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-MLW
	)	Civil Action No. 1:16-cv-11117-MLW
CELLTRION HEALTHCARE CO., LTD., CELLTRION, INC., and HOSPIRA, INC., Defendants.	)	

JANSSEN'S BRIEF ON WHETHER HOSPIRA MAY BE LIABLE ON THEORIES OF JOINT ENTERPRISE, AGENCY OR CONTRACT

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INTRODUCTION

Janssen submits this brief pursuant to the Court's December 23, 2016 Order, directing the parties to submit memoranda on "whether a reasonable jury could find that Hospira is, with Celltrion Healthcare Co., Ltd. and Celltrion Inc., liable for inducing patent infringement under 35 U.S.C. §271(b) on theories of joint enterprise, agency or contract." Dkt. No. 327.

Hospira is much more than a "mere customer" of the two Celltrion companies [1] Hospira, together with Celltrion, is engaged in a joint enterprise for the development and commercialization of Inflectra. Each of these entities would be liable for wrongdoing by the others in furtherance of the joint enterprise, including acts of direct infringement under §271(a) and acts of inducement under §271(b), so that Celltrion's infringing acts under §§ 271(a) and (b) would be imputed to Hospira. Separate and apart from this vicarious liability, a reasonable jury could find that Hospira is liable for its own acts of inducement. At a minimum, there are disputed fact question on these issues that preclude summary judgment.

RELEVANT FACTS

The relevant facts are set forth in Janssen's Statement of Material Facts in Opposition to Defendants' Motion for Partial Summary Judgment ("Janssen SoF") (Dkt. No. 282), and in an Additional Statement of Material Facts that accompanies this brief.

ARGUMENT

I. As a Member of a Joint Enterprise, Hospira Is Liable for Celltrion's Acts of Direct and Indirect Infringement

In *Limelight Networks, Inc. v. Akamai Techs., Inc.*, 134 S. Ct. 2111 (2014), the Supreme Court noted "the possibility that the Federal Circuit [had] erred by too narrowly

[1] As used in this brief and as defined in the parties' Co-Exclusive Development Agreement, "Celltrion" refers collectively to Celltrion Healthcare Co., Ltd. and Celltrion Inc. *See* Dkt. No. 282-79 at 2.

circumscribing the scope of § 271(a)," and invited the Federal Circuit "[on] remand to … [take] the opportunity to revisit [that section] if it so chooses." 134 S. Ct. at 2119, 2120. On remand, the Federal Circuit "avail[ed] [itself] of that opportunity." *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 797 F.3d 1020, 1022 (Fed. Cir. 2015) (en banc). Sitting en banc, the Federal Circuit held that when entities are engaged in a joint enterprise, "[a]ll members of [the] joint venture may be jointly and severally liable for wrongful acts committed in furtherance of the joint enterprise or venture." *Id.* at 1023 (quoting 48A C.J.S. *Joint Ventures* § 62). "[I]n a joint enterprise, the acts of each participant are, by definition, imputed to every member." *Id*. Where a joint enterprise exists, "[t]he law … considers that each [member of the enterprise to be] the agent or servant of the others, and that the act of any one within the scope of the enterprise is to be charged vicariously against the rest." *Id.* (quoting *Restatement (Second) of Torts § 491 cmt. b*).

A. Joint Enterprise Principles Are Fully Applicable to § 271(b)

The joint enterprise issue arose in *Akamai* in the context of divided infringement, where all of the steps of a claimed method were not performed by a single entity. But the relevant principles have general applicability outside that context.

"Patent infringement is a tort," *Wordtech Sys., Inc. v. Integrated Networks Solutions, Inc.*, 609 F.3d 1308, 1313 (Fed. Cir. 2010), and it is a well-established principle of tort law that wrong-doing by "any member of a joint enterprise may be attributed for purposes of liability to … any other member." *Ryba v. LaLancette*, 417 F. Supp. 2d 199, 209-10 (D. Mass. 2006) (citing *Restatement (Second) of Torts* § 491). "[W]here two or more actors form a joint enterprise, all can be charged with the acts of the other, rendering each liable for the steps performed by the other as if each is a single

