

**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.** )

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

**PLAINTIFFS' SURREPLY IN OPPOSITION  
TO DEFENDANTS' MOTION FOR SUMMARY JUDGMENT**

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## I. INTRODUCTION

In reply, Defendants now admit the facts are all disputed and instead premise their motion on erroneous legal arguments. Their motion for summary judgment must be denied.

With respect to Janssen's claim that Celltrion is liable for direct infringement under section 271(a), Celltrion expressly "disputes" *every single one* of the facts presented in Janssen's statement of material facts. But the disputed facts, if accepted by the jury, prove that Celltrion exerts direction and control over HyClone's manufacture of the Celltrion Media, making it vicariously liable as a direct infringer. Dkt. 282 ("Janssen SoF") ¶¶ 5-28. Ignoring the fact dispute, Celltrion now contends that its motion presents a "pure issue of law" – whether *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 797 F.3d 1020, 1022 (Fed. Cir. 2015) (en banc) applies to product claims such as those asserted by Janssen. Dkt. 293 ("Reply Br.") at 1. This argument, which was properly relegated to a footnote in Celltrion's opening brief, makes no sense. As Celltrion itself correctly acknowledged in its opening motion, *Limelight* identifies preexisting legal principles of vicarious liability under section 271(a) that courts have long applied to direct infringement of all kinds of patent. In any event, the disputed facts of Celltrion's direction and control over HyClone preclude summary judgment under any theory of liability.

With respect to Janssen's claims for induced infringement under section 271(b), Defendants ask the Court to ignore the relevant law and the relevant facts. As Janssen demonstrated in its opposition papers, controlling Federal Circuit authority makes clear that whether a defendant induces patent infringement is measured by the defendant's *subjective* state of mind and summary judgment cannot be based on the supposed "objective strength" of the defendant's non-infringement defense. *Unwired Planet, LLC v. Apple Inc.*, 829 F.3d 1353, 1363 (Fed. Cir. 2016). Nevertheless, Defendants, insist that they are entitled to summary judgment on precisely that basis. The litany of evasions, distortions and half-truths to which Defendants

resorted when Janssen asserted its claim, coupled with undisputed evidence of notice to Defendants of Janssen’s patent and its infringement allegations, are more than sufficient to make Defendants’ subjective state of mind a jury question. Furthermore, Defendants have no answer to Janssen’s argument that its claim for prospective relief under section 271(b) and the BPCIA must proceed to trial. Finally, Hospira, the company that will sell biosimilar infliximab in the United States, was privy to largely the same facts as Celltrion and joined in most of the misleading representations. It actively induces the infringement involved in making the product.

## **II. FACTUAL DISPUTES PRECLUDE SUMMARY JUDGMENT ON JANSSEN’S SECTION 271(A) CLAIM FOR DIRECT INFRINGEMENT**

### **A. Direct Infringement Based on the Actions of Contractors and Joint Enterprises Is Not Limited to Method Claims**

In its opening brief, in contending that undisputed facts showed it was entitled to summary judgment, Celltrion relied on the legal standards set forth in *Limelight* for vicarious liability for direct infringement under section 271(a). Dkt. 265 (“Opening Br.”) at 6-14.

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).

*Id.* at 7 (emphasis added; footnote omitted). In opposition, Janssen agreed with Celltrion that liability could be premised on general principles of vicarious liability as recited in *Limelight*, Dkt. 281 (“Opposition Br.”) at 3, but contended that disputed material facts precluded summary judgment, *id.* at 4-8; *see* Janssen SoF ¶¶ 5-28.

Instead of defending its original contention that the facts are undisputed, Celltrion now agrees that the facts are disputed. Dkt. 294 (“Defs.’ Reply SoF”) ¶¶ 5-28. But based on a footnote in its opening brief, Celltrion argues that, except for agency law principles, “general principles of vicarious liability” are “categorically inapposite” to Janssen’s direct infringement

claim. Reply Br. at 3. As discussed below, agency principles are sufficient for this case to go to trial, but Celltrion's argument about vicarious liability is incorrect.

