IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

JANSSEN BIOTECH, INC. Plaintiff, 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 – FILED UNDER SEAL**

DEFENDANTS' REPLY IN SUPPORT OF MOTION FOR PARTIAL SUMMARY JUDGMENT

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Janssen's response—replete with adverbs, invective, and immaterial facts—uses "strong" prose to try and mask a weak case. Partial summary judgment should be entered for Defendants.

First, Janssen's claim of direct infringement by Celltrion raises a pure issue of law: Can a purchaser of custom-made products be held directly liable for the alleged infringing acts of its supplier? The answer is no. Such a claim must satisfy the elements for induced infringement. Janssen invokes *Akamai v. Limelight*, which addresses "divided infringement" of "a claimed method." *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 797 F.3d 1020, 1022 (Fed. Cir. 2015) (en banc). But the instant case does not involve a method—it involves cell culture media compositions. The distinction is critical, and Janssen's unprecedented effort to hold Celltrion vicariously liable for HyClone's alleged infringement is legally flawed.

Second, Janssen has failed to raise a triable issue as to whether Defendants specifically intend to induce infringement. As Janssen admits, the accused products do not literally infringe in at least twelve different ways. Janssen argues that Defendants know that Janssen's expert has offered a disputed opinion on infringement under the doctrine of equivalents, but even knowledge of possible infringement is not enough. Supreme Court precedent "requires more" than "kn[owledge] the acts might infringe"; the defendant must "know the acts were infringing," or be willfully blind to that fact. *Commil USA, LLC v. Cisco Sys., Inc.*, 135 S. Ct. 1920, 1928 (2015). Janssen has no evidence of either type of knowledge. A plausible defense defeats the claim, and Janssen cannot deny Defendants' reasonable, good-faith basis for non-infringement.

Finally, in addition to all the flaws in Janssen's case against Celltrion, Hospira is even further removed from knowing and active inducement. Hospira merely purchases finished infliximab produced by Celltrion. Janssen offers no evidence that Hospira specifically intended any direct infringement Janssen alleges, or that it engaged in "culpable conduct, directed to encour-

aging" it. *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1306 (Fed. Cir. 2006) (en banc). Janssen's failure to create a triable question of fact requires judgment in Hospira's favor.

I. Count 1 Alleging Direct Infringement By Celltrion Fails As A Matter Of Law

A. Janssen Has No Viable Claim For Direct Infringement Under *Limelight*

According to Janssen, *Limelight* "sets forth the controlling legal standard" for its claim that Celltrion directly infringes the '083 patent. Dkt. 281 at 3. "Sitting en banc," the Federal Circuit in *Limelight* "unanimously set forth the law of divided infringement under 35 U.S.C. § 271(a)." *Limelight*, 797 F.3d at 1022. At the outset, the Court held that "an actor is liable for infringement under § 271(a)" in two scenarios: ***either*** the actor "acts through an agent (applying traditional agency principles)," ***or*** the actor "contracts with another to perform one or more steps of a claimed method." *Id*. at 1023. Regarding the latter form of direct infringement, the Court identified "two sets of circumstances" for liability: "(1) where that entity directs or controls others' performance, and (2) where the actors form a joint enterprise." *Id.* at 1022.

As for agency, Janssen has not raised a triable issue of fact as to whether HyClone acted as Celltrion's agent. Indeed, Janssen appears to have abandoned its agency theory of liability, now claiming instead that "whether HyClone is Celltrion's agent or not," the evidence shows direct infringement under a different theory. Dkt. 281 at 4, 8. This is not surprising, because it is clear HyClone is not Celltrion's agent under "traditional agency principles" for all the reasons set forth in Defendants' opening brief. *Limelight*, 797 F.3d at 1023; Dkt. 265 at 6–12. In short, the parties' "mere 'arms-length cooperation'" does "not give rise to direct infringement." *Muniauction, Inc. v. Thomson Corp.*, 532 F. 3d 1318, 1329 (Fed. Cir. 2008).

