UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

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JANSSEN BIOTECH, INC. and	:	
NEW YORK UNIVERSITY,	:	
	:	
Plaintiffs,	:	
	:	
V.	:	Civil Action No. 1:15-cv-10698-MLW
	:	
CELLTRION HEALTHCARE CO., LTD.,	:	
CELLTRION, INC., and HOSPIRA, INC.,	:	
	:	
Defendants.	:	
	Х	

DEFENDANTS' MOTION FOR LEAVE TO FILE SUR-REPLY IN FURTHER OPPOSITION TO PLAINTIFFS' MOTION TO MODIFY THE PROTECTIVE ORDER

Defendants Celltrion Healthcare Co., Ltd., Celltrion, Inc., and Hospira, Inc. (collectively "Defendants") hereby move this Court for leave to file a Sur-Reply Memorandum in further opposition to Plaintiffs' Motion to Modify the Protective Order [*Dkt 69*]. In their proposed Sur-Reply, attached hereto at <u>*Exhibit A*</u>, Defendants will address arguments raised by Plaintiffs in their Reply brief [*Dkt 80*], specifically Plaintiffs' erroneous and inflammatory accusation that Defendants have engaged in "outright deception."

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

Inc. respectfully request that the Court grant leave to file the attached Sur-Reply Memorandum.

Dated: September 25, 2015

Respectfully submitted,

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

By their attorneys,

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LR 7.1(a)(2) CERTIFICATION

I, Andrea L. Martin, hereby certify that Defendants' counsel has conferred with Plaintiffs' counsel concerning the relief requested in this motion. Plaintiffs oppose this Motion.

<u>/s/Andrea L. Martin, Esq.</u> Andrea L. Martin, Esq.

CERTIFICATE OF SERVICE

I, Andrea L. Martin, hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-registered participants on September 25, 2015.

<u>/s/Andrea L. Martin, Esq.</u> Andrea L. Martin, Esq.

4817-2945-3353.1 4817-2945-3353.2

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Civil Action No. 1:15-cv-10698-MLW

DEFENDANTS' SUR-REPLY TO JANSSEN'S MOTION TO MODIFY THE STIPULATED PROTECTIVE ORDER

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Defendants file this short sur-reply to address *ad hominem* attacks by Janssen in its reply brief, which accuses Defendants (particularly Celltrion) of engaging in "outright deception." (Reply (Dkt. 80-1) 1.) *Ad hominem* attacks are never appropriate in judicial proceedings. *See In re Cygnus Telecomms. Tech., LLC. Patent Ltig.*, 536 F.3d 1343, 1360 (Fed. Cir. 2008) ("This court does not condone *ad hominem* attacks. Typically, however, such attacks do more harm than good to the party that launches them."). Janssen's attacks are particularly inappropriate here, because they have no factual basis.

In their opposition, Defendants argued that there were no changed circumstances to warrant Janssen's request to modify the stipulated protective order. (Opp'n (Dkt. 73-1) 12-14.) Before reaching that stipulation, Janssen had enough information to try to negotiate a provision allowing it to use confidential information in a separate complaint against Defendants and thirdparty **mean** But to encourage an immediate production of highly confidential information from not only Defendants, but **mean** as well, Janssen stipulated that such information will be used "solely for the purposes of this litigation." (Hoang Ex. 1 (Dkt. 73-4) ¶ 9.) As courts have held, Janssen should be held to the bargain it struck. *See Ares-Serono, Inc. v. Organon Int'l B.V.*, 862 F. Supp. 603, 609 (D. Mass. 1994) ("Where, as here, 'a protective order is agreed to by the parties before its presentation to the court, there is a higher burden on the movant to justify modification of the order.") (citation omitted).¹

¹ See also Fairchild Semiconductor Corp. v. Third Dimension Semiconductor, Inc., 2009 WL 1210638, at *1 n.5 (D. Me. Apr. 30, 2009) ("When a party to a stipulated protective order seeks to modify that order, that party must demonstrate particular good cause to obtain relief.") (citation omitted); *Omega Homes, Inc. v. Citicorp Acceptance Co.*, 656 F. Supp. 393, 404 (W.D. Va. 1987) ("When, however, the proposed modification affects a protective order stipulated to by the parties, as opposed to one imposed by the court, it is clear that the shared and explicit assumption that discovery was for the purposes of one case alone goes a long way toward denying the movant's request without more.").