According to Celltrion's reply arguments, vicarious liability for direct infringement under section 271(a) can be based on the acts of a third party contractually subject to the defendant's direction and control only for method claims, because of the possibility of divided infringement, and not for product claims. Reply Br. at 2-5. This argument makes no sense and finds no support in *Limelight*. Method steps can be divided, but they are more often performed by a single entity. By Celltrion's implausible reasoning, when a defendant hires a single manufacturer, under its direction and control, to make a patented product, using all the steps of a patented method, that defendant is vicariously liable for direct infringement of the method claim but not the product claim. This is nonsense. *Limelight* does not suggest that "general principles of vicarious liability" vary depending on whether the claim at issue is a product claim or a method claim.<sup>1</sup>

In *Limelight*, the Federal Circuit considered direct infringement under section 271(a) after the Supreme Court unanimously reversed its previous decision in the case, which had created special rules for liability for induced infringement of method claims, as opposed to product claims, under section 271(b). See *Limelight Networks v. Akamai Technologies*, 134 S. Ct. 2111 (2014). It is hardly plausible to read the *Limelight* decision on remand as creating, once again, special rules for method claims, this time for direct infringement. Rather, the court ruled that in addressing the method claims at issue "we continue to consider general principles of vicarious liability." See *Limelight*, 797 F. 3d at 1022. For years, courts have found direct infringement

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<sup>1</sup> Although baseless, Celltrion's attempt to carve out principal-agent relationships from the other vicarious liability principles discussed in *Limelight* is understandable. Any suggestion that principals are not vicariously liable for the actions of their agents would lead to the absurd result that corporations cannot be directly liable for patent infringement carried out by their employees.



under those general principles for both method *and* product claims based not only on agency relationships, but also on independent contractor relationships that, by contract, give the defendant direction and control over a third party's infringing actions. For example, in *Pellegrini v. Analog Devices*, 375 F.3d 1113 (Fed. Cir. 2004), which Celltrion incorrectly says is limited to agency relationships, Reply Br. at 4 n.4, the Federal Circuit expressly recognized that “one cannot escape liability for infringement as a manufacturer of infringing products simply by employing an *agent or independent contractor* to carry out the actual physical manufacturing.” *Pellegrini*, 375 F.3d at 1118 (emphasis added).<sup>2</sup> By definition, an independent contractor is one who creates a product under the direction and control of another. *See, e.g., Independent Contractor Defined*, I.R.S.<sup>3</sup> (“The general rule is that an individual is an independent contractor if the payer has the right to control or direct only the result of the work and not what will be done and how it will be done”).

In *Limelight*, the Federal Circuit applied these “general principles of vicarious liability” to method claims, as it had in the past both to method claims and product claims. *Compare BMC Resources v. Paymentech*, 498 F.3d 1373, 1379–81 (Fed. Cir. 2007) (method claims) *with Centillion Data Sys., LLC v. Qwest Communs. Int'l*, 631 F.3d 1279 (Fed. Cir. 2011) (applying