actor." *Akamai*, 797 F.3d at 1023 (citing *Restatement (Second) of Torts § 491 cmt. b*). Then-Judge Breyer summarized the relevant principle in *Lyon v. Ranger III*, 858 F.2d 22 (1st Cir. 1988): Where a joint enterprise exists, "[t]he law then considers that each [member of that enterprise] is the agent or the servant of the others, and that the act of any one within the scope of the enterprise is to be charged vicariously against the rest.'" *Id.* at 27 (quoting W.P. Keeton, et al., *Prosser & Keeton on Torts* §72 at 517 (5th ed. 1984)); *see also Pritchett v. Kimberling Cove, Inc.*, 568 F.2d 570, 579-80 (8th Cir. 1977) (wrong-doing by a member of a joint enterprise acting within the scope of the enterprise "is imputed to all other members, who become mutually liable.") (citing *Restatement (Second) of Torts* § 491).

Our research has not uncovered any cases in which one member's liability for inducement under § 271(b) has been imputed to a fellow member of a joint enterprise. But the joint enterprise principles discussed above have general applicability, and there is no reason on law or logic why they should not apply to inducement under § 271(b).

Here, Hospira and Celltrion are engaged in a joint enterprise to develop and commercialize Inflectra. As a member of that joint enterprise, Celltrion's wrongdoing in the scope of the enterprise, including its acts of direct infringement under § 271(a) and its acts of inducement under § 271(b), are imputed to all members of the enterprise, so that Hospira is vicariously liable for Celltrion's infringing acts.

B. The Requirements for Joint Enterprise Liability

As *Akamai* explains, "[a] joint enterprise requires proof of four elements," 797 F.3d at 1023:

> (1) an agreement, express or implied among the members of the group;

> (2) a common purpose to be carried out by the group;
>
> (3) a community of pecuniary interest in that purpose among the members; and
>
> (4) an equal right to a voice in the direction of the enterprise, which gives an equal right of control.

Id. (citing *Restatement (Second of Torts) § 491 cmt. c*).

Whether these elements are met in a given case is "necessarily [a] fact intensive" inquiry, *Duke Energy Int'l, L.L.C. v. Napoli*, 748 F. Supp. 2d 656, 674 (S.D. Tex. 2010), and generally presents "a question for the jury, under proper direction from the court." *Restatement (Second of Torts) § 491 cmt. c*); *see also Estate of Antonio v. Pedersen*, No. 5:11-cv-41, 2012 U.S. Dist. LEXIS 174987, at *14-15 (D. Vt. Dec. 11, 2012) ("the majority of courts have found whether a joint venture exists is a question of fact for the jury."); *id.* at n.2 (collecting cases).

C. The Requirements for a Joint Enterprise Are Satisfied Here

All of the elements *Akamai* identifies are present here. To the extent Defendants dispute the factual basis for any element, the issue would need to be resolved by the jury on the evidence at trial, not decided by the Court on summary judgment.

1. There Is An Agreement Among the Members of the Enterprise

An agreement between the members of a joint enterprise can be "express or implied." *Akamai*, 797 F.3d at 1023. Here, the parties have an express written agreement, *i.e.*, the Co-Exclusive Distribution Agreement between Hospira and the two Celltrion entities, as amended in a series of written Amendments. *See* Dkt. No. 282-79; Exs. 1-8. The Co-Exclusive Distribution Agreement is dated December 22, 2009, before the formulation of the infringing Celltrion cell media was complete. *Id.*; Janssen SoF ¶ 91.

2. The Enterprise Has a Common Purpose

The common purpose of the Celltrion/Hospira joint enterprise is to develop and commercialize Inflectra. The preamble to the parties' Co-Exclusive Distribution Agreement discusses that common purpose (Dkt. No. 282-79 at 1):

[redacted]

3. The Members of the Joint Enterprise Have a Community of Pecuniary Interest

As explained in the Co-Exclusive Distribution Agreement, [redacted]

[redacted]

Dkt. No. 282-79, § 5.13 at 23-24 (emphasis added). It is hard to imagine a clearer example of a common pecuniary interest.

