IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

JANSSEN BIOTECH, INC., and NEW YORK UNIVERSITY,	)	
Plaintiffs,	)	
v.	)	**Civil Action No. 1:15-cv-10698**
CELLTRION HEALTHCARE CO., LTD., CELLTRION, INC., and HOSPIRA, INC.,	)	**Civil Action No. 1:16-cv-11117**
Defendants.	)	

PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

Defendants wisely do not move for summary judgment on the underlying question whether the cell culture media used in their biosimilar infliximab product (the "Celltrion Media") infringe U.S. Patent No. 7,598,083 ("the '083 patent"). That question, Defendants concede, can only be decided by the jury. For purposes of this motion, therefore, the Court must assume that the Celltrion Media do infringe. Defendants nevertheless contend that they should get a free pass for their role in creating and buying the Celltrion Media because, supposedly, they cannot be held directly or indirectly liable for the making of the infringing media. When Defendants made the same arguments in their motion to dismiss, this Court urged them to reconsider because their arguments were not amenable to resolution on the pleadings as a matter of law. Their motion for summary judgment does not substantially change their arguments and should be denied.

First, Defendants' contention that Celltrion is not a direct infringer fails to address the relevant law or the relevant facts. On the law, Defendants ignore that direct infringement can be established through facts proving direction or control over the infringement and is not limited to principal/agent or joint enterprise relationships. On the facts, Defendants ignore the evidentiary record, which provides copious evidence that Celltrion directed and controlled the formulations of the Celltrion Media. Indeed, Celltrion's own witness confirmed at his deposition that the Celltrion Media "are made to Celltrion's specifications" and that Celltrion requires the manufacturer HyClone to make them according to Celltrion's "precise formulation." Courts have routinely found direct infringement on these facts.

Second, Defendants' argument that they could not have known they were inducing infringement ignores recent Federal Circuit case law and flies in the face of the facts. The Federal Circuit recently explained that because knowledge is a question of fact and the relevant question depends on the Defendants' ***subjective*** state of mind, summary judgment of no

inducement cannot be granted based on analysis of the objective merits of defendant's defense (even when, unlike in this case, the defense is strong). The record is full of facts supporting the inference that Defendants knew, or willfully ignored the probability that, the Celltrion Media infringe the '083 patent. For example, upon learning of the '083 patent, Defendants attempted to mislead Janssen into believing that the Celltrion Media were made overseas (despite their knowledge to the contrary), and that they were not even aware of the formula for the media. Now, with Janssen's case supported by compelling – and unrebutted – scientific evidence,

[redacted] a compelling admission of infringement. It is for the jury that assesses the merits, and not this Court, to evaluate what it thinks of Defendants' subjective state of mind.

Furthermore, even if everything in Defendants' motion were true, neither the inducement claims nor Janssen's claims under the Biologics Price Competition and Innovation Act ("BPCIA") should be dismissed because Janssen seeks forward-looking declaratory and injunctive relief. Whether or not Defendants have knowingly induced infringement of the '083 patent up till now, Janssen is entitled to a trial on whether the Celltrion Media themselves infringe. If the Celltrion Media are found to be infringing, then future orders of the media would knowingly induce infringement and Janssen would be entitled to the declaratory judgment and injunction that it seeks. Because Defendants have not moved for summary judgment on infringement, they cannot avoid trial on Janssen's claims.

Finally, Hospira's separate attempt to avoid liability for inducement fails because Hospira has been aware of the exact same information that Celltrion has regarding the Celltrion Media's infringement of the '083 patent. Hospira is well aware that by marketing the infliximab made by Celltrion, it is causing Celltrion to have the Celltrion Media made in the United States.

Hospira, like Celltrion, is therefore inducing the infringement of the '083 patent.

STATEMENT OF FACTS

For a full presentation of the facts relevant to this motion, Janssen respectfully refers to its Statement of Material Facts in Opposition to Defendants' Motion for Summary Judgment ("SoF"). The most pertinent facts are summarized in the Argument section below.

ARGUMENT

I. FACT ISSUES PRECLUDE SUMMARY JUDGMENT ON JANSSEN'S CLAIM THAT CELLTRION DIRECTLY INFRINGES

Celltrion moves for summary judgment on Count 1, Janssen's claim against Celltrion for direct infringement of the '083 patent under 35 U.S.C. § 271(a), contending that its contract with HyClone defeats direct infringement as a matter of law. Def. Br. at 6-14. Celltrion's arguments fail. Under settled law, the jury will be permitted to conclude that Celltrion is liable for direct infringement because it directs and controls HyClone's infringing actions.