Janssen tries to save Count 1 by distorting the second form of liability under *Limelight*—"contract[ing] with another to perform one or more steps of a claimed method"—as supporting a new and legally erroneous theory: that Celltrion may be liable as a direct infringer because the

"Supply Agreement provides for 'Custom' cell culture media to be supplied to Celltrion by Hy-Clone[.]" Dkt. 281 at 5. *Limelight* provides no basis for this theory.

Limelight's "directs or controls" and "joint enterprise" bases for divided infringement apply to ***method claims***, as *Limelight* made clear repeatedly. 797 F.3d at 1022 ("We will hold an entity responsible for others' performance of method steps …"); *id*. at 1023 ("[A]n actor is liable…if it…contracts with another to perform one or more steps of a claimed method."); *id*. ("[T]o determine direct infringement, we consider whether all method steps can be attributed to a single entity."); *id.* ("[O]ther factual scenarios may arise which warrant attributing others' performance of method steps to a single actor."). Since *Limelight*, the Federal Circuit has confirmed that it has "applied joint infringement to method claims and not system claims." *Lyda v. CBS Corp.*, 838 F.3d 1331, 1338–39 (Fed. Cir. 2016).[1] It is undisputed that the claims here are directed to products. Dkt. 277 ¶¶ 11–12. The circumstances in which *Limelight* permits "hold[ing] an entity responsible for others' performance of method steps" are categorically inapposite.

The distinction between method and product claims is critical, and makes sense. Before *Limelight*, a party could avoid infringement of a method claim by having different parties perform steps of the method, leaving the patentee without any action for direct infringement. The same cannot be said for a product claim. *See, e.g.*, *Akamai Techs., Inc. v. Limelight Networks, Inc*., 692 F.3d 1301, 1305–06 (Fed. Cir. 2012), *rev'd*, 134 S. Ct. 2111 (2014) ("When claims are directed to a product or apparatus, direct infringement is always present," but parties "can often

[1] *See also* Federal Circuit Bar Association Model Patent Jury Instructions (2016), B.3 3.7, https://fedcirbar.org/IntegralSource/Model-Patent-Jury-Instructions; A. Fischer, et al., *Expansion of Direct Infringement in Federal Circuit's Akamai Decision a Big Win for Patent Holders*, The Biologics Law Blog of Patterson Belknap Webb & Tyler LLP (Aug. 13, 2015), http://www.biologicsblog.com/blog/expansion-direct-infringement-federal-circuits-akamai-decision-big-win-patent-holders.

arrange to share performance of the claimed [method] steps between them.").[2] The present case illustrates this very principle: Janssen alleges that HyClone made the accused products and is a direct infringer, and has filed a separate infringement action against HyClone. Dkt. 277 ¶ 20.

Claiming that "[c]ontractual arrangements such as the Celltrion/HyClone contracts have repeatedly been found to give rise to direct infringement" (Dkt. 281 at 6), Janssen cites but a single post-*Limelight* decision from a district court in Wisconsin, *Wisconsin Alumni Research Foundation v. Apple, Inc.*, No. 14-62, 2015 WL 6453842 (W.D. Wis. Oct. 26, 2015) *("WARF")*. But the decision in *WARF*, which has not been appealed, involved questions of damages, not the sufficiency of evidence to create a triable question on liability. *Id.* at *3–4.[3] The remainder of Janssen's cases predate *Limelight*, and therefore cannot have applied *Limelight*, Janssen's "controlling legal standard for establishing direct infringement." Dkt. 281 at 6 & n.2, 3.[4]

In short, Janssen has not even attempted to meet its burden of showing a triable issue of fact as to agency, and *Limelight*'s "unanimous[] set[ting] forth [of] the law of divided infringement under 35 U.S.C. § 271(a)" does not countenance the theory that Celltrion may be liable as a

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[2] *See also* T. Mikaelian, *Divided Infringement of Method Claims: Federal Circuit Broadens Direct Infringement Liability, Retains Single Entity Restriction*, 49 SUFFOLK U. L. REV. 343, 346–47 (2016).

[3] *WARF*'s facts differ as well. The evidence of "sufficient control over Samsung's manufacturing process" was due in part to Samsung's use of "Apple's specifications" to make products "to be used only in Apple's end products." *Id*. [redacted] Dkt. 277 ¶¶ 26, 30; SOF ¶ 34.

