 492 F. Supp. 2d 608, 638–39 (E.D. Tex. 2007) (no inducement as a matter of law where alleged inducer entered into "arm's-length contract to purchase…services" that "could be provided in a noninfringing manner and did not encourage [alleged direct infringer] to use the allegedly infringing systems and methods"). The most Janssen can establish is knowledge by Hospira that Celltrion has made biosimilar infliximab in South Korea, using cell culture media that included compositions made in the United States. This mere "knowledge of the [alleged] direct infringer's activities" is insufficient as a matter of law to establish inducement. *DSU*, 471 F.3d at 1306. Hospira cannot be liable for inducement as asserted in Count 3, and summary judgment must be granted.[6]

[5] Janssen's use of the term "media" in its complaints is confusing. [redacted]

[6] Count 3 also fails at least with respect to the allegation that Hospira induced Celltrion's alleged infringement, because Janssen cannot establish that Celltrion has directly infringed the '083 patent. *See* Section I, *supra*. An inducer "must have 'knowingly aided and abetted'

IV. Summary Judgment Should Be Granted On Count 6 In The 2015 Action, Which Is Based On The Same Theories Of Liability As Counts 1, 2, And 3 In The 2016 Action

Count 6 of the complaint in the 2015 Action asserts infringement of the '083 patent on the basis that Defendants allegedly committed a technical act of infringement under the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"). Dkt. 1 at ¶ 172. Janssen's BPCIA claim, however, requires it to establish at least one act of patent infringement under 35 U.S.C. § 271. *See Amgen, Inc. v. Sandoz, Inc.*, 794 F.3d 1347, 1352, 1356–57 (Fed. Cir. 2015); 42 U.S.C. § 262(l). The only theories of infringement Janssen has advanced are those set forth in its complaint in the 2016 Action. SOF ¶¶ 18–19. With the 2015 and 2016 Actions consolidated, and the parties having stipulated that discovery concerning the '083 patent that has taken place in the 2015 Action applies to both actions (*see* Dkt. 212), judgment in Defendants' favor on Counts 1–3 in the 2016 Action necessarily means judgment in Defendants' favor on Count 6 in the 2015 Action. Claim preclusion and issue preclusion also would bar relitigation of Count 6. *Caballero-Rivera v. Chase Manhattan Bank, N.A.*, 276 F.3d 85, 87 (1st Cir. 2002); *Dowd v. Soc'y of St. Columban*s, 861 F.2d 761, 764 (1st Cir. 1988); *Grella v. Salem Five Cent Sav. Bank*, 42 F.3d 26, 30 (1st Cir. 1994) (internal quotation marks and citations omitted).[7]

CONCLUSION

For the foregoing reasons, the Court should grant Defendants' motion for partial summary judgment of non-infringement of the '083 patent.

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direct infringement." *Takeda*, 785 F.3d at 630 (emphasis added). Because Celltrion has not committed direct infringement, Hospira cannot have induced Celltrion.

[7] Aside from the Counts addressed in this motion, the only remaining Count in the litigation is Count 1 in the 2016 Action, which asserts that "Defendants have failed to comply with the mandatory requirements of the BPCIA" with respect to providing certain pre-litigation information to Janssen. Dkt. 1 at ¶¶ 137–44. Defendants have explained to Janssen that there is no basis for this claim and no cognizable injury, and that the claim is moot or at a minimum will be moot if the patent infringement claims are disposed of. Janssen has declined to dismiss the BPCIA Count and has not explained its basis for maintaining it.

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Respectfully submitted,

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By their attorneys,

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CERTIFICATE OF SERVICE

I, Andrea L. Martin, hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-registered participants on October 19, 2016.

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