4. The Members of the Joint Enterprise Have an Equal Right to a Voice in the Direction of the Enterprise

To have an "equal right to a voice in the direction of the enterprise," *Akamai*, 797 F.3d at 1023, every member of a joint enterprise need not have an equal voice in each and every decision. For example, "parties to a joint venture may choose to divide the responsibilities between themselves and defer … to each other's different areas of expertise." *Estate of Antonio*, 2012 U.S. Dist. LEXIS 174987, at *31 (quoting *Halloran v. Ohlmeyer Comms. Co.*, 618 F. Supp.

1214, 1219 (S.D.N.Y. 1985)). "To establish [this] element of a joint enterprise, 'each [participant] must have an authoritative voice or, … must have some voice and right to be heard.'" *Duke Energy*, 748 F. Supp. 2d at 673-74 (quoting *Texas Dept. of Transp. v. Able*, 35 S.W.3d 608, 613 (Tex. 2000) (alterations in *Duke Energy*)). It is sufficient if "every party ha[s] some degree of input into the operation of the venture." *Payton* v. Abbott Labs, 512 F. Supp. 1031, 1036 (D. Mass. 1981). As then-Judge Breyer explained in *Lyon*, 858 F.2d 22, the applicable standard is met where each participant has the opportunity to "participate[ ] actively and equally" in decisions so that "each alone could have suggested alteration." 858 F.2d at 28 (Breyer, J.).

The relevant agreements leave no doubt that Hospira has the requisite "right to a voice in the direction of the enterprise." *Akamai*, 797 F.3d at 1023.

a. The Joint Steering Committee

[redacted]

[redacted]

b. Other Joint Committees and Joint Teams

Hospira also participates equally with Celltrion in other joint committees and joint teams on important issues concerning the affairs of their joint enterprise. For example:

- [redacted]
- [redacted]
- [redacted]

- [redacted]
- [redacted]
- [redacted]

[redacted]

- [redacted]

c. Joint Responsibility for Investigating Issues of Possible Patent Infringement

[redacted]

d. Other Evidence of Hospira Having an Equal Voice in the Direction of the Enterprise

[redacted]

[redacted]

D. Acts of Direct or Indirect Infringement by Other Members of the Joint Enterprise Are Imputed to Hospira

The facts discussed above establish that Hospira and Celltrion are engaged in a joint enterprise for the development and commercialization of Inflectra. As a result, "all [members of the enterprise] can be charged with the acts of the other, rendering each liable for

the steps performed by the other" in furtherance of the enterprise. *Akamai*, 797 F.3d at 1023. Under *Akamai*, Hospira is chargeable with Celltrion's direct and indirect acts of infringement.

II. Hospira is Independently Liable for Its Own Acts of Inducement

Separate and apart from Hospira's vicarious liability for Celltrion's acts of infringement resulting from their joint enterprise, Hospira also is liable under 35 U.S.C. § 271(b) for its own actions in inducing infringement because it "knew of the patent and that 'the induced acts constitute patent infringement,'" *Commil USA, LLC v. Cisco Sys.*, 135 S. Ct. 1920, 1926 (2015) (quoting *Global-Tech Applicances, Inc. v. SEB S.A.*, 563 U.S. 754, 766 (2011)), and took "affirmative steps to bring about the desired result …." *Global-Tech*, 563 U.S. at 760.

A. Hospira Had Knowledge of Celltrion's Infringement of the '083 Patent

As this Court stated in the December 22, 2016 hearing, "[t]he record includes evidence that Celltrion knew about the '083 patent and the fact that HyClone's media may have infringed it since at least December 2014 when Janssen identified the patent as potentially infringed. That was the basis for analyzing inducement in *Fujitsu Ltd. v. Netgear Inc.*, 620 F.3d 1321, 1330 (Fed. Cir. 2010)]." Dkt. No. 332 (Dec. 22, 2016 Conf.) at Tr. 19:8-15. The evidence supporting such a finding as to Celltrion also provides a basis on which a reasonable jury could reach the same conclusion as to Hospira. Hospira and Celltrion both were notified of the potential infringement in the same communication, in 2014. *See* Janssen SoF ¶¶ 29-32, ¶¶ 96-99. Indeed, since that time, Hospira has been responsible for the defense of this case and has known every relevant fact known to Celltrion. Thus, for example, Hospira, represented by the same counsel as Celltrion, is responsible for counsel's misrepresentations and evasions, as identified by Janssen, including falsely implying that HyClone's manufacturing activities took place abroad, when they actually took place in Logan, Utah. *See* Janssen SoF ¶¶ 35, 48-56.