Janssen's pre-*Limelight* cases are distinguishable in any event. *Rowe* involved a seller of jukeboxes and jukebox networks who contracted out to others manufacture of certain components. *Rowe Int'l Corp. v. Ecast, Inc.*, 586 F. Supp. 2d 924, 933 (N.D. Ill. 2008). *TGIP* involved multiple actors alleged to have contributed components of claimed systems or "performed steps essential to" claimed methods. *TGIP, Inc. v. AT&T Corp.*, 527 F. Supp. 2d 561, 577–78 (E.D. Tex. 2007). There is no allegation that Celltrion makes any component of the accused products. *Pellegrini* and *Lineguard* referenced traditional agency principles, which, as discussed already, do not apply here. *Pellegrini v. Analog Devices*, 375 F.3d 1113, 1118 (Fed. Cir. 2004); *Lineguard, Inc. v. Linetec, Inc.*, 1987 WL 11832, at *1 (N.D. Ill. June 1, 1987).

direct infringer because it purchases an alleged "custom" product. *Limelight*, 797 F.3d at 1022.

B. Janssen's Unprecedented Theory Would Subvert 35 U.S.C. §§ 271(a) And (b)

As discussed in Defendants' opening brief, § 271(b) addresses situations where one entity induces another to engage in an infringing act. Congress created a higher burden for this type of liability, requiring not only knowledge but specific intent. *Commil*, 135 S. Ct. at 1927–28. But under Janssen's view of the law, any foreign purchaser who requests particular features when buying a car, computer, or myriad other items of commerce would be liable for infringement if the supplier were to make an infringing product—without any showing of the purchaser's mental state. That is not the law. Expanding *Limelight* as Janssen proposes "would subvert the statutory scheme for indirect infringement." *BMC Res., Inc. v. Paymentech, L.P.*, 498 F.3d 1373, 1381 (Fed. Cir. 2007). Janssen effectively concedes as much in arguing that the same facts make Celltrion liable under both §§ 271(a) and (b).

Section 271(a)'s inapplicability to Celltrion's alleged conduct is further supported by the text of the statute, and "[t]he traditional understanding that our patent law 'operates only domestically and does not extend to foreign activities,'" an understanding "embedded in the Patent Act itself." *Microsoft Corp. v. AT & T Corp.*, 550 U.S. 437, 455 (2007). Indeed, § 271(a) by its express terms is limited to one who "makes, uses, offers to sell, or sells any patented invention, ***within the United States*** or imports into the United States any patented invention…" What Janssen proposes would radically change the law of § 271(a), particularly for foreign purchasers like Celltrion, who are presumed not to be liable for infringement because their use of a product is overseas. *Cf. Microsoft*, 550 U.S. at 454 (2007) ("Any doubt that Microsoft's conduct falls outside § 271(f)'s compass would be resolved by the presumption against extraterritoriality…").

II. Count 2 Alleging Inducement By Celltrion And Hospira Fails As A Matter Of Law

To prove inducement under § 271(b), Janssen must prove that Defendants "knew the acts

[at issue] were infringing." *Commil*, 135 S. Ct. at 1928; *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 766 (2011). Janssen has no such proof. Moreover, Defendants have an undisputed, objectively reasonable basis for non-infringement. To avoid summary judgment, Janssen must establish the existence of a genuine and material question of fact. *Mottolo v. Fireman's Fund Ins. Co.*, 43 F.3d 723, 725 (1st 1995). Janssen has not done this.

A. Janssen Has Put Forth No Evidence Raising A Triable Issue As To Intent

Janssen has presented ***no*** direct evidence of subjective, specific intent to induce infringement. Instead, Janssen points to three types of purported circumstantial evidence: (1) "experimental results" that Janssen claims show direct infringement; (2) allegations that Defendants "hid" information about accused products; and (3) Defendants' [redacted] None raises a material factual dispute as to whether Defendants acted with specific intent to cause infringement.