A. A Defendant Is Directly Liable for Patent Infringement If It Directs or Controls the Infringement

Celltrion grudgingly concedes that the Federal Circuit's *en banc* decision in *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 797 F.3d 1020, 1022 (Fed. Cir. 2015), sets forth the controlling legal standard for establishing direct infringement based on control over or joint participation in the actions of another. Def. Br. at 7. Under *Limelight,* a defendant is directly liable for the infringement of another "in two sets of circumstances: (1) where that entity ***directs or controls*** others' performance, and (2) where the actors form a ***joint enterprise***." *Limelight,* 797 F.3d at 1022 (emphasis added); *accord BMC Resources, Inc. v. Paymentech, L.P.*, 498 F.3d 1373, 1379-81 (Fed. Cir. 2007).[1]

[1] Celltrion suggests in a footnote that the *Limelight*/*BMC Resources* test for direct infringement applies only to method claims and not to product or composition claims. Def. Br. at 7 n.3. Celltrion does not

Instead of addressing whether Celltrion directs or controls the creation of the Celltrion Media, Celltrion assumes that *Limelight* requires Janssen to prove that Celltrion and HyClone had a principal-agent relationship. Def. Br. at 6-11. But agency is not the only way of establishing direct infringement under the "direction and control" test. As *Limelight* noted, "an actor is liable for infringement under § 271(a) . . . if it acts through an agent (applying traditional agency principles) ***or*** contracts with another to perform one or more steps of a claimed method." *Limelight*, 797 F.3d at 1023 (emphasis added); *accord BMC Resources*, 498 F.3d at 1379-81. By ignoring the fact that direct infringement can be proven by "contractual arrangements," *Limelight*, 797 F.3d at 1023, Celltrion fails to make even a *prima facie* showing that it is entitled to summary judgment.

B. The Evidence Establishes That Celltrion Directs and Controls the Formulations of the Celltrion Media

The ***only*** record evidence on which Celltrion relies is the Supply Agreement between Celltrion and HyClone. Statement of Material Facts in Support of Defendants' Motion for Partial Summary Judgment ("Def. SoF") ¶¶ 21-30. This agreement is not only insufficient to support summary judgment, it affirmatively shows that Celltrion directs and controls HyClone's activities through a contractual arrangement. Additional documentary and testimonial evidence confirms that a jury will be permitted to conclude that Celltrion directly infringes.

1. The Celltrion/HyClone Contracts Show That Celltrion Controls the Compositions of the Celltrion Media

Celltrion relies exclusively on the Supply Agreement between Celltrion and HyClone, arguing that its boilerplate language that the contract does not create an agency relationship or

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rely on this argument in the body of its motion. The Federal Circuit has never suggested that 35 U.S.C. § 271(a) operates differently for method claims than for product claims and there is no logical reason it should. Accordingly, multiple district courts have applied the *Limelight*/*BMC Resources* test for direct infringement where, as here, the defendant is accused of infringing a product patent. *See* p. 6 *infra*.

establish a joint enterprise defeats direct infringement. Def. Br. at 8-9. But, as discussed above, an agency relationship or joint enterprise is not necessary to establish direct infringement. Furthermore, as Celltrion itself acknowledges, *id.* at 9, contractual "labels are not dispositive, rather the facts and circumstances of the parties' relationship determines whether an agent-principal relationship existed." *Northern Shipping Funds I, LLC v. Icon Capital Corp.*, 921 F. Supp. 2d 94, 103 (S.D.N.Y. 2013); *see Onebeacon Insurance Co. v. Forman International, Ltd.*, No. 04-2271, 2005 U.S. Dist. LEXIS 648 at *3 (S.D.N.Y. Jan. 19, 2005) (collecting cases).

Here, the facts and circumstances of Celltrion's relationship with HyClone demonstrate that Celltrion ***does*** exercise direction and control over the Celltrion Media. Indeed, the very contract on which Celltrion relies shows this. [redacted] SoF ¶ 7. [redacted] *Id.* (emphasis added). The parties' Supply Agreement thus provides for joint control over the specifications by which the Celltrion Media are made. Even taking Celltrion's evidence at face value, the making of the Celltrion Media is a joint operation that gives rise to direct infringement. *See Limelight*, 797 F.3d at 1023.