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<sup>2</sup> *See also e.g., Centillion Data Sys., LLC v. Qwest Communs. Int'l*, 631 F.3d 1279 (Fed. Cir. 2011) (applying “our vicarious liability precedent” to find no direct infringement of systems claim); *Wis. Alumni Research Found. (WARF) v. Apple, Inc.*, No. 14-cv-062, 2015 U.S. Dist. LEXIS 144744, at \*10 (W.D. Wis. Oct. 26, 2015) (direct infringement of product claims based on “control and direction” of third-party manufacturer); *Rowe Int'l Corp. v. Ecast, Inc.*, 586 F. Supp. 2d 924, 932-933 (N.D. Ill. 2008) (direct infringement of systems claims where defendant “contracted out” the manufacture of jukeboxes to others); *TGIP, Inc. v. AT&T Corp.*, 527 F. Supp. 2d 561, 578 (E.D. Tex. 2007) (direct infringement of systems claims based on direction and control); *Lineguard, Inc. v. Linetec, Inc.*, No. 87-C-2368, 1987 U.S. Dist. LEXIS 4525 at \*2 (N.D. Ill. May 29, 1987) (direct infringement of product claims by defendants that “did not manufacture any detectable marking tape themselves. They had it made by non-party Sealcraft Packaging, Inc.”). Celltrion's efforts to distinguish these cases are futile, Reply Br. at 4, as all these cases contradict Celltrion's argument that vicarious liability under 271(a) is limited to method claims. Contrary to Celltrion's contention, moreover, neither *Pellegrini* nor *Lineguard* are distinguishable as principal-agent cases. Both cases address third-party contract manufacturers.

<sup>3</sup> <https://www.irs.gov/businesses/small-businesses-self-employed/independent-contractor-defined>.

“our vicarious liability precedents” to find no direct liability for infringement of system or apparatus claim because “Qwest in no way directs its customers to perform nor do its customers act as its agents”).<sup>4</sup> The only novel holding of *Limelight* is that vicarious liability under “[s]ection 271(a) is **not limited** solely to principal-agent relationships, contractual arrangements, and joint enterprise” – an issue not presented here.<sup>5</sup> *Id.* at 1023 (emphasis added). Nothing about *Limelight* changes preexisting law that vicarious liability for direct infringement of both method and product claims can be based on “principal-agent relationships, contractual arrangements, and joint enterprise.” 797 F. 3d at 1023.

Because it wrongly dismisses the pre-*Limelight* precedents cited by Janssen, Celltrion makes no serious effort to distinguish them. *See supra* n. 2. Celltrion also fails to distinguish *WARF v. Apple, Inc.*, 2015 U.S. Dist. LEXIS 144744, at \*10, which expressly applies *Limelight* to a product claim. Reply Br. at 4. Although the context was damages, the question was whether Apple was directly liable for infringement based on products made on its behalf by Samsung. 2015 U.S. Dist. LEXIS 144744, at \*10. And like the product in *WARF*, the Celltrion Media are custom made for Celltrion and for Celltrion only according to Celltrion’s specifications. Janssen SoF ¶¶ 5-15; Janssen Supplemental SoF ¶ 34 . Celltrion may disagree about the facts, but that is a dispute for trial, not a basis for distinguishing the case law.

In sum, the law is clear that Celltrion can be directly liable under section 271(a) for the acts of HyClone acting under its direction and control pursuant to contract, whether or not the claim at issue is a method claim. The only case cited by Celltrion, *Lyda v. CBS Corp.*, 838 F.3d

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<sup>4</sup> The *Limelight* court noted that in patent law the term “vicarious liability” is something of a “misnomer,” but “as both vicarious liability and joint patent infringement discern when the activities one entity are attributable to another, we derive our direction or control standard from vicarious liability law.” *Limelight*, 797 F. 3d at 1022 n.2.

<sup>5</sup> This holding is the reason that commentary on the decision has correctly identified *Limelight* as expanding liability under 271(a) in relation to previous case law. *See* Reply Br. at 3 n. 1 & 4 n.2.

1331 (Fed. Cir. 2016), does not support its argument to the contrary. *Lyda* states that “joint infringement” is a doctrine applicable to method claims, *id.* at 1339, not that *vicarious liability* under section 271(a) is so limited.<sup>6</sup> Indeed, in support of this point, *Lyda* cites *Centillion*. *Id.* at 1339. But, as noted above, *Centillion* expressly recognizes that Federal Circuit “vicarious liability precedents” apply to systems or apparatus claims, not just method claims. *Centillion*, 631 F.3d at 1287. In fact, Celltrion itself cited *Centillion* in its opening brief, correctly noting that *Centillion* “discuss[es]” the applicable “direction and control” standard for vicarious liability under section 271(a). Opening Br. at 7-8.