1. Janssen's Purported Evidence Is Not Evidence Of Specific Intent

In attempting to show that "Defendants were well aware" of the alleged direct infringement, Janssen relies on the "same evidence" that allegedly shows direct infringement—Janssen's "experiments." Dkt. 281 at 16, 14; Dkt. 282 ¶ 72. For at least three reasons, Janssen's "experiments"—which it claims are "strong" evidence of infringement, but which Defendants dispute—do not create a triable question of fact as to specific intent. Dkt. 281 at 14.

First, Janssen has offered literally no evidence—not one stitch—that any decision maker of Defendants' agrees with Janssen's experts' analysis. Janssen's reliance on its purported evidence of direct infringement is thus reduced to an argument that Defendants should have known that the accused products infringe. That is not enough. The Patent Act "requires more" than "kn[owledge] the acts might infringe"; the defendant must "kn[o]w the acts were infringing," or at least be willfully blind to that fact. *Commil,* 135 S. Ct. at 1928. Janssen's expert's "experi-

mental data" do not establish Defendants' "subjective state of mind." Dkt. 281 at 9. *See, e.g.*, *Tecsec, Inc. v. Int'l Bus. Mach. Corp.*, 769 F. Supp. 2d 997, 1015 (E.D. Va. 2011), *rev'd in part on other grounds*, 731 F.3d 1336 (Fed. Cir. 2013) (granting summary judgment of no inducement where "TecSec merely referenced its infringement contentions and expert reports, neither of which contains any evidence that IBM intended to cause infringement, or that it took actions knowing that those actions would result in infringement by third parties.").

Second, Janssen has conceded that its expert's opinions are subject to at least reasonable debate. Earlier this year, Janssen told the Court that "there are differences between [the accused] cell media and our patent claims," and that Janssen was "studying them extremely closely" and "gathering evidence that would support a preliminary injunction." Feb. 9, 2016 Status Conf. Tr. at 43:9–14. Janssen further stated, "We will not file [a motion for preliminary injunction] unless we have that evidence" and "unless we think we can win it." *Id.* at 43:14–15, 44:4–5. After receiving its expert's test results, Janssen opted not to seek a preliminary injunction. That Janssen could not even show "likelihood of success on the merits" alone forecloses the notion that its tests could somehow permit an inference that Defendants "knew the [accused] acts were infringing," or were willfully blind to the same. *Commil*, 135 S. Ct. at 1928.

Third, even if Janssen had presented evidence that Defendants knew their acts were infringing, Janssen has not created a triable question of fact regarding whether Defendants took any "affirmative steps" to bring about infringement at a time when Janssen claims they had knowledge of direct infringement. *See Global-Tech*, 563 U.S. at 766; *Commil*, 135 S.Ct. at 1926; *Walker Digital, LLC v. Facebook, Inc.*, 852 F. Supp. 2d 559, 565 (D. Del. 2012) (plaintiff "prohibited from collecting damages related to indirect infringement for any pre-knowledge" conduct). According to Janssen, to "assess infringement," Defendants "needed" to "read Janssen's

laboratory report." Dkt. 281 at 15. But the first time Janssen's "laboratory report" reflecting tests performed by Janssen's paid expert was provided to Defendants—and the first time Janssen "detailed" its infringement allegations, as it claims—was when Janssen served its opening expert reports on August 31, 2016. Dkt. 282 ¶ 72. Janssen has not alleged any acts it claims were affirmative steps to bring about infringement after this time.

Also problematic, Janssen's expert reports, and its April 2016 version of a report on results of certain testing, were provided confidentially under the protective order, accessible only to outside counsel and limited in-house counsel, restricted to use only for purposes of the litigation. *Id.* ¶ 72; SOF ¶ 35; Dkt. 170 ¶ 9. Janssen does not explain how such reports could convey the requisite knowledge. The only non-confidential provision of any portion of Janssen's "laboratory report" was when Janssen included select data in its June 2016 complaint. No. 16-11117 Dkt. 1 ¶¶ 84–98. For all the reasons discussed above, Janssen cannot meet its burden of showing a genuine issue of material fact regarding specific intent to induce infringement by pointing to nothing more than the allegations of infringement set forth in its complaint.[5,6]