But in fact, the record shows that control over the specifications of the Celltrion Media belongs to Celltrion alone. In addition to the Supply Agreement, Celltrion and HyClone entered into a Quality Agreement that governed the production and control of the Celltrion Media. SoF ¶¶ 5-6. [redacted] *Id.* ¶ 6 (emphasis added). Celltrion's corporate

witness confirmed at his deposition [redacted] (emphasis added). Consistent with Celltrion's ultimate control over the products, the Quality Agreement provides that [redacted] *Id.* ¶¶ 6, 16.

Contractual arrangements such as the Celltrion/HyClone contracts have repeatedly been found to give rise to direct infringement. *See, e.g., 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 by Apple where "the evidence demonstrates that Samsung manufactured chips for Apple, using Apple's specifications, to be tested according to Apple's requirements, and to be used only in Apple's end products"); *Rowe Int'l Corp. v. Ecast, Inc.*, 586 F. Supp. 2d 924, 932-933 (N.D. Ill. 2008) (direct infringement where defendant "contracted out" the manufacture of jukeboxes according to "in essence, technical specifications"); *cf. Pellegrini v. Analog Devices, Inc.*, 375 F.3d 1113, 1118 (Fed. Cir. 2004) ("[O]ne 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 . . . .").[2]

2. The Evidentiary Record Further Confirms Celltrion's Direction and Control of the Celltrion Media

Beyond the contracts, the documentary and testimonial evidence confirms that Celltrion directs and controls the formulations of the Celltrion Media. Although development of the

[2] *See also TGIP, Inc. v. AT&T Corp.*, 527 F. Supp. 2d 561, 578 (E.D. Tex. 2007) (direct infringement based on direction and control where defendant "provided specifications to each of its retailers directing the retailers on the processes" that constituted patent infringement); *Lineguard, Inc. v. Linetec, Inc.*, No. 87-C-2368, 1987 U.S. Dist. LEXIS 4525 at *2 (N.D. Ill. May 29, 1987) (despite defendants' not having manufactured the allegedly infringing detectable marketing tape, an issue of material fact still exists since "one may infringe a patent if he has infringing products made for him").

media began with preexisting HyClone products, Celltrion worked intensively with HyClone to transform these products into the Celltrion Media. *See* SoF ¶¶ 8-15. In particular, Celltrion (not HyClone) chose to [redacted] *Id.* ¶ 12. From there, Celltrion dictated multiple further changes to the media based on experiments performed with infliximab. *Id.* ¶¶ 8-15. The final formulations of the Celltrion Media are the result of Celltrion's modifications to HyClone's original products.

After the formulations for the custom Celltrion Media were developed, Celltrion exercised complete control over their manufacture. Indeed, by 2013, Celltrion obtained the precise formulations for the media [redacted] *See id.*¶¶ 20-21. As Celltrion's corporate witness confirmed, [redacted] *Id.* ¶ 13. He further testified that [redacted] *Id.* ¶ 21.

Celltrion's admission that it "assigns the task of making" the Celltrion Media to HyClone confirms that Celltrion not only directs and controls the formulations of the Celltrion Media, but that it employs HyClone as its agent in doing so. *See Scholastic, Inc. v. Stouffer*, No. 99-Civ-11480, 2000 U.S. Dist. LEXIS 11516 at *16 (S.D.N.Y. Aug. 14, 2000) (noting that 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"). At the very least, this raises a triable dispute

for the jury. *See, e.g., Cabrera v. Jakabovitz*, 24 F. 3d 372, 385-86 (2d Cir. 1994) (determination of agency relationship is a "mixed question of law and fact" that should generally be decided by a jury); *Anwar v. Fairfield Greenwich, Ltd.*, 728 F. Supp. 2d 372, 435 (S.D.N.Y. 2010) (determination of agency relationship is highly factual). But in any event, whether HyClone is Celltrion's agent or not, the undisputed evidence is that Celltrion requires HyClone to make the Celltrion Media precisely according to Celltrion's specifications. This suffices to permit the jury to find direction and control by Celltrion and to establish direct infringement.

C. Applying the Controlling Legal Standards for Direct Infringement Would Not "Subvert the Patent Act"

Celltrion contends that holding it liable for direct infringement would "subvert the Patent Act" by eliding the distinction between direct and indirect infringement. Def. Br. at 12-14. But the Federal Circuit was well aware of that distinction when it decided *Limelight, BMC Resources*, and the other controlling cases on direct infringement on which Janssen relies. It is true, as the court noted in *BMC Resources*, that indirect infringement is the "normal recourse under the law" when a "defendant participates in or encourages infringement but does not directly infringe a patent." *BMC Resources*, 498 F.3d at 1379. That principle applies to Hospira, which encourages and induces infringement by marketing infliximab without directly infringing the '083 patent. *See* Sections II-III *infra*. *BMC Resources* emphasized, however, that a "party cannot avoid infringement . . . simply by contracting out steps of a patented process to another entity. In those cases, the party in control would be liable for direct infringement." *Id*. at 1381. Applying these settled standards to the facts of this case does not subvert the Patent Act.[3]