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Janssen has no credible response, so it turns to *ad hominem* attacks. As Janssen puts it, "the record unequivocally demonstrates that Celltrion *aggressively misled Janssen* about both the fact and location of infringement." (Reply 2 (emphasis added).) Celltrion purportedly misled Janssen by contending that "any infringing activity *by Celltrion* takes place outside the territorial reach of the patent act." (*Id.* at 3 (emphasis added).) This statement is hardly "outright deception" (*id.* at 1)—it is true.

Back in October 2014, well before this litigation—and months before the stipulated protective order dated May 29, 2015—Celltrion disclosed its biosimilar application to Janssen. That application, in turn, informed Janssen that a company called

(*See, e.g.*, Hoang Ex. 3 (Dkt. 73-4) at 20; Hoang Ex. 4 (Dkt. 73-4) at 1.) Janssen argues that this product, , infringes the '083 patent. (Reply 6.) But Celltrion does not make this cell growth media; does.

(*Id.* at 3.) Janssen does not allege otherwise. In fact, as Janssen concedes, it does not even claim any direct infringement by Celltrion. (*Id.* at 10.)

Janssen nonetheless argues that Celltrion "aggressively misled Janssen," because "[t]here was no way for Janssen to know" that **Section** manufactured its cell media in the U.S. until "finally revealed it on June 8." (*Id.* at 2, 3.) In other words, according to Janssen, Celltrion engaged in "outright deception" by leading Janssen to believe that **Section** manufactures the allegedly infringing cell media outside of the U.S. (*Id.* at 1, 3.) Not so.

Celltrion's biosimilar application represents to the FDA that is based in



(Hoang Ex. 4 (Dkt. 73-4) at 1.)

While Janssen argues that **a** also has an affiliated facility in **a** (Reply 3), Celltrion's application never mentions this facility. Nor did Celltrion suggest to Janssen that allegedly infringing cell media is manufactured in that **a** facility. Thus, before the parties filed the stipulated protective order, Janssen's counsel expressed their "understanding ... that **a** is in **a** and that *the media are made there*." (Hoang Ex. 16 (Dkt. 73-4) at 1 (emphasis added).) Under no stretch of the imagination did Celltrion "aggressively mislead" Janssen into believing that **a** and that **a** manufactures its cell culture media in **a** as opposed to the U.S. (Reply 2.)

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ment – **Marcola Constant Constant and Service Service**

that

(*Id*.)

Moreover, Janssen's own concessions belie its claim for induced infringement. Janssen admits, as it must, that a good-faith belief in non-infringement defeats a claim of induced infringement. (Reply 10 ("As an indirect infringer, Celltrion cannot be liable unless it can be shown that Celltrion *knew* that 'induced acts constitute patent infringement.") (quoting *Commil USA, LLC v. Cisco Sys.*, 135 S. Ct. 1920, 1926 (2015)).) Of course Celltrion has a good-faith belief of noninfringement. As Janssen further admits, **Constitute** cell culture do not literally satisfy **Constitute** claim elements. (Opening Mem. (Dkt. 69-2) 6.) In our opposition, we noted that Janssen's application of the doctrine of equivalents for **Constitute** claim elements is unprecedented—and Janssen did not argue otherwise in its reply. (Opp'n 9.)

As the facts of this case make clear, therefore, Celltrion did not mislead Janssen at all, and certainly never engaged in "outright deception." (Reply at 1.) The Court should focus on Janssen's failure to show changed circumstances to warrant modifying the protective order and not its inappropriate accusations of "outright deception." (*Id.*)

In short, Janssen had the opportunity and motive to try to negotiate a less restrictive protective order to allow a future suit against **sector** based on confidential data. It failed to do so. Thus, there is no basis to grant Janssen's request to modify the stipulated protective order. *See Omega Homes*, 656 F. Supp. at 404 ("The court refuses to endorse Omega's tactic of inducing broad disclosure under a set of ground rules and of then avoiding any limitations on itself by asking the court to come in and change those rules.").²

For these reasons, Defendants request that this Court deny Janssen's motion to modify the stipulated protective order or, in the alternative, grant Defendants' cross-motion to stay Plaintiffs' motion pending this Court's judgment on the '083 patent.

Dated: September 25, 2015

Respectfully submitted,

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Attorneys for Defendants Celltrion Healthcare Co., Ltd., Celltrion, Inc., and Hospira, Inc.

² This sur-reply focuses on Janssen's *ad hominem* attacks and is not intended to respond to all of Janssen's arguments in its reply brief. Accordingly, Defendants' silence as to any particular argument raised by Janssen should not be viewed as a tacit admission.

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> /s/Andrea L. Martin, Esq. Andrea L. Martin, Esq.