2. Janssen's Other Purported Evidence May Not Be Considered

According to Janssen, Defendants allegedly "hid" information about the accused HyClone media products, thus creating circumstantial evidence of specific intent to infringe. Dkt. 281 at 13. Janssen mischaracterizes the facts. Resp. to SOF ¶¶ 29–66. Regardless, numerous

[5] Cases Janssen cites from the motion to dismiss context are inapposite. Dkt. 281 at 15 & n.5; *Walker Digital*, 852 F. Supp. at 565; *Script Sec. Solutions LLC v. Amazon.com, Inc.*, 170 F. Supp. 3d 928, 936–38 (E.D. Tex. 2016). Pleading a case for inducement based on an allegation in a complaint is not the same as showing a genuine issue of material fact for trial based on such an allegation.

[6] Janssen asserts that Defendants "conced[e] infringement for purposes of this motion" and "the Court [m]ust [a]ssume [i]nfringement for [p]urposes of this [m]otion." Dkt. 281 at 9, 14. This is not correct. It remains Janssen's burden to prove direct infringement. Defendants dispute that the accused products infringe, and dispute that the differences between the asserted claims and the accused products are "insubstantial." *Id*. at 15. But summary judgment is warranted for reasons separate from these disputes. Fed. R. Civ. P. 56.

problems with this purported "evidence" render it inadmissible and immaterial. Janssen's claim that Defendants "hid" information is based on a 41-paragraph declaration from outside counsel, Irena Royzman, which is chock full of attorney argument and characterizations about Defendants' outside counsel's statements during discovery. *See* Dkt. 281 at 13–14; Dkt. 283. "Attorney argument is no substitute for evidence" (*Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 424 F.3d 1276, 1284 (Fed. Cir. 2005)), and Plaintiffs' counsel's characterizations of discovery disputes are hardly evidence of Defendants' state of mind.

Indeed, it appears Janssen is not making Ms. Royzman available to testify, making her declaration incapable of raising a triable question of fact. SOF ¶ 36. Moreover, many of Ms. Royzman's statements (or those of a different attorney about her statements) are inadmissible hearsay. *Id.*; Dkt. 283; Fed. R. Evid. 801, 802. The declaration suffers from the additional problem that it puts Janssen's state of mind at issue. *See, e.g.*, Dkt. 283 ¶ 11 [redacted] Janssen may not use privilege as both a sword and a shield. *In re Keeper of Records*, 348 F.3d 16, 24 (1st Cir. 2003). Janssen's theory that Defendants "hid" evidence also is improper because neither the theory, nor Ms. Royzman as a witness, were disclosed during discovery. *See* Fed. R. Civ. P. 37(c)(1). Moreover, the theory makes no sense: the communications pointed to occurred before Janssen disclosed testing results Defendants allegedly "needed" in order to "assess infringement." Dkt. 281 at 15; Dkt. 283. The Court should summarily reject this purported "evidence."

Janssen also claims that, "after the close of fact discovery," Defendants [redacted] which allegedly shows an "attempt[] to…avoid further infringement." Dkt. 281 at 16. Defendants dispute this characterization of the facts, but the dispute is immaterial. Any suggestion that

such "evidence" shows culpability for inducement is squarely foreclosed by the prohibition on evidence of subsequent remedial measures.[7] Inadmissible evidence "may not be considered on summary judgment." *Vazquez v. Lopez-Rosario*, 134 F.3d 28, 33 (1st Cir. 1998).

Where, as here, a plaintiff does not adduce evidence sufficient to create a triable question regarding specific intent, summary judgment of no inducement is appropriate.[8]

B. Defendants' Good Faith Non-Infringement Basis Precludes A Finding Of Inducement

"[I]t is clear that a good-faith belief of non-infringement is relevant evidence that tends to show 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 on other grounds*, 135 S. Ct. 1920. This is why the law protects from liability a "defendant [that] reads the [asserted] patent's claims differently from the plaintiff, and that reading is reasonable." *Commil, Inc.*, 135 S. Ct. at 1928.