**B. The Material Facts Are Disputed Under Any Theory of Direct Infringement**

If Celltrion can be liable for the acts of HyClone – a company that it affirmatively contends is an independent contractor – then summary judgment must be denied. In response to Janssen’s statement of facts demonstrating that HyClone operates under Celltrion’s direction and control, Celltrion “disputes” *every single fact*. Defendants’ Reply SoF ¶¶ 5-28. Celltrion’s sole argument now is that this legal theory is limited to method claims. Once that is rejected, fact disputes necessarily preclude summary judgment on these issues.

But even if Celltrion were correct on the law, Janssen also alleges that HyClone acted as Celltrion’s agent. Celltrion agrees that that is a viable theory of vicarious liability, but it asserts that Janssen has “abandoned” its agency theory of direct liability. Reply Br. at 2. That is not true. To the contrary, Janssen demonstrated in its opposition papers that Celltrion “employs HyClone as its agent,” relying on many of the same facts – all disputed by Celltrion – that

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<sup>6</sup> The reason that joint infringement is limited to method claims is that, unlike products, the use of a method can be divided among multiple entities such that no single entity practices the entirety of the claim. *See Akamai Techs., Inc. v. Limelight Networks, Inc.*, 692 F.3d 1301, 1305–06 (Fed. Cir. 2012), *rev’d*, 134 S. Ct. 2111 (2014). That does not mean, however, that parties cannot be vicariously liable for infringement of product claims.

demonstrate direction and control. Opposition Br. at 7-8. These include: [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Celltrion’s control is sufficient to make HyClone its agent. *See Scholastic, Inc. v. Stouffer*, No. 99-11480, 2000 U.S. Dist. LEXIS 11516 at \*16 (S.D.N.Y. Aug. 14, 2000) (control of principal over agent “need not rise to the level of absolute control over the acts or decisions of the putative agent; rather, it may involve the ability of the principal to influence such acts or decisions by virtue of the parties’ respective roles”). Celltrion’s motion for summary judgment fails under any theory of section 271(a) liability.<sup>7</sup>

### **III. FACT ISSUES PRECLUDE SUMMARY JUDGMENT ON JANSSEN’S CLAIMS FOR INDUCED INFRINGEMENT**

Janssen will present overwhelming circumstantial evidence from which the jury can reasonably find that Defendants subjectively believed they were infringing the ‘083 patent or were willfully blind to infringement. Defendants ignore most of the evidence in their reply.

#### **A. Defendants’ Knowledge of Janssen’s Infringement Allegations Creates a Factual Dispute As to Their Subjective Intent**

At the simplest level, Defendants cannot dispute that they learned Janssen was asserting the ‘083 patent no later than December 2014, Janssen SoF ¶ 32, that they were informed of Janssen’s specific infringement allegations by August 2015, *see* Dkt. 69, and that they were

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<sup>7</sup> Celltrion also argues that applying the case law on vicarious liability would subvert the Patent Act and somehow violate the presumption against extraterritoriality. Reply Br. at 5. The former argument was presented in essentially the same form in Celltrion’s opening brief, Opening Br. at 12, and Janssen addressed it in its opposition brief. Opposition Br. at 8. The presumption of extraterritoriality has no applicability here because the Celltrion Media are made in the United States.

given Janssen's scientific evidence of infringement in April 2016, Janssen SoF ¶ 69.<sup>8</sup> As Janssen explained in its opposition papers, summary judgment of no inducement has repeatedly been denied on analogous facts, because whether the defendant subjectively believed the plaintiff's allegations is an inference that can only be drawn by the jury. Opposition Br. at 9-12. Indeed, Defendants' failure to move for summary judgment on the underlying question of infringement is a concession that the Celltrion Media can reasonably be found to infringe the '083 patent. A jury could therefore reasonably infer, from the same evidence, that Defendants subjectively believed that they were infringing or were willfully blind to infringement.