[3] Defendants' contention that Celltrion and HyClone had an "arms-length" relationship, Def. Br. at 13, is just another way of arguing that Celltrion did not direct or control HyClone's infringement. *See Muniauction, Inc. v. Thomson Corp*., 532 F. 3d 1318, 1329 (Fed. Cir. 2008) (distinguishing between when "one party exercises 'control or direction'" over the infringing process and "mere 'arms-length cooperation'" that "will not give rise to direct infringement").

II. FACT ISSUES PRECLUDE SUMMARY JUDGMENT ON JANSSEN'S CLAIMS FOR INDUCED INFRINGEMENT

Both Defendants seek summary judgment on Janssen's inducement claims, arguing that because Janssen proceeds under the doctrine of equivalents, Defendants "objective[ly]" must have lacked the state of mind required by *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754 (2011), and its progeny. Def. Br. at 2. This argument fails for at least three reasons. First, Defendants' legal argument is wrong. Inducement focuses on a defendant's subjective state of mind, which the jury must assess, not the court's objective analysis of the non-infringement defenses. This principle is true whether or not the plaintiff relies on the doctrine of equivalents ("DOE"). In any event, with Defendants ***conceding infringement*** for purposes of this motion, the mere fact that infringement is under the DOE cannot possibly "objectively" establish anything about Janssen's case. Second, applying the correct legal standard to the facts, there is ample evidence from which the jury could conclude that Defendants knew of the '083 patent and of the infringing nature of the Celltrion Media and continued to induce their manufacture. Third, even if Defendants could somehow establish that they previously lacked the mental state necessary to be liable for inducement, Janssen's request for declaratory and prospective relief against future inducement forecloses summary judgment.

A. Subjective Knowledge of Infringement Is a Factual Question That Cannot Be Resolved on Summary Judgment

Defendants are correct that under *Global-Tech*, "induced infringement under [35 U.S.C.] § 271(b) requires knowledge that the induced acts constitute patent infringement." *Global-Tech*, 563 U.S. at 766. They are wrong, however, that their purported "objective, good-faith defense" to non-infringement "compel[s] summary judgment of no inducement." Def. Br. at 2. Induced infringement involves the defendant's ***subjective*** state of mind, not an objective assessment of the strength of its defense. The defendant's state of mind is to be inferred from all the relevant

facts and circumstances, and this inference must virtually always be drawn by the jury.

This is clear from *Global-Tech* itself, both in the Supreme Court and the Federal Circuit. In *Global-Tech*, the jury found defendant Pentalpha liable for induced infringement of the patent for a "cool-touch" deep-fryer. 563 U.S. at 757-59. Pentalpha unsuccessfully moved for judgment as a matter of law, arguing that the evidence showed that it did not even know about the patent, and thus could not know that it infringed. *Id.* at 759. The Supreme Court, after clarifying the legal standards for inducement, proceeded to ***affirm*** the judgment of infringement. The Court held that although there was no evidence that Pentalpha knew about the patent, a jury could have reasonably inferred that it was willfully blind because it did not inform its attorney that it had copied the plaintiff's design. *Id.* at 770-71. This "evidence was more than sufficient for a jury to find that Pentalpha subjectively believed there was a high probability that SEB's fryer was patented, that Pentalpha took deliberate steps to avoid knowing that fact, and that it therefore willfully blinded itself to the infringing nature of Sunbeam's sales." *Id.* at 771.

Although the Supreme Court did not address the objective reasonableness of Pentalpha's non-infringement defense, the lower courts in *Global-Tech* did. Applying the Federal Circuit's then-controlling case on willful infringement, *In re Seagate Technology, LLC*, 497 F.3d 1360 (Fed. Cir. 2007) (en banc),[4] the Federal Circuit affirmed the district court's finding that Pentalpha's infringement was ***not*** willful because the evidence of infringement was not sufficiently "one-sided or overwhelming" to make Pentalpha's actions objectively baseless as a matter of law. *SEB S.A. v. Montgomery Ward & Co., Inc.*, 594 F. 3d 1360, 1380-81 (Fed. Cir. 2010), *aff'd sub nom. Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754 (2011). But the objective reasonableness of the defendant's non-infringement defense – the sole basis of

[4] *Seagate* has since been overruled by the Supreme Court. *See Halo Electronics, Inc. v. Pulse Electronics*, 136 S. Ct. 1923 (2016).