Janssen does not dispute the objectively reasonable basis for non-infringement actually stated in Defendants' motion. Instead, Janssen mischaracterizes the motion as stating that, "because Janssen proceeds under the doctrine of equivalents, Defendants 'objective[ly]' must have lacked the state of mind required by *Global-Tech*." Dkt. 281 at 9. Janssen ignores the actual basis for Defendants' good-faith belief in non-infringement. Dkt. 265 at 2 ("Janssen admits the accused products do not literally infringe the asserted claims in *at least twelve different ways*.

[7] *See* Fed. R. Evid. 407; *see also, e.g.*, *Mikkelsen Graphic Eng'g Inc. v. Zund Am., Inc.*, No. 07-0391, 2011 WL 1330782, at *11 (E.D. Wis. Apr. 7, 2011), *aff'd in part, vacated in part on other grounds*, 541 F. App'x 964 (Fed. Cir. 2013); *Deflecto, LLC v. Dundas*Jafine Inc.*, No. 13-0116, 2015 WL 9413148, at *2 (W.D. Mo. Dec. 22, 2015); *Plew v. Ltd. Brands, Inc.*, No. 08-3741, 2012 WL 379933, at *8 (S.D.N.Y. Feb. 6, 2012); *Vardon Golf Co. v. BBMG Golf Ltd.*, 156 F.R.D. 641, 652–53 (N.D. Ill. 1994).

[8] *See, e.g.*, *Adrea, LLC v. Barnes & Noble, Inc.*, No. 13-4137, 2016 WL 859685, at *6 (S.D. N.Y. Feb. 24, 2016); *Health Grades, Inc. v. MDX Med., Inc.*, No. 11-00520, 2014 WL 5762002, at *4–5 (D. Colo. Nov. 4 , 2014); *Interwoven, Inc. v. Vertical Computer Sys.*, No. 10-04645, 2013 WL 3786633, at *6 (N.D. Cal. Jul. 18, 2013).

…[W]ith 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"). In fact, Janssen's opposition never addresses the fact that the accused products contain twelve ingredients outside the ranges recited in the asserted claims by as much as an order of magnitude, or the fact that Janssen's sole direct infringement theory requires it to demonstrate that the accused products are equivalent to the asserted claims on a limitation-by-limitation basis, *i.e.*, twelve times over. *See Lockheed Martin Corp. v. Space Sys./Loral, Inc.*, 324 F.3d 1308, 1317 (Fed. Cir. 2003). Nor does Janssen respond to the fatal flaws in its infringement theory under Supreme Court precedent. *See* Dkt. 265 at 16. And Janssen still has not identified a single case where infringement was found based on a twelve-way doctrine of equivalents theory, much less a case where a defendant was found to have specific intent to induce such infringement.

The cases Janssen cites do not address this issue; they involved claims for which a single element was alleged to be met under the doctrine of equivalents. *SEB S.A. v. Montgomery Ward & Co.*, 137 F. Supp. 2d 285, 289 (S.D.N.Y. 2001) ("*SEB*"); Johnstech Int'l Corp.'s Discl. of Infr. Cont., *Johnstech Int'l Corp. v. JF Microtech. SDN BHD*, 2016 U.S. Dist. LEXIS 106548 (N.D. Cal. Aug. 11, 2016), ECF No. 112-1. Moreover, in *Global-Tech* (*SEB*), the "ring segments" alleged to be equivalent to the claimed "ring" were a feature that the accused infringer had *purposely modified* in an attempt to avoid infringement and circumvent an injunction. *SEB S.A. v. Montgomery Ward & Co.*, 594 F.3d 1360, 1367 (Fed. Cir. 2010), *aff'd sub nom. Global-Tech*, 563 U.S. 754; *SEB*, 137 F. Supp. 2d at 289. Those facts have no parallel here.