In view of Hospira's extensive interactions with Celltrion concerning product development, *see* Janssen SoF ¶¶ 93, 99-102, a reasonable jury also could find that Hospira had the same knowledge of direct infringement as Celltrion. [redacted] By its own admission, Hospira considers "access to [Celltrion's] data" about the infliximab biosimilar "key to the success of Hospira's launch plan." Janssen SoF ¶ 102. Finally, Hospira itself has admitted that it was a co-applicant with Celltrion on the application to the FDA to sell infliximab in the United States. Ex. 11 at 2; *see also* Dkt. No. 305 (Janssen Sur-Reply to Motion for Partial Summary Judgment) at 14 (citing Janssen SoF ¶¶ 98-101); *In re Rosuvastian 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)). In a submission to the FDA Advisory Committee, Celltrion and Hospira admitted that they had "optimized" the cell culture media used in order to ensure that their product was similar to Remicade. Ex. 12 at 267.

In addition, as discussed above, [redacted] Hospira and Celltrion claim that they were unaware of the '083 patent until December 2014, when Janssen

put them on notice of that patent. But a routine patent search of the website of the U.S. Patent and Trademark Office for "Centocor" [Janssen's predecessor] as assignee and "media" in a patent's title would have turned up only one patent: the '083 patent. Hospira [redacted] or was engaged in "willful blindness" on the issue. *Global Tech.*, 563 U.S. 766-70; *see* Janssen's Additional SoF ¶ 142. Moreover – as the documents it provided to the FDA Advisory Committee demonstrate, *see* page 13, *supra* – Celltrion's objective in seeking approval to sell a biosimilar was to make the biosimilar as similar as possible to Remicade, *see* Dkt. No. 282-15 [Lee dep.] at 25:8-11; *see also id.* at 19:21-24; and it would have understood that "the composition of the cell culture media" has an "important" effect on the ability to achieve similarity between the biosimilar and Remicade, *id.* at 48:9-23. A reasonable jury could "infer[] from all of the[se] circumstances" that Hospira was aware of the underlying direct infringement to the same extent as Celltrion, and that both were aware of the '083 patent, at least by December 2014 (and were, at best, willfully blind to it before then). *Warsaw Orthopedic, Inc. v. NuVasive, Inc.*, 824 F.3d 1344, 1347 (Fed. Cir. 2016).

B. Hospira Took Affirmative Steps to Bring About Infringement

There also is sufficient evidence on which a reasonable jury could find that Hospira took "affirmative steps to bring about the desired result …." *Global-Tech*, 563 U.S. at 760.

Of course, Hospira has made repeated purchases from Celltrion of biosimilar, each time requiring the acquisition and use of infringing cell media. Since at least 2014, Hospira has been aware that HyClone is the source of the Celltrion media, and it has been aware of the components of that media. Janssen SoF ¶¶ 96-97. It admitted that the Celltrion Media are "an

absolute requirement" to manufacturing the infliximab antibody, *id.* at ¶ 104, and knows that if Celltrion were to use any other media to manufacture infliximab, it "would be very likely" to require a new FDA approval, representing a change to the information discussed in the aBLA, *id.* at ¶ 103. Nevertheless, it has continued to purchase infliximab from Celltrion for distribution in the United States and abroad, knowing that those orders require Celltrion to buy Celltrion Media from Hyclone. *Id.* at ¶¶ 96, 104-05.

Hospira has argued that it cannot possibly be liable for inducing infringement because "A Mere Purchaser Is Not Liable For Inducement." Defendants' Slide 65 from the Dec. 22, 2016 hearing; *see also* Dkt. No. 332 (Dec. 22, 2016 a.m. transcript) at 30 (relying on Slide 65). But as discussed in Point I, *supra*, the Co-Exclusive Distribution Agreement, as amended, makes clear that Hospira is much more than a "mere purchaser" of goods from Celltrion. Its liability is not predicated on the notion that it is a "mere purchaser."