Defendants' motion here – did not prevent either the Federal Circuit or the Supreme Court from affirming the jury's finding of inducement.

Recently, the Federal Circuit made this point explicitly, holding that the objective strength of a non-infringement defense cannot support summary judgment of no inducement. In *Unwired Planet, LLC v. Apple Inc.*, 829 F.3d 1353, 1363 (Fed. Cir. 2016), the district court held that "no reasonable juror could conclude" that Apple induced infringement "because of 'the strength of Apple's non-infringement argument.'" The Federal Circuit vacated and remanded:

> The district court erred by basing summary judgment on its own estimation of the objective strength of Apple's non-infringement defense. ***The proper focus of indirect infringement analysis is on the subjective knowledge of the accused infringer***, and the district court's conclusion that Apple's non-infringement defenses were strong at most created a factual question as to Apple's own subjective beliefs.

Id. (emphasis added). *See also Presidio Components, Inc. v. Am. Tech. Ceramics Corp.*, No. 14-cv-02061, 2016 U.S. Dist. LEXIS 110212, at *25 (S.D. Cal. Aug. 17, 2016) ("To the extent [defendant] is arguing that an objectively reasonable non-infringement defense negates a finding of inducement, the Federal Circuit has recently rejected this contention.") Assuming – but not agreeing – that there is an objective basis for Defendants' defense, the question of inducement would still need to go to the jury.

Indeed, a finding of no inducement can rarely be made as a matter of law. As the Federal Circuit recently observed, "*Global-Tech* affirmed the Supreme Court's and our court's earlier precedents, which held that the 'requisite intent to induce infringement may be inferred from all of the circumstances.'" *Warsaw Orthopedic, Inc. v. NuVasive, Inc.*, 824 F.3d 1344, 1347 (Fed. Cir. 2016) (quoting *Broadcom Corp. v. Qualcomm, Inc.*, 543 F.3d 683, 699 (Fed. Cir. 2008)). Because "'the drawing of inferences'" is "'peculiarly within the province of the fact finder,'" the question of intent should ordinarily be left to the jury. *See Broadcom*, 543 F.3d at 700 (Fed. Cir.

2008) (citation omitted). An alleged "good-faith belief [in non-infringement] presents a factual question," and "not an entitlement to a no-knowledge finding as a matter of law." *Smith & Nephew Inc. v. Arthrex, Inc.*, 603 F. App'x 981, 990 (Fed. Cir. 2015); *see also EveryScape, Inc. v. Adobe Sys.*, No. 10-cv-11597, 2014 U.S. Dist. LEXIS 119467, at *6-7 (D. Mass. Aug. 27, 2014) (the subjective belief of the accused infringer "is, of course, a quintessential issue of fact.").

The fact that Janssen relies on the DOE does not change matters. Defendants assert that they are "aware of no case" since *Global-Tech* "in which inducement was found based solely on infringement under the DOE." Def. Br. at 16. But *Global-Tech* itself is that case. Two fryers were accused of infringing, one literally and the other under the DOE. *See SEB*, 594 F. 3d at 1367. The defendant was found liable for inducement of "both versions of the fryers" – the one that literally infringed and the one that infringed under the DOE – and this judgment was affirmed. *Id*. at 1367-68. Similarly, in *Johnstech Int'l Corp. v. JF Microtechnology SDN BHD*, No. 14-cv-02864, 2016 U.S. Dist. LEXIS 106548, (N.D. Cal. Aug. 11, 2016), the court denied summary judgment as to no inducement, holding that a reasonable jury could find willful blindness under *Global-Tech*, *id.* at *16-*17, even though the ***sole*** infringement theory left in the case was based on the DOE, *id.* at *4-*16. As the district court recognized, the law of inducement is the same whether infringement is literal or under the DOE.

B. The Record Supports the Inference That Defendants Knew the Celltrion Media Infringe the '083 Patent

Although ultimately a question of fact for the jury, the record contains strong evidence that Defendants actively induced the creation of the Celltrion Media knowing, or willfully ignoring the probability that, the Celltrion Media infringe the '083 patent.

1. Defendants Concealed Facts and Hid Their Knowledge of the Celltrion Media

Janssen notified Defendants of the '083 patent by including it on a list of patents that might be infringed, which it served on Defendants under the BPCIA in December 2014. SoF ¶ 32. At the time, Janssen did not know the formulations of the Celltrion Media, or where they were made, and Defendants had refused Janssen's explicit requests to provide this information. *Id.* ¶ 31. Over the course of the next several months, Defendants repeatedly obstructed Janssen's attempts to find out these basic facts about its case. This obfuscation supports an inference of intent to infringe. *See Global-Tech*, 563 U.S. at 770-771.