Defendants' contention that the plaintiff's infringement allegations are insufficient to support a finding of subjective intent is contrary to the law. Reply Br. at 6-7. The sole case on which Defendants rely, *TecSec, Inc. v. International Business Machines*, 769 F. Supp. 2d 997 (ED Va. 2011), does not support the proposition. There, the defendant presented "[u]ndisputed evidence" that it had "recommended *against* using the products in the allegedly infringing manner." 769 F. Supp. 2d at 1015 (emphasis in original). Here, there is no evidence that Defendants discouraged HyClone's infringement of the '083 patent. In these circumstances, the plaintiff's infringement allegations can by themselves support a finding of knowing inducement. *See, e.g., Fujitsu Ltd. v. Netgear Inc.*, 620 F.3d 1321, 1330, 1332 (Fed. Cir. 2010) (reversing summary judgment of no inducement when a letter from plaintiff "that identified the '952 patent and stated that all 802.11 compliant products infringe" created "factual issues" as to "whether Netgear had the requisite intent to induce infringement").

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<sup>8</sup> Defendants contend that the April 2016 laboratory results were "problematic" because they were provided under confidentiality agreements that restricted their use to outside and in-house counsel for purposes of their litigation. Reply Br. at 8. But nothing prevented Celltrion's in-house counsel from assessing Janssen's evidence and providing advice to Celltrion on that basis and in any event, Defendants sought and obtained permission to share the report more widely. *See* Janssen Supplemental SoF ¶ 35.

Defendants' argument that they are entitled to summary judgment because Janssen's infringement allegations are subject to "reasonable debate" or had an "objectively reasonable basis" is also contrary to the law. Reply Br. at 7, 10-12. Although Defendants reiterate their irrelevant argument that twelve out of the 120-plus claim elements are not literally met, the law is clear that summary judgment of no inducement cannot be based on the Court's objective assessment of the non-infringement case. See *Unwired Planet*, 829 F.3d at 1363 (Fed. Cir. 2016); Opposition Br. at 11-12. Effectively admitting this, Defendants contend that *Unwired Planet* cannot "overrule" the holding of *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754 (2011) and *Commil USA LLC v. Cisco Systems, Inc.*, 135 S. Ct. 1920, 1926 (2015) that knowledge is required for inducement. Reply Br. at 11. But *Unwired Planet* does not overrule *Global-Tech* or *Commil*. It simply explains that the inquiry under these cases is subjective rather than objective and that summary judgment cannot be granted based on the Court's assessment of the parties' infringement positions. This holding is entirely consistent with the Supreme Court's reasoning in *Global-Tech*. See *Global-Tech*, 563 U.S. at 770-71 (concluding that knowledge requirement was met without conducting any analysis of the objective strength of the defendant's non-infringement defense); Opposition Br. at 10.

The Federal Circuit's decision in *Koninklijke Philips N.V. v. Zoll Med. Corp.*, No. 2014-1764, 2016 U.S. App. LEXIS 13710 (Fed. Cir. July 28, 2016), relied on by Defendants, only further confirms that the defendant's subjective knowledge is a jury question. See Reply Br. at 12. Defendants inaptly quote *Koninklijke*'s statement that "if 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." *Koninklijke*, 2016 U.S. App. LEXIS 13710 at \*43 (quoting *Commil*, 135 S. Ct. at 1928) (emphasis added). As this passage makes

perfectly clear, a reasonable reading of the patent alone is not enough to avoid infringement; the jury must find that is what the defendant in fact subjectively believed. *See Unwired Planet*, 829 F.3d at 1363. The Court then held that it would not set aside, as a matter of law, the jury’s finding of no inducement because the defendant’s objectively reasonable non-infringement defense was a “*sufficient basis* on which to ground the jury’s implicit finding of insufficient knowledge.” *Koninklijke*, 2016 U.S. App. LEXIS 13710 at \*44 (emphasis added). The objective reasonableness of the defense meant the jury’s assessment of the defendant’s subjective state of mind was not contrary to the evidence. It did not warrant taking the question away from the jury. Here, as in *Koninklijke*, Defendants can argue at trial that they did not believe the Celltrion Media infringe the ‘083 patent. But they are not entitled to summary judgment.