Janssen cites *Unwired Planet, LLC v. Apple Inc.*, 829 F.3d 1353 (Fed. Cir. 2016) (Dkt. 281 at 11), which cannot overrule *Commil*, *Global-Tech*, or other cases regarding a reasonable defense of non-infringement. There, the Federal Circuit vacated a grant of summary judgment of

no inducement "based exclusively on its view of the strength of Apple's non-infringement argument." *Unwired Planet*, 829 F.3d at 1364. The Court also noted, however, that Apple argued "that none of the evidence supports an inference that Apple knew or was willfully blind to any infringing acts," and "[i]f correct, this would be a basis for summary judgment." *Id.*

Here, there is a complete lack of evidence supporting an inference that Defendants knew or were willfully blind to alleged direct infringement, and there is additionally evidence of a good-faith and objectively reasonable non-infringement defense that Janssen does not dispute. Moreover, six days after the Federal Circuit decided *Unwired Planet*, it held that an accused infringer's "good faith belief in non-infringement," based on its "arguments against…direct infringement," "negate[d] the knowledge requirement" for contributory infringement under § 271(c), which, like § 271(b), requires knowledge that the product in question "was both patented and infringing." *Koninklijke Philips N.V. v. Zoll Med. Corp*., 2016 WL 4045330, at *15 (Fed. Cir. July 28, 2016). The Court relied on *Commil*: "[I]f an accused infringer 'reads the patent's claims differently from the plaintiff,' and if 'that reading is reasonable,' then the accused infringer should not be liable for indirect infringement." *Id.* (quoting *Commil*, 135 S.Ct. at 1928). This authority supports summary judgment on Count 2.

C. Janssen Has No Claim For "Prospective" Inducement

A party may not proceed to trial where it lacks evidence for an essential element of its claim. Having no evidence that can establish or even create an inference of specific intent, Janssen attempts to take an unprecedented tack: wait and see if it is able to obtain a finding of direct infringement at trial, then ask the Court to order that "selling infliximab in the U.S. or buying [accused products from] Utah would induce infringement," apparently on the belief that if the media products have been adjudged to infringe, Defendants will specifically intend to induce infringement from that point on. Dkt. 281 at 16. There are several problems with this theory.

First, Janssen's approach would effectively turn inducement into a strict liability offense rather than one requiring actual knowledge of infringement and specific intent. As Janssen would have it, a plaintiff could proceed to trial without any evidence of knowledge of direct infringement, try for a finding of direct infringement and the requisite "affirmative acts" at trial, then hold the defendant liable for inducement. This sidestep of § 271(b) cannot be reconciled with the Supreme Court's clear mandate on the statute's intent requirement.

Second, Janssen's reliance on cases in the motion to dismiss context, permitting a declaratory judgment on an inducement theory at the pleading stage, is misplaced. *See* Dkt. 281 at 16; *Fina Research, S.A. v. Baroid, Ltd.*, 141 F.3d 1479, 1484 (Fed. Cir. 1998); *Takeda Chem. Indus. v. Watson Pharms., Inc.*, 329 F. Supp. 2d 394, 401–02 (S.D.N.Y. 2004). The question is not whether Janssen has satisfied the plausibility standard for a complaint, but rather, whether Janssen may go to trial with no evidence of an essential element of its claim. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007) (plausibility standard merely requires "rais[ing] a reasonable expectation that discovery will reveal evidence" to prove a claim).

Third, Janssen's request for "prospective" relief is apparently premised on the assumption that if Janssen were to obtain a judgment of direct infringement, Defendants would purchase media products found to infringe. Janssen has not established a "substantial controversy" of "sufficient immediacy and reality" giving rise to declaratory judgment jurisdiction under this theory. *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007). Without this showing, Janssen's "if, then" request for relief amounts to an impermissible request for an advisory opinion. *Sandoz Inc. v. Amgen Inc.*, 773 F.3d 1274, 1277 (Fed. Cir. 2014).