In response to Janssen's BPCIA notice, Defendants misleadingly asserted that the '083 patent was not infringed because Celltrion did not conduct any infringing activities in the United States. SoF ¶¶ 34-35. The argument was misleading because HyClone makes the Celltrion Media on Defendants' behalf in Utah. *Id.* ¶ 56. But Janssen did not know that fact at the time and Defendants aggressively concealed it. Thus, Defendants asserted that Janssen lacked "a good-faith basis to assert infringement for any acts by Celltrion that are conducted ***entirely*** outside the territorial reach of its U.S. patents. ***This point, alone, is dispositive***." *Id.* ¶ 38 (emphasis added). When Janssen began to suspect that the Celltrion Media were made in Utah and asked for clarification, Defendants refused to confirm that fact. Instead they responded that Janssen's "***requests going to territorial issues are irrelevant"*** – a jarring change from "dispositive." *Id.* ¶ 53. Janssen ultimately learned the truth from HyClone, not Defendants. *Id.* ¶ 56.

Defendants also attempted to conceal the fact that they knew the formulations of the Celltrion Media and how similar they are to the claims of the '083 patent. Defendants initially asserted that they did not infringe by citing only a handful of differences in the formulation,

while concealing from Janssen the overwhelming number of similarities. *See id.* ¶ 36. When Janssen asked for the complete formulation so that it could assess the issue itself, Defendants insisted that Janssen would have to obtain that information from third-party HyClone. *Id.* ¶¶ 44-46. Only after eleven months of discovery – and only after Janssen challenged Celltrion's production – did Defendants finally admit that Celltrion had the formulations all along. *Id.* ¶¶ 58-62.

As in *Global-Tech*, 563 U.S. at 770-71, it is difficult to "fathom what motive [Defendants] could have had for withholding [the] information" about the Celltrion Media other than to conceal evidence of their infringement.

2. The Evidence of Infringement Is Strong and the Court Must Assume Infringement for Purposes of this Motion

Defendants have made no motion for summary judgment that the Celltrion Media do not infringe the '083 patent, and so the Court must assume on this motion that it does. And Janssen will prove it at trial. Although Defendants disparage Janssen's infringement case in their motion, in discovery they have failed to dispute it as a matter of science.

It is undisputed that the Celltrion Media contain every ingredient required by the '083 patent and literally meet the overwhelming majority of the claimed concentration limitations. Def. Br. at 15. As to the small percentage of ingredients in the Celltrion Media that fall literally outside of the claimed concentration ranges, Janssen has performed sophisticated experiments showing that these small differences do not result in cell media that are substantially different in any way than that claimed in the '083 patent. SoF ¶¶ 69. This analysis has been confirmed by Janssen's internationally known experts in cell culture science. *Id.* ¶¶ 69, 72.

In response to Janssen's case, Defendants failed to produce any experimental data of their own. SoF ¶¶ 73-74. This is despite the fact that Defendants opposed Janssen's motion for an

expedited trial schedule by saying that they needed time to conduct experiments of their own. *See* Case No. 1:15-cv-10698, Dkt. 164 (Tr. of May 19, 2016 Hear'g on Mot. to Expedite) at 24:16-21. Apparently, Defendants did not like what they found. Even more tellingly, Defendants' own expert confined himself to making improper legal arguments and quibbling about Janssen's experiments. SoF ¶ 73; Ex. 63. Significantly, he did not join issue on the key question: ***he did not opine that the few differences between the claims of the '083 patent and the Celltrion Media are substantial***. SoF ¶ 73. The upshot is that Defendants have failed to dispute Janssen's substantive infringement theory as a matter of science.