**B. Circumstantial Evidence of Defendants’ Knowing Infringement Must Be Considered on This Motion**

Quite apart from Defendants’ knowledge of Janssen’s infringement allegations, Janssen has presented ample circumstantial evidence that Defendants’ knowingly induced infringement of the ‘083 patent. Once again, Defendants expressly dispute all of Janssen’s evidence. Defendants’ Reply SoF ¶¶ 29-66. Defendants are wrong that these factual disputes can be disregarded for purposes of this motion. Reply Br. at 8-10.

In its opposition, Janssen showed that Defendants have repeatedly concealed facts about the Celltrion Media in the course of this litigation, thus displaying a guilty conscience from which the jury can properly infer knowing infringement. Opposition Br. at 13-14; Janssen SoF ¶¶ 29-66. Contrary to Defendants’ contention, this evidence is not based on the testimony of outside counsel. Reply Br. at 9. Rather, it consists of documented communications between the parties, memorialized in 27 exhibits, the import of which Defendants vigorously dispute. Janssen SoF ¶¶ 29-66 & Exs. 30-56; Defendants’ Reply SoF ¶¶ 29-66. The misleading

documents authored by Defendants’ representatives are not inadmissible hearsay but rather admissible party admissions under Federal Rule of Evidence 801(d)(2). *See, e.g., Matamoros v. Starbucks Corp.*, 699 F. 3d 129, 136 (1<sup>st</sup> Cir. 2012) (noting that documented statements by defendant “are party admissions, *see* Fed. R. Evid. 801(d)(2), and party admissions are potent evidence”). Defendants cannot wish away their own statements or their implications.

Rather than grapple with the substance of their own statements – which plainly support a jury verdict of guilty knowledge – Defendants have unleashed a torrent of irrelevant objections. Reply Br. at 9. Defendants have long been on notice of Janssen’s allegations, as much of the evidence in Janssen’s motion was submitted in August 2015 in conjunction with Janssen’s motion to modify the protective order, Dkt. 69, and the theory is expressly alleged in the complaint in Civil Action No. 1:16-cv-11117, Dkt. 1 ¶¶ 53-56. These parties have expressly stipulated that these pleadings are incorporated into Janssen’s infringement contentions. Dkt. 244. Although Janssen believes that it is unnecessary for either party’s litigation counsel to testify at trial, Janssen has not refused to make anyone available for a deposition. Janssen Supplemental SoF ¶ 36. It would prefer, however, to present this evidence through a witness who has personal knowledge of the communications but is not trial counsel. *Id.* For purposes of the present motion, the relevant point is that the documents in question are admissible, not how they will be introduced at trial. *See* Fed. R. Civ. P. 56(c)(1)(A) (parties may rely on “documents” in connection with summary judgment).

The fact that Defendants [REDACTED] [REDACTED] is also admissible evidence supporting an inference of knowing infringement. Opposition Br. at 16; Janssen SoF ¶ 87. Evidence of this decision is not inadmissible under Federal Rule of Evidence 407. Reply Br. at 9-10. Rule 407 holds that evidence of measures