III. Count 3 Alleging Induced Infringement By Hospira Fails As A Matter Of Law

For all the reasons set forth above, Janssen has not raised a genuine factual dispute as to whether Celltrion or Hospira specifically intended to induce alleged direct infringement. But

Janssen's case against Hospira, specifically, which is still further removed from the "facts" at issue, is even weaker. Janssen cannot, as a matter of law, show that Hospira had the requisite knowledge or mental state for inducement as to Celltrion, because "induced infringement under § 271(b) requires knowledge *that the induced acts constitute patent infringement*." *Global-Tech*, 563 U.S. at 766 (emphasis added). Even if there were a viable theory under which Celltrion could directly infringe the '083 patent (there is not), Janssen has failed to raise any question at all that Hospira knew of and specifically intended direct infringement by Celltrion, including all the facts Janssen alleges amount to direct infringement. Dkt. 282 ¶¶ 5–28. Janssen nevertheless attempts to create a dispute over whether Hospira has "actively" induced alleged direct infringement under § 271(b), but even if presumed true for purposes of summary judgment, Janssen's alleged "facts" do not create a triable question.

Regarding HyClone, Janssen does not allege *any* conduct by Hospira constituting "active" inducement directed at HyClone, or even a relationship between Hospira and HyClone with respect to the accused products. Absent "active" and affirmative steps to bring about infringement directed at the alleged direct infringer, there can be no inducement. *See, e.g.*, *Takeda Chem. Indus. v. W-Ward Pharm. Corp.*, 785 F.3d 625, 630 (Fed. Cir. 2015) (inducer "must have 'knowingly aided and abetted' direct infringement"); *New Hampshire Ins. Co. v. R.L. Chaides Const. Co.*, 847 F. Supp. 1452, 1459 (N.D. Cal. 1994).

As for the claim that Hospira induced Celltrion, Janssen must show "affirmative steps to bring about" the alleged direct infringement. *Global-Tech.*, 563 U.S. at 760. Janssen does not, and cannot, make this showing. According to Janssen, direct infringement by Celltrion involved entering into contracts with HyClone having particular terms, having "direction and control" over the media products' formulations, plus myriad other acts. Dkt. 281 at 3–8; Dkt. 282 ¶¶ 5–

28. Janssen makes no claim, nor could it, that Hospira took "affirmative steps to bring about" these acts. Instead, Janssen merely alleges that Hospira is a "co-applicant[] for FDA approval" and "understands" that the accused products are "required" to make biosimilar infliximab, and that ordering infliximab means Celltrion will "obtain [the accused products] from HyClone." Dkt. 281 at 19. The most these purported facts, even if true, could possibly show is that Hospira knew Celltrion would use or purchase accused products. But Janssen does not claim that Celltrion's use or purchase alone is a direct infringement under § 271(a), nor could it.

Finally, *Columbia Univ. v. Roche Diagnostics GmbH*, 272 F. Supp. 2d 90 (D. Mass. 2002), cited by Janssen, is not analogous. First, it predates *Global Tech* and *Commil*, and used an intent standard—"encourag[ing]…actions that it knew or should have known would infringe"—that no longer applies. *Id*. at 106. Also, *Columbia* is factually distinguishable. The defendant in *Columbia* (Roche) marketed a drug made by a third party (GI), who produced it using genetically engineered cells. *Id*. at 96. The plaintiff, whose patents covered cell lines and processes for creating engineered cells, alleged that GI directly infringed when it made and used cells to produce the drug, and that Roche induced GI's infringement, including through its involvement in development of the drug. *Id*. at 104–07. Here, in contrast, Hospira is at least an additional step, and an entire additional relationship, removed from the alleged direct infringement: it purchases the drug from Celltrion, which makes the drug by harvesting infliximab from cells, which are grown in culture media, which include accused products. Janssen cites no authority supporting a finding of affirmative acts to bring about infringement in such attenuated circumstances.

CONCLUSION

Janssen has created no triable question of fact regarding its claims of infringement of the '083 patent. Summary judgment should be granted on Counts 1–3 in its 2016 Complaint, and on Count 6 in its 2015 Complaint.

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Respectfully submitted,

Celltrion Healthcare Co., Ltd., Celltrion, Inc. and Hospira Inc.

By their attorneys,

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CERTIFICATE OF SERVICE

I certify that on November 23, 2016, this document, filed through the ECF system, will be sent electronically to the parties or their counsel who are registered participants as identified on the Notice of Electronic Filing and if not so registered, that copies will be electronically mailed to such parties or their counsel.

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