Seeking to make a virtue of their lack of non-infringement evidence, Defendants argue that the very sophistication of Janssen's experiments shows that Defendants couldn't have known the Celltrion Media are infringing. Def. Br. at 16-17. But as Janssen's expert witness explained (and Defendants' expert did not dispute), the results of Janssen's experiments were not surprising because the literal differences between the '083 patent and the Celltrion Media are manifestly insubstantial. SoF ¶ 72. That is why Janssen could allege infringement in good faith based on the formula of the Celltrion Media, even before its experiments were completed. In any event, since April 2016 Defendants have been in possession of Janssen's experimental results. SoF ¶ 69. Defendants did not need to conduct their own experiments to know they were infringing; all they needed to do to assess infringement was to compare their formulation to the '083 patent and to read Janssen's laboratory report. *See Walker Digital, LLC v. Facebook, Inc.*, 852 F. Supp. 2d 559, 565 (D. Del. 2012) (explaining that post-litigation information can give rise to knowledge of infringement and establish inducement).[5] The jury that concludes that the

[5] *See also Script Sec. Solutions LLC v. Amazon.com, Inc*., No. 15-cv-1030, 2016 U.S. Dist. LEXIS 34259, at *24-25 (E.D. Tex. Mar. 16, 2016) (collecting cases showing that post-litigation information can establish inducement).

Celltrion Media are infringing will have no difficulty in concluding, from the same evidence, that the Defendants were well aware of that fact.

3. [redacted] Any defense of good faith will be thoroughly impeached by these facts.

C. Defendants' Purported Lack of Knowledge Is No Defense to Janssen's Claims for Declaratory and Prospective Relief

Defendants' motion on inducement is fundamentally misguided for a final reason. Even if it were true that Defendants are not liable for past inducement (which they are), Janssen would still be entitled to pursue its claims for *prospective* relief, including a declaratory judgment that selling infliximab in the U.S. or buying Celltrion Media in Utah would induce infringement and an injunction against future infringement and inducement. It is well established that so long as there is a justiciable case or controversy, a plaintiff may bring suit to enjoin or declare future acts of inducement even where infringement has yet to occur. *See, e.g., Fina Research, S.A. v. Baroid Ltd.*, 141 F.3d 1479, 1484-85 (Fed. Cir. 1998); *Takeda Chem. Indus. v. Watson Pharms., Inc.*, 329 F. Supp. 2d 394, 400-03 (S.D.N.Y. 2004). Once it is established at trial that the Celltrion Media infringe the '083 patent, any future orders of Celltrion Media, or product made from them, will knowingly induce infringement. *See Bose Corp. v. SDI Techs., Inc.*, 558 F. App'x 1012, 1023 (Fed. Cir. 2014) (summary judgment of no inducement "improperly absolved SDI of potential post-verdict liability" because defendant would not be able to "credibly argue"

that it did not know it infringed "following a verdict to the contrary").

True for Janssen's inducement claim under 35 U.S.C. 271(b), this principle applies with special force to Janssen's claim under the BPCIA. Indeed, adjudication of future infringement is the very purpose of the BPCIA. The relevant statute, 35 U.S.C. § 271(e)(2)(C), defines patent infringement by reference to 42 U.S.C. 262(*l*)(3), which applies to patents that "***could reasonably be asserted . . . if***" an unlicensed party engaged in otherwise infringing acts. 42 U.S.C. 262(*l*)(3) (emphasis added).

The BPCIA was designed specifically to provide an avenue to adjudicate anticipated future acts of infringement in connection with the prospective marketing of a biosimilar product. As the Federal Circuit has explained, the BPCIA, like the Hatch-Waxman Act, "provide[s] for certain early adjudications of patent issues that would be presented by future market-entry activity in the FDA setting." *Sandoz Inc. v. Amgen Inc.*, 773 F.3d 1274, 1281 (Fed. Cir. 2014). Defendants' purported lack of ***past*** knowledge of infringement cannot immunize them from liability for inducing infringement in the ***future***, if the Celltrion Media are found at trial to infringe. Thus, Defendants' defenses to past inducement cannot defeat Janssen's demand for judgment and an injunction aimed to prevent future inducement. *See Forest Labs., Inc. v. Ivax Pharms., Inc.*, 501 F.3d 1263, 1272 (Fed. Cir. 2007) (proper for court to enjoin inducement of acts "that *will* constitute direct infringement upon approval of the ANDA" (emphasis added)); *Allergan, Inc. v. Alcon Labs.*, 324 F.3d 1322, 1332 (Fed. Cir. 2003) ("Summary judgment of non-infringement under [Hatch-Waxman], therefore, is inappropriate where the plaintiff can demonstrate the existence of a genuine issue of material fact with respect to the claim that the ANDA filer *will* induce infringement of its patent upon approval of the ANDA." (emphasis

added)).[6]

III. HOSPIRA ACTIVELY INDUCES INFRINGEMENT BY MARKETING INFLIXIMAB

Hospira makes a separate argument that, even if the inducement claims against Celltrion are not dismissed, it is entitled to summary judgment nonetheless. To the extent its argument is "[f]or the reasons set forth" with respect to Celltrion, Def. Br. at 18, it is meritless for the same reasons. All of Janssen's evidence of infringement was provided simultaneously to both parties, SoF ¶¶ 69-72, and Janssen's request for a future injunction applies equally to both parties.