“that would have made an earlier injury or harm less likely to occur” cannot be used to establish culpability, FRE 407, and rests on the “social policy of encouraging people to take, or at least not discouraging them from taking, steps in furtherance of added safety,” FRE 407 Adv. Comm. Notes. Defendants’ [REDACTED] has nothing to do with either the language of the Rule or its policy. *See, e.g., Kowalski v. Anova Food, LLC*, No. 11-795, 2015 U.S. Dist. LEXIS 34521, at \*8 (D. Haw. Feb. 18, 2015) (“Defendant’s subsequent remedial measure argument is inappropriate in a patent infringement case.”).<sup>9</sup> Furthermore, if Defendants argue at trial that they did not believe, or take seriously, Janssen’s infringement allegations, the evidence of [REDACTED] as impeachment even if Rule 407 were applicable. *See Harrison v. Sears, Roebuck and Co.*, 981 F.2d 25, 31 (1<sup>st</sup> Cir. 1992); *Petree v. Victor Fluid Power Inc.*, 887 F.2d 34, 38 (3rd Cir. 1989).

**C. Janssen’s Claims for Declaratory and Prospective Relief Under Section 271(B) and the BPCIA May Be Litigated In Any Case**

Finally, Defendants’ purported lack of knowledge is no defense against Janssen’s claims for declaratory and prospective relief under section 271(b) and the BPCIA. Opposition Br. at 16-18. Defendants’ reply brief fails to refute the authority on which Janssen relies and it provides none in support of Defendants’ position. Reply Br. at 12-13. Tellingly, Defendants fail even to discuss *Bose Corp. v. SDI Techs., Inc.*, 558 F. App’x 1012 (Fed. Cir. 2014), in which the Federal Circuit reversed summary judgment of no inducement on the ground that it “improperly absolved” the defendant of “potential post-verdict liability”:

A jury could, at trial, find the patent not invalid and infringed. In this scenario, SDI’s opinion of counsel would not shield it from post-verdict liability because SDI could not credibly argue that it maintained its good-faith belief of invalidity

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<sup>9</sup> *See also Duhn Oil Tool, Inc. v. Cameron Int’l Corp.*, No. 5-1411, 2011 U.S. Dist. LEXIS 5711, at \*3 (E.D. Cal. January 12, 2011).

following a verdict to the contrary. The summary judgment improperly absolved SDI of potential post-verdict liability.

*Id.* at 1023. Summary judgment here would be reversible error for the same reason.

This case is more compelling than *Bose* because of Janssen's claim under the BPCIA, which is expressly future-looking and which Defendants also fail to discuss. The BPCIA allows drug makers such as Janssen to litigate patents that "could reasonably be asserted . . . *if*" a biosimilar maker marketed its product without a license. 42 U.S.C. 262(l)(3) (emphasis added); *see* 35 U.S.C. § 271(e)(2)(C) (incorporating by reference 42 U.S.C. 262(l)(3)). Plainly, the statute allows Janssen to try its claims for future inducement, as the case law under the analogous Hatch-Waxman Act holds. *See, e.g., Forest Labs., Inc. v. Ivax Pharms., Inc.*, 501 F.3d 1263, 1272 (Fed. Cir. 2007); *Allergan, Inc. v. Alcon Labs.*, 324 F.3d 1322, 1332 (Fed. Cir. 2003).

Finally, Defendants' argument that there is no case or controversy as to future inducement is directly refuted by *Fina Research, S.A. v. Baroid Ltd.*, 141 F.3d 1479, 1484-85 (Fed. Cir. 1998), which holds that a plaintiff may bring seek injunctive and declaratory relief against future induced infringement, as well as by the Hatch-Waxman cases just cited. Contrary to Defendants' characterization, *Fina* is not a case about pleading standards. Rather, it concerns subject matter jurisdiction, which "may be raised by a party, or by a court on its own initiative, at any stage in the litigation." *Arbaugh v. Y & H Corp.*, 546 U.S. 506 (2006). And although Defendants cite *Sandoz, Inc. v. Amgen Inc.*, 773 F.3d 1274, 1277 (Fed. Cir. 2014), which holds that there is no case or controversy over biosimilar patent disputes *before* a biosimilar application is filed, they have properly conceded subject matter jurisdiction in this case, brought pursuant to the BPCIA *after* Defendants' application was filed and accepted for review.