A seller and "mere purchaser" would not [redacted] They would not [redacted] They would not [redacted] A seller and a "mere purchaser" would not [redacted] They

would not [redacted] Moreover, a "mere purchaser" would not [redacted] A "mere purchaser" would not [redacted] For these reasons and others, the parties' agreements refute any suggestion that Hospira is a "mere purchaser" of product from Celltrion. All of the acts on the part of Hospira under its contract with Celltrion establish that, over and above its purchases of goods, it has an active role in the inducement of infringement – the creation of the infringing cell media without which nothing else would be possible.

C. Judge Gertner's Decision in *Columbia v. Roche* is Applicable Here

This Court was correct when it stated in the hearing on December 22, 2016 (Dkt. No. 332 at 22) that "this case seems to be analogous" to Judge Gertner's decision in *Trs. of Columbia Univ. v. Roche Diagnostics GmbH*, 272 F. Supp. 2d 90 (D. Mass. 2002). In *Columbia v. Roche*, plaintiff Columbia University owned three patents covering the process of inserting two genes – one to generate a certain desired protein, erythropoietin ("EPO"), and one to express a marker protein – into a cell and the resulting cell lines. *Id.* at 97. Genetics Institute ("GI") entered into a "Development & License Agreement" with Roche, a European pharmaceutical company, to develop and commercialize EPO in Europe. *Id.* at 97-98. At the time that the Agreement was signed, Roche "had no involvement with the specifics of GI's production" of EPO, and "[n]o detailed technical information" concerning production. *Id*. at 98-99. After

entering the Agreement, GI produced a line of EPO-expressing cells and shipped both vials of the cells and bulk EPO to Roche in Europe. *Id.* at 99-100. Several years later, it was enjoined from making, using, or selling EPO in a separate case. *Id.* at 100.

Analogizing liability under § 271(b) to criminal statutes imposing liability on accessories before the fact, Judge Gertner concluded that Roche had "knowingly aided and abetted" GI's direct infringement, and had specifically intended to encourage GI to infringe Columbia' patents by creating bulk EPO. *Id.*, 272 F. Supp. 2d at 104, 107. Roche argued – as Hospira does here – that, as a "mere purchaser" of GI's infringing products, its actions could not constitute inducement. Judge Gertner rejected this argument, finding that Roche had not "arrived on the scene after GI finished creating the bulk EPO." *Id.*

The Hospira/Celltrion agreements make Hospira at least as involved in the procurement of infringing cell media as Roche was in the development of infringing cell lines. As in *Roche*, Hospira entered into a distribution agreement prior to the finalization of an infringing product that was key to developing the product that would be distributed. Janssen SoF ¶ 91. As in *Roche*, [redacted] Moreover – unlike the Distribution & Licensing Agreement in *Roche* – the Co-Exclusive Distribution Agreement here [redacted] The Co-Exclusive Distribution Agreement [redacted] bolstering the conclusion that Hospira took affirmative steps to induce infringement. Janssen SoF ¶ 93; Dkt. No. 282-79, § 3.1 at 12.

Hospira either obtained the relevant information or was engaged in "willful blindness." *Global Tech.*, 563 U.S. at 766-70.

To paraphrase Judge Gertner's decision in *Columbia v. Roche*, there is sufficient evidence for a jury to conclude that, "[w]ith respect to the creation of the [infliximab biosimilar], [Hospira] acted as an accessory before the fact with full knowledge that [Celltrion] would utilize the [infringing cell media] to manufacture the [infliximab biosimilar]." *Columbia v. Roche*, 272 F. Supp. 2d at 107.

CONCLUSION

Summary judgment should be denied as to Hospira because a reasonable jury could find that: (1) Hospira is vicariously liable under joint enterprise principles for Celltrion's acts of direct infringement under 35 U.S.C. § 271(a) and for Celltrion's acts of inducement under § 271 (b), and separately, (2) Hospira is liable for its own acts of inducement under § 271(b).

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CERTIFICATE OF SERVICE

I certify that on January 3, 2017, this document, filed through the Court's ECF system, will be sent electronically to the parties or their counsel who are registered participants as identified on the Notice of Electronic Filing.

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