Hospira's second argument is that as a matter of law it cannot be found to induce infringement because it only sells infliximab and does not "instruct, demand, or require" Celltrion to use the Celltrion Media to make infliximab. Def. Br. at 19. But active inducement does not require that the inducer instructed, demanded, or required infringement. It only requires the "taking of affirmative steps to bring about" the infringement. *Global-Tech*, 563 U.S. at 760. 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." *Tegal Corp. v. Tokyo Electron Co.*, 248 F.3d 1376, 1379 (Fed. Cir. 2001) (quoting *Fromberg, Inc. v. Thornhill*, 315 F.2d 407, 411 (5th Cir. 1963)). "'[C]ontrol is not a necessary condition for a finding of inducement liability.'" *Nuance Communs. Inc. v. Tellme Networks, Inc.*, 707 F. Supp. 2d 472, 485 (D. Del. 2010) (quoting *Trs. of Columbia Univ. v. Roche Diagnostics GmbH*, 272 F. Supp. 2d 90, 106 (D. Mass. 2002)) ("*Columbia v. Roche*").

In *Columbia v. Roche*, Judge Gertner rejected the argument that Hospira is making here

[6] Defendants' reliance on the doctrine of res judicata is mistaken because that doctrine applies only to subsequent litigation, not claims brought in the same action. *See, e.g., Waste Mgmt. of Ohio, Inc. v. City of Dayton*, 169 F. App'x 976, 984 (6th Cir. 2006).

and found inducement on analogous facts. That case, like this one, involved technology that was used to make a complex pharmaceutical product but was not present in the product itself. *See Columbia v. Roche*, 272 F. Supp. 2d at 104. The defendant Roche, like Hospira here, marketed the drug but did not manufacture it. Roche argued that it was a "mere purchaser of goods who is not liable for purchasing a product that a third party happened to make with an infringing process" because "it did not control the details" of the "processes to produce" the drug. *Id.* at 106. Judge Gertner rejected this argument, holding that the "key question is not whether Roche controlled [the manufacturer's] actions, but whether Roche encouraged those actions with the requisite prior knowledge and specific intent to infringe." *Id.*

Judge Gertner's ruling was a finding of fact made after trial. Here, a reasonable jury could find (1) that Hospira and Celltrion are co-applicants for FDA approval to sell Celltrion's biosimilar, SoF Response ¶ 6 at p. 28; (2) that Hospira fully understands that the Celltrion Media are necessary – and required – to make that product, SoF ¶ 104; (3) that Hospira understands that its placement of orders with Celltrion requires Celltrion in turn to obtain Celltrion Media from HyClone, *id.* at ¶¶ 96, 104; and (4) that, at least since 2014, Hospira has done so knowing that the Celltrion Media infringe the '083 patent, *id.* at ¶ 105. Pursuant to its 2009 Co-Exclusive Distribution Agreement with Celltrion, Hospira has been actively involved in the regulatory approval process for Celltrion's infliximab product worldwide since long before the product was ever marketed, and it has had wide access to information about the processes for manufacturing infliximab. SoF ¶¶ 91-92, 94, 98-101. In particular, H

Id. ¶¶ 96, 104. Hospira knows further that if Celltrion were to use any other media to manufacture infliximab, it "would be very likely" to require FDA approval, representing a

change to the information disclosed in the aBLA. *Id.* ¶ 103. [redacted] *Id.* ¶¶ 96, 104-105. By continuing to market infliximab on Celltrion's behalf despite knowing of the facts establishing infringement, Hospira actively induces the infringement by Celltrion and HyClone.

IV. CONCLUSION

For the reasons set forth above, Defendants' motion for summary judgment fails. On direct infringement, Celltrion overlooks the relevant law and does not even attempt to establish that it is entitled to summary judgment under the correct legal standard. Under this standard – direction or control – there is clearly a triable issue of fact as to direct infringement. On inducement, Defendants erroneously rely on the supposed objective strength of their non-infringement defense and do not even attempt to show that they acted with the lack of subjective intent that is necessary to establish lack of inducement. Again, the evidence, viewed under the proper legal test, easily presents an issue for trial – and in any event, Janssen is entitled to trial on the question of prospective infringement. Finally, Hospira's attempt to avoid liability fails because it knows what Celltrion knows and still causes Celltrion to have infringing cell culture media made in the United States. Defendants' motion must be denied in its entirety.

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