No evidence or case law supports Defendants' suggestion that subject matter will somehow disappear at some point in the future. On the contrary, Defendants continue to reserve

the right to [REDACTED]

[REDACTED] Janssen SoF ¶ 87. There is an active controversy over Janssen's entitlement to an injunction, a declaratory judgment, and other prospective relief against these ongoing practices.

#### **IV. HOSPIRA ACTIVELY INDUCES INFRINGEMENT**

Janssen's claim for induced infringement against Hospira must also proceed to trial. Because Celltrion and Hospira were informed of Janssen's infringement allegations simultaneously through joint counsel, Hospira's argument that it could not have possessed the requisite knowledge or mental state for inducement fails for the reasons given above. *See* Janssen SoF ¶¶ 69-72. Hospira is moreover a party to the stream of misleading communications to Janssen that show guilty knowledge. Hospira's argument that it took no affirmative steps to cause Celltrion and HyClone's infringement also fails. Reply Br. at 13-14.

There is no dispute that the Celltrion Media are necessary to make infliximab, and that Hospira well knows that. Hospira – not Celltrion – is the company that will actively market and sell infliximab in the United States (and is already doing so in other countries). Hospira is also a co-applicant on the application to sell infliximab in the United States, which expressly indicates that the product is made in cell culture media supplied by HyClone. Janssen SoF ¶¶ 98-101. *See In re Rosuvastatin Calcium Patent Litig. v. Aurobindo Pharma Ltd.*, 703 F.3d 511, 528-29 (Fed. Cir. 2012) (an entity is considered a submitter of an FDA drug application if it participates in its preparation and intends to benefit directly therefrom by selling the product upon approval). By taking these actions, Hospira has caused and encouraged the Celltrion Media to be made in violation of Janssen's patent. That is inducement. *See LaserDynamics, Inc. v. Quanta Computer, Inc.*, 694 F.3d 51, 76 (Fed. Cir. 2012) (noting that “active inducement of infringement is, by definition, conduct that causes and encourages infringement”); *Tegal Corp. v. Tokyo*

*Electron Co.*, 248 F.3d 1376, 1379 (Fed. Cir. 2001) (explaining that the term “inducement” is “as broad as the range of actions by which one in fact causes, or urges, or encourages, or aids another to infringe a patent”).

Hospira’s contention that it cannot be liable for inducement because it has no “relationship” with HyClone is incorrect. Reply Br. at 14. Companies are often held liable for inducing infringement where, as here, they cause and encourage the infringement, even when they do not directly deal with the direct infringer. For example, generic drug manufacturers can be held liable for inducing infringement of method claims by consumers or doctors, even when they market their products through distributors and have no direct contact with consumers. *See, e.g., AstraZeneca Lp v. Apotex, Inc.*, 633 F. 3d 1042, 1059 (Fed. Cir. 2010).

Finally, Hospira fails to distinguish *Trs. of Columbia Univ. v. Roche Diagnostics GmbH*, 272 F. Supp. 2d 90 (D. Mass. 2002), which held that a pharmaceutical company induced infringement of a manufacturing patent by marketing the resulting drug product. The fact that *Columbia* predates *Global-Tech* is irrelevant, since Janssen relies upon *Columbia* for active inducement, not intent, and *Global-Tech* did not change the law on this issue. Hospira argues that its involvement in the manufacture of infliximab is more “attenuated” than Roche’s, Reply Br. at 15, but that is disputed and is no basis for summary judgment. Like the contract in *Columbia*, Hospira’s contract with Celltrion is “not merely a contract to purchase goods,” 272 F. Supp. 2d at 107, but [REDACTED]. Janssen SoF ¶¶ 91-94. If the Celltrion Media infringe the ‘083 patent, Hospira, as the seller of the product the Celltrion Media are used to make, should not be allowed to escape liability for this infringement.

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**CERTIFICATE OF SERVICE**

I certify that on December 9, 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.

/s/ Alison C. Casey